

# Fast, Furious and Flexible

The story of  
Health Action International (HAI)

**1981 – 2006**

with special focus on Health Action International Asia Pacific (HAIAP)



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A compilation of memories of members  
and  
writings of Dr. K. Balasubramaniam



HEALTH ACTION INTERNATIONAL ASIA PACIFIC

OCTOBER 2006

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*The nature of networking has been captured in a phrase - “fast, furious and flexible”. But, of these, it is surely the flexibility that is the defining advantage. It is this quality that has - after 25 years - seen a surprising consistency and permanence. Many of the original HAI partner organisations are still working effectively, defying the difficulties of finding resources year after year. Many of the individuals are still actively contributing.*

*Networks (as opposed to organisations, where staff rapidly come and go and focuses of interest change) preserve a constant evolution of a necessary body of work, and are the curators of its history. They cross vertical barriers to shape and modify global and national policies, and they dig deep to reach the specifics of local practice. No network better exemplifies these achievements than HAI.*

- Philippa Saunders

**Edited by Radha Holla with assistance from Lakshmi Menon**

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# Foreword

Social movements, like people, die three times, or in three ways. Firstly, they die when they lose their soul, their spirit, their vision, and their vitality. Secondly, they die when their legal, physical, and institutional structure ceases to operate. And thirdly, social movements die a third death when no one remembers them, or their issues!

Health Action International (HAI), fortunately, is alive and well - its full of vitality, its unique interactive structure is a model for global organising, and its issues capture the minds of all those who seek justice in health care around the globe.

This special collection of recollections, woven into a tapestry by Radha Holla, tells the remarkable story of a quarter century of health activism, speaking of the many dimensions of the journey - the people, the places and the passions, the vision, the victims and the victories, the initiatives, the inspirations and the ingenuity.

It also reminds us of the challenges we still face. An increasingly globalised world driven by violence, by deception, waste and greed, compounded by misplaced priorities have made the global campaign for "Health For All" even more urgent and necessary.

The triple challenges of economics, of equity and of ecology make health issues probably the single most important issue both at the personal and global level. Remembering, recording and sharing the story of the struggles of HAI will surely inspire us all to strive even harder in the coming years as we continue our journey toward "HEALTH FOR ALL, NOW"!

**Anwar Fazal**

*Island of Penang, Malaysia*

*12th March 2006*

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# Abbreviations

ACASH	Association for Consumers' Action on Safety and Health
ACC	Afghan Children Centre
ACHAN	Asian Community Health Action Network
ADB	Asian Development Bank
ADR	Adverse Drug Reaction
AIDAB	Australian International Development Assistance Bureau
ARDA	Action for Rational Drugs in Asia
ASEAN	Association of Southeast Asian Nations
AusAID	Australian Agency for International Development
BUKO	Bundeskongresss Entwicklungspolitischer Aktionsgruppen
CARICOM	Caribbean Community Secretariat
CDMU	Community Development Medicinal Unit
CDP	Committee for Policy Development (a UN body)
CHD	Council for Health and Development
CI	Consumers International (formerly IOCU)
CIDOC	Consumer Information and Documentation Centre (of IOCU)
CIROAP	Consumers International Regional Office for Asia and the Pacific
CNAC	Cambodia NGO Alliance for Cooperation
CPTech	Consumer Project on Technology
CSDH	Commission on Social Determinants of Health
DANIDA	Danish International Development Agency
DAP/WHO	Drug Action Programme/World Health Organisation
DES	Diethyl Stilboesterol
DGIS	Dutch Ministry of Foreign Affairs
DIC	Drug Information Centre
DTCA	Direct to Consumer Advertising
EMRO	Eastern Mediterranean Regional Office (of WHO)
ERDU	Educators for Rational Drug Use
EZE/EED	Evangelische zentralstelle fur Entwicklungshilfe EV/Evangelischer Entwicklungsdienst
FDA	Food and Drug Authority
FEDCOT	Federation of Consumer Organisations - Tamil Nadu
FINNIDA	Department of International Development Cooperation, Finland
FMRAI	Federation of Medical Representatives' Associations of India
FOMCA	Federation of Malaysian Consumers Association

GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GK	Gonoshasthya Kendra
GMP	Good Manufacturing Practices
GOBI-FFF	This acronym (originally simply 'GOBI') refers to a set of WHO primary care initiatives aimed at improving the health of children worldwide:
	G Growth monitoring, for example by the use of road-to-health charts
	O Promotion of oral rehydration therapy for the management of diarrhoea
	B Promotion of breastfeeding
	I Immunisation
	To this have been added:
	Family spacing
	Female education
	Food supplementation
HAI	Health Action International
HAI/AIS	Health Action International/Accion Internacional para la Salud
HAIAP	Health Action International Asia-Pacific
HAIN	Health Action Information Network
HDI	Human Development Index
HDL	High Density Cholesterol
HDR	Human Development Report
HE	Health Expenditure
HEAD	Health Alliance for Democracy
HFA	Health for All
IBFAN	International Baby Food Action Network
ICADIS	Information Centre Against Drug Induced Sufferings
ICCO	Interkerkelijk Organisatie Voor Internationale
ICIUM	International Conferences on Improving Use of Medicines
IFI	International Financial Institutions
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IMF	International Monetary Fund
INN	International Non-proprietary Name
INRUD	International Network for Rational Drug Use
IOCU	International Organisation of Consumer Unions
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
LDL	Low Density Cholesterol
MaLAM	Medical Lobby for Appropriate Marketing
MCO	Managed Care Organisation
MLF	Murman Liberasyon Forum (an NGO in Mauritius)
MMA	Malaysian Medical Association
MNCs	Multinational Corporations
MSF	Médecins Sans Frontières
MSG	Mono Sodium Glutamate (also known as Ajinomoto)

NAM	Non-Aligned Movement
NDP	National Drug Policy
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation & Development
OTC	Over the Counter
PDAN	Philippine Drug Action Network
PDR	People's Democratic Republic
PEPFAR	President's Emergency Plan for AIDS Relief - a US initiative
PHA	Peoples Health Assembly
PHC	Primary Health Care
PHM	Peoples Health Movement
PRSPs	Poverty Reduction Strategy Papers
SAPRI	Structural Adjustment Participatory Review Initiative
SAPRIN	Structural Adjustment Participatory Review Initiative Network
SAPs	Structural Adjustment Programmes
SEARO	South East Asia Regional Office (of WHO)
SIDA	Swedish International Development Agency
SIS	Selective Information Service
SMON	Sub-acute Myelo Optic Neuropathy
TB	Tuberculosis
TCM	Traditional Chinese Medicine
TNCs	Transnational Corporations
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TV	Television
TWN	Third World Network
UK	United Kingdom
UN NGLS	United Nations Non-governmental Liaison Service
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNCTC	United Nations Centre on Transnational Corporations
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organisation
USA	United States of America
USD	US Dollars
USM	Universiti Sains Malaysia
VHAI	Voluntary Health Association of India
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organisation
WPRO	Western Pacific Regional Office (of WHO)
WTO	World Trade Organisation
YLKI	Yayasan Lembaga Konsumen Indonesia (Indonesian Consumers Organisation)



# GLOBAL ACTION ON HEALTH

The story of the birth of Health Action International

**Anwar Fazal**

*More money is spent on marketing and promotion of drugs worldwide than the total cost of healthcare in the Third World. This is a certain prescription for ill health and disease.*

**Mr. Permadi**, President, Indonesian Consumers Organisation, 1981

Telling the story of a social movement helps us remember the original vision, the strategic thinking and specific direct actions envisaged by the pioneers.

On the special occasion of 25 years of one very special such movement, HAI, I will try to capture some of the key elements of how we addressed one of the greatest continuing issues of humankind - ill health and disease, greed and irresponsibility.

The birth of Health Action International (HAI) emerged from several streams of thinking, planning, and action - locally and globally.

## CONSUMER MOVEMENTS

Firstly, the International Organisation of Consumers Unions (IOCU), now known as Consumers International, did two pioneering global comparative studies in the 1970s: it examined the marketing and labelling of the drug 'chloremphenicol' (1972) and 'clioquinol' (1975). The results were nothing short of scandalous - double standards, deceit, denial and deliberately taking advantage of countries with weak regulatory authorities, and of the Third World in general.

Robert Ledogar's 1975 book, *Hungry for Profits*, a scathing insight into the behaviour of Multinational Corporations in Latin America, and that of Charles Medawar of Social Audit fame - *Insult or Injury* - in 1979, were funded by the Consumers Union of USA and the Consumers Association of the UK. Both organisations were key players in IOCU and were becoming increasingly activist globally, challenging the power of Multinational Corporations worldwide. IOCU also made important contributions on this subject to the United Nations 'Group of Eminent Persons,' whose work led to the historic establishment of a UN Centre for Transnational Corporations, which sadly but not surprisingly, fizzled out.



## **THE JAPAN LINK**

The 1979 Kyoto International Conference against Drug-Induced Sufferings was another landmark and linked us to a global network of medical pharmaceuticals and legal specialists. We are particularly grateful to the late Mr. H. Izumi, whose team not only gave HAI its first grant, but also funded the 'Olle Hansson Award.'

The SMON (Sub-acute Myelo Optic Neuropathy) Lawsuit Attorneys Group and the SMON Lawsuit Plaintiffs Group (thirty three of them attended the IOCU 10th Congress in the Hague in 1981) were a great inspiration and support group. Noraiki Mizuma of the Information Centre Against Drug-Induced Sufferings (ICADIS) and the Consumers Union of Japan under the leadership of Naokazu Takeuchi, Mrs. Nomura, and H. Ando were always there for us. That link also later triggered the historic International Conference on Consumer Health and Safety held in April 1983, in Ranzan, Japan, where Mike Muller gave the keynote address and Olle Hansson again played a key role. 'The Ranzan Declaration became another powerful clarion call for justice in the health and safety area. And it brought us many allies who gave us much strength over the years.

## **THE PENANG LINK**

In Penang, at IOCU's regional office for Asia and the Pacific, a young team comprising of Ms. Foo Gaik Sim and two Austrian junior experts, Wolfgang Howorka and Eva Lachkovics did some excellent surveys during my many years as Director of that office. This enthusiastic young team led a flourishing *HAI Clearing House* and *HAI News*, both launched in October 1981, and sustained the HAI network by providing a visible, high profile facilitating and linking hub and anchor. This helped everyone involved to "feel" and "see" the movement as a credible worldwide network from the start.

## **THE INSPIRATION OF IBFAN**

Parallel to these efforts was a global campaign to protect the culture of breastfeeding, which had been murderously undermined by a global infant formula industry fuelled by cash register ethics. The groups developed a loose but effective global network - a word so much used now but then was a pioneering way of working - light, participatory, action-oriented and built on the various strengths of its core members - with a clear vision and target of do-able things - anytime and anywhere. The International Baby Food Action Network (IBFAN) was born in Geneva in October 1979. It provided the model for HAI.

The greatness of the network was its simplicity and the fact that diverse partners were able to engage in diverse ways to link and multiply. What was fortuitous was that so many groups involved in the campaign were 'development' and social justice activists who had concerns about the pharmaceutical industry and 'unhealthy' business, in general.

## **CELEBRATIONS THROUGH ACTION**

I saw a great opportunity of building on this first wave. So when the World Health Organisation passed (with one dissenting vote from USA) the Code of Marketing of Breastmilk Substitutes, we decided on a celebration. Not only did we have a meeting to strategise on the follow up to our victory in getting the first 'consumer' code, at

## *Some special people*

Health professionals and activists were central to the development of our movement. I remember a special team from California:

- Milton Silverman and Philip R Lee, with their classic *Pills, Profits and Politics*
- Milton Silverman's *Drugging of the Americans* (1976)
- Milton Silverman, Philip R. Lee and Mai Lydecker's *The Drugging of the Third World* (1982)

Mike Muller of South Africa, who gave us the classic expose on the baby food scandal, *The Baby Killers*, which raised hell, and later gave us *The Health of Nations*.

Diana Melrose of OXFAM, who gave us *Bitter Pills - Medicines and the Third World Poor* in 1982, was among the pioneers and the OXFAM Public Affairs Unit was a great support.

Surendra J. Patel organised with Dr. Bala and others a truly landmark collection of articles in "Pharmaceuticals and Health in the Third World". It appeared in 1983 as a special issue of the journal *World Development*, Volume 11, number 3 and later as a separate book. It contains many special and memorable documents including the "Special Resolutions on Pharmaceuticals by the Non-Aligned Countries" (1976) and the historic 1982 "HAI Draft Proposal for an International Code on Pharmaceuticals".

The team from The International Research Group for Drug Legislation and Programmes - Richard Blum, Andrew Herxheimer, Catherine Stenzl and Jasper Woodcock - gave us the best 'sourcebook' for our advocacy work - *Pharmaceutical and Health Policy - International Perspectives on Provision and Control of Medicines*. Printed in 1981, it was later reprinted as a paperback for HAI and widely distributed.

Olle Hansson, the Swedish Neurologist and Paediatrician, who gave us the book, *Inside Ciba Geigy* and linked us with the campaigners against SMON.

the same time, we, launched an aggressive global campaign for rational drug use, just as we had done for the 'de-marketing' of breastmilk substitutes.

And so we convened an International NGO Seminar on Pharmaceuticals in Geneva, at the end of this historic 34th World Health Assembly (WHA), from 27-29 May 1981. It was co-sponsored by IOCU and a German-based health activist group, BUKO (Bundeskongress Entwicklungspolitischer Aktionsgruppen). We were helped by the United Nations Non-governmental Liaison Service (NGLS), led by a very special UN official, the first of the best in caring and commitment - Ross Mountain.

That meeting was attended by more than 50 organisations from 26 countries, from diverse countries such as Brazil and Bangladesh, and involved diverse organisations such as OXFAM and War on Want in UK, Cefemina in Costa Rica, Gonoshasthya Kendra in Bangladesh, Nafia in Norway, and Murman Liberasyon Forum (MLF) in Mauritius, just to mention the diversity. Every continent was represented. Every stakeholder - medical and health, UN and civil society, women, consumer, church groups - brought together the power of humanity.

That three-day meeting was the tipping point that marked the end of spotty, disparate action and gave birth to a movement - a name, a vision, and plan of action, decentralised and yet deliberately determined.

**Press Statement Issued on 29 May 1981**

*New "International Antibody" will Resist  
"Ill-treatment of Consumers by Multinational Drug Companies"*

Representatives of non-governmental organisations from 26 different countries concluded a three-day conference in Geneva today - and have formed an international coalition, Health Action International, "to resist the ill-treatment of consumers by multinational drug companies".

The coalition - described by one speaker, as "an international antibody" comprises a broadly based network of consumer, professional, development action and other groups. Mr. Anwar Fazal, the President of the International Organisation of Consumers Unions - one of the two main bodies behind the conference - welcomed the setting-up of the new coalition, saying "where multinational drug companies are concerned, all groups expect one and the same thing: remedies, and remedies that work."

Fazal told the conference: "We have different priorities, but we agree on the diagnosis. We agree unanimously that the multinational drug industry is deeply implicated in the trade in hazardous, useless, inappropriate and often unconscionably expensive drugs. And we are unanimously agreed that we will not tolerate this ill-treatment of consumers particularly when they are sick and poor."

The Geneva conference was co-sponsored by BUKO, a West German coalition of development action groups. Explaining the significance of the meeting in Geneva, a spokesman for BUKO, Roland Fett, stated: "Multinationals have developed skill and experience in influencing the UN System in their favour. In particular, in recent years, the pharmaceutical industry has blocked the WHO Essential Drugs Programme and other initiatives meant to control the international trade in hazardous and useless drugs. We intend to resist such obstruction by drug multinationals through community action at the grassroots level."

The conference was attended and addressed by senior officials from three agencies of the United Nations: WHO, UNCTAD and UNIDO. There was "extensive accord" on priorities identified by participants and those mentioned by representatives of the UN System.

In a joint statement, the conference organizers emphasised their specific concern about the activities of drug multinationals in developing countries; and the commitment of Health Action International to "a sustained, vigorous and multifaceted international campaign".

"The stranglehold of the international pharmaceutical industry on the provision of healthcare is one of the main issues on the agenda of the Group of 77. We shall seek full working cooperation with them to bring about long overdue changes in the way drugs are produced and marketed - and also withheld. Access to medicines is vital to the health of the world. If the drug industry can give such access, then well and good. If not - if the industry is to continue in its customary ways - our prescription for it will inevitably cause it irritation and pain."

The conference discussed issues which ranged from the provision of traditional and alternative medicines to the risks associated with long-term, injectable contraceptives. But most criticism was of: "Costly, high-pressure marketing and promotional methods by drug multinationals;" "the provision of irrelevant and inappropriate drugs, especially in developing countries;" "the sale of vast numbers of useless or positively dangerous products;" "excessive profit-taking, monopoly practice and other market abuse;" and "the provision of inadequate, often misleading information to doctors about the products they were encouraged to prescribe."

This criticism of the industry comes within weeks of the announcement by IFPMA of a new code of international marketing practice. Participants at the conference clearly saw this as an attempt to deflect criticism

and forestall external regulation. There was applause for the speaker who suggested: “When the sharks sit down to work out a code on how to treat the fish, it’s time for the fishes to get together and decide how they want to be treated”.

Member groups of Health Action International will address such issues as:

- “An end to the commercial anarchy of prescription drug competition” (for instance, in India, there are some 15,000 branded drugs on sale compared with just 225 “essential drugs” identified by WHO).
- An end to patent protection for essential drugs. The “essential drugs” identified by WHO “are too important to be left in a monopoly domain”.
- The progressive replacement of proprietary brands with generic drugs which usually cost many times less.
- The “decommercialisation of essential drugs” - assuring that people who need drugs get them.
- Regional or national production and bulk-buying arrangements to reduce to an absolute minimum the cost of essential drugs.

Immediate action plans for the new coalition, Health Action International, include:

- Setting up an international clearinghouse for information on commerciogenic disease; pharmaceutical industry structure, ownership and marketing practices; and for the coordination of consumer action campaigns.
- The launching of an International Hazardous Product Warning Network - the “Consumer Interpol”. The withdrawal or restriction on the use of any drug in any one of five reference countries will trigger immediate communication to each of over 110 different organisations in some 50 countries. The aim is to encourage local groups to pressure government and industry to effect simultaneous restrictions - and to avoid the commonly-found double standards between developed and developing countries.
- Direct actions will be aimed at the worst offenders in the drug industry: publication of counter information, such as the leaflet on Lomotil released at the IOCU-BUKO conference by the British research-action group, Social Audit; confrontation at companies’ annual general meetings; and the possibility of international consumer boycotts and legal actions against “the truly intransigent”.

## THE UN LINK

The three-day seminar also brought us close to the key people on the UN – Dr. A. Tcheknavorian of UNIDO, Dr. F.S. Antezana of WHO, Dr. Surendra Patel, and Dr. K. Balasubramaniam of UNCTAD. The synergy was terrific: there was so much unanimity and agreement on moving forward towards rational drug use and to end the abuses of the huge and powerful pharmaceutical industry.

## ONE LONG NIGHT

It was already past midnight, and we were into 29 May. We were debating furiously the final document and press release to launch Health Action International. I had persuaded Ed Baer of Interfaith Centre for Corporate Responsibility to write the draft - he did a brilliant job, titling it, “Ill treatment of consumers by multi-national drug companies.” He was, like me, all brave and optimistic, with a “can do, will do” upbeat assertiveness.

Charles Medawar, who played a pivotal role in the creation of HAI, contributed the name 'Health International.' I got him to add 'Action' to the name. Charles was seriously worried about the 'wildness' of our promises. Dr Andrew Herxheimer of *Drugs and Therapeutics Bulletin* fame, another pivotal player, was as gung ho as us and we persuaded Charles to go for it. So, HAI was hosted by the IOCU office in Penang, Malaysia, which acted as the 'clearing house' and defacto facilitator.

With financial support from our Japanese colleagues (and I particularly, remember H. Izumi) we launched *Dear Doctor* letters and *HAI News*, and became a force at WHA and globally. Very quickly and dramatically in the first year, HAI had a coordinating office in Europe. It made its presence felt in the WHA in the following year, where a strong resolution on the Essential Drugs Programme was adopted. The greatest credit paid to HAI came from one of the industry critics, who said that HAI "has shown a genius for winning the minds of elite decision-makers from Bangladesh to Sweden." Campaigns in Sri Lanka and Bangladesh showed how important this new global civil society force was. We could fight back and set the agenda! We linked HAI's work with 'Consumer Interpol' - another direct action information/investigative framework, which I initiated out of IOCU in Penang.

In 1982, I presented "A Draft Code on Pharmaceuticals" on behalf of HAI to the UNCTAD Committee on the Transfer of Technology. Dr. Balasubramaniam, who later became the leading light of HAI Asia-Pacific, had prepared the draft code (which was printed by HAI as a booklet in 1983) at the behest of Diana Melrose and Ross Mountain soon after HAI was set up. It covered all the major ethical aspects of the pharmaceutical industry. We hoped that UNCTAD would collaborate with WHO and other concerned

## *Health Action International — Its Vision and Mission*

### **VISION**

Health Action International is working towards a world where people, especially the poor and disadvantaged have a human right to health and an equitable access to affordable quality Primary Health Care. HAI works towards just societies where people can equitably participate in decision-making and allocation of resources.

### **MISSION**

HAI promotes the essential medicines concept (that fewer than 350 medicines are necessary to treat more than 90 per cent of health problems requiring medicines).

HAI works towards increasing access to these essential medicines and ensuring that they are available at affordable prices when treatment is needed, especially for the poorest.

HAI advocates for greater transparency in all aspects of decision-making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.

HAI promotes the rational use of medicines: that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.

HAI works for better controls on drug promotion and the provision of balanced, independent information for prescribers and consumers.

agencies to develop a UN International Code on the marketing of and rational use of pharmaceuticals. The agencies tried but of course, there was massive resistance from the industry, and some powerful governments, who were determined to stop a repeat of civil society's success in the struggle to protect breastfeeding. We did not get a Code but there was some success through various other measures. Most of all, our voices were never silent, not then, not now and the struggle continues.

## THE FUTURE

HAI grew and grew, and eventually grew out of the bosom of IOCU, which had so strategically hosted and facilitated HAI's work for many years.

Now HAI is a fully autonomous force, global and alive, reinforced by the historic Peoples Health Assembly (PHA). When we were born, we promised "a sustained, vigorous and multifaceted international campaign." 25 years later, we can proudly say we delivered and will continue this spirit of vigilance and action towards "real health for real people."

The HAI story of partnership between North and South, scientists and social activists, between global groups and grassroots' efforts, made for a universality that was truly unique for civil society, and what was beginning to be called "third force", the governments and business being the first two and often engaging in "unholy alliances".

The rampant globalisation and free marketing is posing new challenges but it is also arousing public interest groups all over the world to join and strengthen the network for change. International Peoples Health University, for example, is one of those new hopes. To all those who travelled with me over the last 25 years of HAI's journey, I say, "Thank you. Keep in touch. Tell me your stories." This work has truly been a force for happiness!

### *Good Wishes from Ciroap*

Consumers International has the honour and distinction of having played a key role in the founding of HAI and ARDA and in hosting HAI Asia Pacific for 16 years.

As a founding partner in the network, and as a host, CI management and staff were intensely involved in a number of activities including the publication and dissemination of *HAI News* (the flagship of HAI), the organisation of regional and international conferences and the coordination of research projects resulting in several high impact reports and publications.

CI and HAI AP together with partners from other regions vigorously pursued the cause of rational drug use, drug pricing and HEALTH FOR ALL right up to the portals of the WHO's World Health Assembly.

There are many individuals from CI whose commitment and dynamism was instrumental in steering HAIAP/ARDA to fulfil its true potential in this region - among them are Anwar Fazal and Foo Gaik Sim, former Regional Directors of CI Asia Pacific office. It was their vision and enlightened leadership in the early years that led HAIAP/ARDA to grow to what it is today.

Heartiest congratulations on the 25th anniversary of HAIAP /ARDA!

*Rajeswari Kanniah*



# HOW HAI CAME ALIVE

## A Personal View

Jörg Schaaber

As a network has many mothers and fathers, there must be several stories about its inception. Imagine a young sociologist specialised in development studies volunteering in a Third World solidarity group. One day the national network of such groups (BUKO) asks him whether he would be willing to coordinate a campaign on pharmaceuticals. A few papers and one or two books on the topic had been collected. A few people had done some research on the international trade with human blood plasma. Some other volunteers had looked beyond the German borders for people who were already working on the subject. Wouldn't it be a good idea to quickly learn about the issue by inviting those people to Germany for a seminar? A few days after the invitations for the speakers went out we got a call from UN-NGLS in Geneva. Ross Mountain said he was impressed by the list. Another organisation, called IOCU, had quite the same plan, and there was considerable overlap in planned speakers. Could I "just" drop in and discuss with him? UN-NGLS would pay. This was overwhelming! A few days later, we sat together in a Geneva pub and drafted an agenda for the meeting with the help of Pascale Brudon, a nice young academic.

In May 1981, at the International Seminar on Pharmaceuticals in Geneva, I learned that there was already a loose network of quite a number of brilliant people around. There was Charles Medawar from Social Audit with his beautiful leaflet on Lomotil. Anwar Fazal from IOCU with his concept of a network as train stations with rails connecting them in many different ways. Looking back 25 years, he was perfectly right. HAI grew and survived because it never became dependent on a top down structure but operated as many strings across the continents that connected people and groups. Dianna Melrose from OXFAM who would soon publish *Bitter Pills*. The expert, Andrew Herxheimer who patiently explained to the ignorant BUKO man complex pharmaceutical and medical issues in a language that could be understood. On the panel, a senior UNCTAD expert who was speaking plain language - quite unusual for an UN man. His name: Dr. Balasubramanian. Sandhya Roy from Gonoshasthaya Kendra in Bangladesh reported on her project and the brand new essential drugs factory they had just started. Many more could be named. There emerged the possibility of meeting and working together with them again - a network was founded!

## *Looking Back to Move Forward*

I am really pleased that you have taken the initiative for a celebration of 25 years of Health Action International. It is an important time to look back, and forward.

Health Action International has been remarkably effective in the past 25 years, despite resource limitations. The key has been great commitment and global collaboration in evidence-based advocacy. The past five years we have decentralised our operations with regional offices taking a lead in the campaigns. This is an important step in strengthening our network. At the same time the global arena has changed dramatically. Where 25 years ago the World Health Organisation started playing a key global role in the field of medicines policy, now we see many more international actors such as Global Fund and PEPFAR, who are providing huge resources for medicines programmes in poor countries. And WTO processes define access to drugs. The influence of commerce on public health has not declined despite 25 years of advocacy. The pressure to increase markets for blockbuster drugs has increased.

HAI needs to use its 25th anniversary to reflect on its past successes and future strategy. Our mission is far from achieved. I am eager to hear what will come out of the jubilee celebrations of HAI AP. I look forward to many more years of global collaboration.

*Anita Hardon*

If one reads the press statement of this meeting today he or she will find the key issues HAI is still working on: promoting the essential medicines concept, fighting against patent protection for these drugs to lower prices and to secure access, fight bad marketing practices. And, though there have been many successes, there is still a long way to go. Let's do it!

## *Congratulations to HAI on your 25th Anniversary*

In a world where people's and NGO networks spin into life everyday, and many turn into dust the very next, longevity deserves praise. HAI has not only survived, it has thrived and made a real difference to people of the world in terms of access to and quality of their medicines and healthcare.

HAI lives today because of the individuals and organisations that gave it energy and vision in its infant years. I remember, amongst many, Dr. Olle Hansson, the SMON patients' group and their lawyers, Ross Mountain of UN-NGLS, our man in Geneva, Bangladesh's Zafrullah Chowdhury and India's Mira Shiva. I think too of the unstinting generosity of IOCU that bore much of HAI's secretariat responsibilities. To those who were there at HAI's birth and are still forging on, honour is due for you have stayed the course. To those who have joined in its later years, to fight for people's rights regarding drugs, congratulations, for you have others who share your courage and energy.

*Foo Gaik Sim*

## *More Good Wishes*

Many of the targets and indicators for the achievement of the eight Millennium Development Goals by 2015 are health related. This mirrors the state of the health of the people today in developing countries, 27 years after the Alma Alta Declaration of HEALTH FOR ALL. The work of HAI therefore is even more critical and challenging until 2015 and beyond.

In the last 25 years, the HAI network led by passionate and committed individuals and organisations in the various fields of health, has worked relentlessly to influence health and drug policies based on the concept of Primary Health Care at the community, national and international levels.

Many challenges continue to confront the work of HAI. They range from the political, socio-economic, globalisation factors, to issues related to WTO and natural disasters such as the Asian tsunami, hurricane Katrina and the South Asian earthquake. These challenges are important determinants of health and healthcare.

Fortunately, HAI has a network of talented and committed individuals with skills and expertise on health, medicines, patents, advocacy, and campaigns that are world class to confront these challenges.

In the Asia-Pacific region, the unique expertise and work of Dr. K. Balasubramanian, better known as Dr. Bala has contributed significantly to the remarkable achievements of HAI. Dr. Bala's research and analysis have been instrumental in influencing the work of health activists, academia and policy makers in the region and globally.

This publication, which also contains selected papers of Dr. Bala, will inspire many more individuals to work in the public interest for health. Congratulations to Dr. Bala and HAIAP secretariat for their resourcefulness and hard work in bringing this out. A billionaire philanthropist recently said that he wished he had written a great book instead of making billions, as the book would be read for thousands of years.

*Josie Fernandez*

# EARLY DAYS WITH HAI

**Wilbert Bannenberg**

On a cold February day, we (Jörg Schaaber of BUKO and I) travelled by train and boat to the UK, to attend my first HAI meeting. In London, we found a group of hard-working individuals including Virginia Beardshaw, who would soon become the first HAI coordinator and set up the HAI network from the office space donated by IOCU's international office in Emmastraat 9 in The Hague, Netherlands.

## OF MARKETING CODES AND MUESLI AND NORTH-SOUTH POLITICS

Our first need was to raise awareness: the blatant double standards in drug marketing. During visits to Africa, I had discovered that the Dutch drug company Organon was marketing anabolic steroids for the treatment of malnutrition in children, something that was unthinkable in the Netherlands. During the early 1980's pharma companies were easy targets for campaigns. Switzerland and Germany had many drug companies exporting bad products to developing countries. So, in May 1982 some 25 HAI activists joined powers in Geneva to lobby for a WHO Code of Marketing Practices in the World Health Assembly.

Lobbying a World Health Assembly was new to all of us: some of us wore jackets for the first time! I remember helping colleague activists with the knot in their ties! It was very encouraging to be part of a new movement, and work with colleagues from other countries and continents. 'Fort Knox' was our bunker, where we slept in bunk beds, ate muesli, and had endless plenary meetings to discuss our strategies. We could not (yet) afford wine or expensive Geneva restaurants, so we were quite happy to lobby delegates at the daily cocktail parties in WHO.

Dr. Halfdan T. Mahler was the visionary Director General at that time in WHO. He had developed the concepts of Primary Health Care and Essential Drugs. Drug companies were heavily opposed to these revolutionary concepts, and attacked the newly formed 'Drug Action Programme,' headed by another visionary Dane – Dr. Ernst Lauridsen.

The drug companies had learned some lessons from the baby-food industry debacle one year earlier: to forestall a compulsory code, they had developed a self-regulating 'voluntary' code of conduct under their lobby tool, the IFPMA. They had also lobbied several Western governments to block our demand for a WHO Marketing Code for

the drug industry. IFPMA probably had an even bigger team than HAI at the World Health Assembly.

The USA, which was paying 25 per cent of WHO's contribution, warned Dr. Mahler that it would leave the organisation if WHO went for a Marketing Code. Obviously, HAI didn't get its code.

HAI launched two books in Geneva: Dianna Melrose's *Bitter Pills*, and Mike Muller's *The Health of Nations*, both heavily criticising the drug companies' behaviour in developing countries. Two years later, in 1984, we even had a complete journalists' team producing a daily newspaper exposing bad practices and creating awareness among the delegates.

## **TAKING ON THE PHARMA INDUSTRY**

In the early 1980's, HAI also tried to stop the exports of ineffective or unsafe products from Europe. We tried hard lobbying the European Commission in Brussels. I remember long meetings in Virginia's house in Brussels, often ending with songs, accompanied by Lars Broch or Ross Mountain on the piano. However, the EU, being a trade organisation, refused to stop, or even control exports of unregistered products from Europe to developing countries.

The message was clear: HAI had to move the action to developing countries, to help them stop the import of inappropriate products from their side. HAI sent me on a seven-month data collection and local awareness raising safari through Eastern and Southern Africa in 1983.

Setting up drug-related networks in Africa was not easy, as most NGOs were busy trying to develop poor communities and provide emergency assistance. Technical issues as drug promotion or double standards weren't their first priorities. Drug companies also had substantial influence in African governments. I remember George, the fresh HAI-Kenya coordinator, being sent on an involuntary three-year scholarship to the UK.

My HAI-Africa safari had shown me many problems with the use of medicines in Africa. We decided to produce campaign material to raise the awareness in North and South. I still remember the London pub where Andrew Chetley and I made a list of target drugs for the very successful *HAI Problem Drugs* publication.

## **DIVERSE CRISES**

Having failed to get an effective WHO Code of Marketing Practices, the rational use of drugs became our new target. Drug companies tried hard, but failed to stop WHO from organising the landmark Nairobi Rational Use of Drugs meeting. I still remember the USA being the only vote against the 'Nordic' resolution requesting WHO to organise the meeting.

IOCU had set up other HAI networks in Asia and Latin America. The WHO Assemblies in Geneva became the meeting place of global HAI activists. Collaboration was not always easy, as we had such different backgrounds and priorities. HAI nearly collapsed at the 1986 Bogève meeting, but a new regional structure gave the needed autonomy to the regional organisations, while maintaining global collaboration through the meeting of HAI coordinators.

HAI Europe became a bit too big for IOCU, and, after a difficult process, we made ourselves autonomous. Without funding or an office, but with sufficient ideas, action and volunteers, HAI invaded my attic in Amsterdam as an emergency office. The HAI Europe Foundation was set up for guarding the subsidies, and the HAI Europe Association was set up to ensure democracy.

After some fierce fundraising in Scandinavia, HAI Europe was able to employ its own staff and rent an office in a renovated warehouse in Amsterdam-West. Catherine Hodgkin succeeded Virginia Beardshaw, and Rose de Groot was hired as a temporary secretary. HAI never moved, although the staff probably still dislikes the office when it becomes too hot to work in summer.

Being close to the donor countries (Scandinavia, UK, Holland), HAI Europe arranged the funding for the global HAI programme. Being close to WHO, HAI Europe also coordinated the lobby in Geneva.

## **COMMUNICATION CHALLENGES**

Communication was problematic in the early HAI-days: air tickets were expensive, telephone lines were of poor quality, and fax, email, or mobile phones didn't yet exist. We worked with airmail letters, and then waited one month for an answer. If it was urgent, we could send telegraphic style one-minute telex messages. Remember daisy-wheel printers, or that brilliant IBM typewriter with exchangeable font-heads? Remember the wet photocopy machines, or the stencil-machine with ink dropping out on all sides? Computers did exist, but had a maximum of 32 or 64 Kbytes of memory and no hard disks. Writing a long article meant saving it in five different files!

Global communication became essential for activists. The fax was really a brilliant invention! We got computers, a CompuServe address, and we always travelled with a screw driver and toolbox to fix telephone sockets in hotel rooms to connect our modems with 300 or 1200 baud. The first 9600-baud modems were a revolution! Annual HAI meetings were organised by members in several European countries. There was always a public seminar, to create some local awareness, or to launch a new report. The next day, HAI staff, and members would exchange reports and ideas what action to take. In the evenings, many new campaigns were planned with a glass of beer or red wine.

## **GROWING OLDER**

HAI was growing and getting older. It was time to train the next generation! From all over Europe they came in 1986 to Sweden for the famous, one and only 'HAI Summer School.' Surrounded by fresh air and forests, aspirant HAI activists learned about the four phases of Drug Research, industry's tricks, acquired skills in lobbying and computing, told each other about successes and failures, and planned campaigns. In the evenings, we socialised, and made bonds for life.

Twenty years later, we have grown up, got married, started jobs, had children, become experts, and travelled the world. New issues have come: TRIPS, access to essential drugs, and pharmaco-economics. New organisations have joined the debate, such as MSF and CPTech. HAI regions are alive and kicking. In my work as a public health consultant in Africa, I encounter problems daily.

Enough work for HAI for another 25 years!



## *Information Networking - Key to the Success of HAI*

Information networking contributed greatly to the successful growth of the HAI network both geographically as well as in its expanded activities and in building international solidarity. It kept alive the interest in HAI's various campaigns. The networking not only helped us make new contacts on health issues, it also gave us the opportunity to interact with movements working on other issues like baby food, environment and women's issues.

IOCU's Consumer Information and Documentation Centre (CIDOC) in Penang, under the able guidance of Foo Gaik Sim, coordinated HAI's information networking activities in the early days. Coordinating CIDOC work during 1981-85, I was also involved in HAI's information networking activities. CIDOC focused on health issues, collecting books, journals and information in other forms such as printed documents and audio visual materials, and developed activities such as information dissemination and information exchange with HAI members, preparing useful resource tools, such as *The Health Portfolio*.

CIDOC's selective information service (SIS) involved identifying HAI contacts, recognising their needs and disseminating relevant information to them. SIS was based on the principle of the right information to the right organisation/person at the right time, which contributed to the success of each campaign. CIDOC also helped gather information for HAI research and publications. HAI's campaigns depended heavily on information and information networking. The most active campaign was the one against the anti-diarrhoeal drug clioquinol or the SMON campaign, which led to compensation for SMON victims and an apology by Ciba Geigy. It also led to the establishment of the Olle Hanson Award. HAI's campaigns included anabolic steroids, phenylbutazone and oxyphenbutazone, hazardous drugs, diethylstilbestrol (DES), Depo Provera, and MSG. Other equally important campaigns promoted essential drugs and rational drug therapy.

HAI also gave support to national campaigns in other countries, such as the oestrogen progesterone (EP) drug campaign in India in mid 1980s - crucial support in the form of latest information and technical data, which were submitted at public hearings. This international solidarity provided much-needed assurance and hope for the weary and disheartened activists as the campaign dragged on for several years. It also helped to put pressure on the national government.

We were very efficient without electronic information technologies in those days. At CIDOC, we managed pretty well using manual information systems and communicated effectively even without modern communications means.

With its foundation based in a very active international consumer organisation (IOCU) headed by a great visionary Anwar Fazal, and with the help of highly committed Foo Gaik Sim along with Eva Lachkovics and a hard working team, and supported by a very efficient CIDOC, HAI has been able to reach very far. My heartfelt congratulations to HAI and best wishes for its continued success in its great work.

*Lakshmi Menon*

# NETWORKING

## SOME REFLECTIONS ON 25 YEARS OF HAI

**Philippa Saunders and Andrew Herxheimer**

We have trawled our combined memories of HAI over the quarter century of its life.

I (Andrew) remember only faintly the small meeting at which HAI was born, in Geneva. When we had agreed on the name and the acronym HAI, I said that in German the word 'Hai' means 'shark', and Surendra Patel, Technology Director of UNCTAD, said, "When the sharks threaten the fishes, the fishes must join together to defend themselves." We did. (Incidentally, IBFAN has creatively translated this concept of unity against big sharks into a Tee Shirt design).

From the beginning, the various strands of HAI's work have been entwined with the development of medicines and policies, globally and nationally. For example, Sri Lanka was one of several developing countries that - even before 1980 - had established a National Drug Policy that was developed before the WHO Essential Drugs Concept. WHO later took up the pioneering work of Professor Seneka Bibile and others as the global blueprint for the rational selection, management and use of affordable and effective medicines. Dr Bala's career drew on the early inspiration of Professor Bibile in Sri Lanka, to evolve within the UN system, and later return to its origins when he took on the task of coordinating HAI Asia-Pacific. Later, in 1985, the Rational Use of Medicines became a formal and necessary component of HAI work.

The work of individuals and national HAI groups, coordinated by first three, and now four regional offices was informed by the new policy framework, led by WHO's Drug Action Programme. HAI also did much to give substance to the programme through education, research, advocacy, and hard-edged campaigns. Promotion was a particular focus, as it still is. Charles Medawar's hard-hitting campaign leaflets - for example on Lomotil - were the models for many HAI groups in different parts of the world. In Pakistan regulatory action followed when campaigners showed in a shocking television programme that the drug was responsible for the deaths of infants. The Pakistan Network - now a national consumer body with considerable influence - grew from these beginnings. And MaLAM (Medical Lobby for Appropriate Marketing) was founded by Peter Mansfield at this time, and is still with us, now with its new title 'Healthy Skepticism'.

Perhaps the single most successful and powerful campaign from the 1970s before HAI was formed, which HAI joined when it was founded, brought to the attention of the world the harm caused by clioquinol, marketed as Entero-Vioform since the 1930s. Olle Hansson, who first publicised the condition SMON (drug-induced blindness and

paralysis), led the campaign. This action undoubtedly led to heart-searching and reforms within industry, as well as stronger regulatory oversight and awareness of responsibilities worldwide. Olle Hansson's example is kept alive through the award made in his name.

However, in the mid 1980s it became clear that campaigning against individual useless and harmful drugs could soak up all our energies forever, and that the enormous underlying problem was the appallingly inappropriate use of all medicines. So, the fights against 'problem drugs' were replaced by campaigns against problem behaviours by companies and the other actors in the medicine scene, a vastly bigger task. HAI's participation in the 1985 WHO Nairobi Conference on Rational Use of Drugs was a landmark.

And so HAI has continued, with a very diverse and substantial body of work. Andrew had been working with the UK Consumers' Association, editing *Drug & Therapeutics Bulletin*, and then taking part in IOCU from 1980-1996 as chair of its Health Working Group. IOCU became a major participant in HAI, and as its focus

### *The Political Edge of HAI*

It was around 1984 that I joined Health Action International (HAI), drawn by a new movement that created the space for a profound look at what was happening in the field of pharmaceuticals. Health Action International network soon acquired a 'watch dog' profile in the worldwide, national, and regional pharmaceutical scene.

As HAI began strengthening its area of expertise and, as such, contributing proposals to the different levels (international, national, and regional) for creating a "new international pharmaceutical order", it increasingly became evident that the "pharmaceutical question" was intimately linked to social injustice and inequity, forcing us to recognise that "poverty and social injustice are huge barriers to achieving conditions of good health and of sustainable development" as well as reiterating our commitment to working for "just societies, where everyone participates in the decision making processes that affect their health and well-being."

HAI has thus taken on a political edge that pushes us to participate in new arenas where decisions related to the access to medications and their rational use are made. Poverty, and international relationships among countries are seen as critical issues in the everyday work of the organisations of HAI/AIS. The organisation is becoming more political without neglecting the technical approach and is reaching important spaces in decision making bodies at every level, as well as creating important strategic and tactical alliances with other organisations. Health and, in particular, access to essential medicines as substantial elements of a person's right to life cannot be left in the hands of the market; therefore, we at HAI assume an active problem-solving character in order to change the material conditions along with the regulations that could be on a collision course with that fundamental right.

Twenty-five years have passed since the inception of HAI, for learning as well as collective action. We have taken important steps in creating the world that we want, but there is always so much more to do. Chiefly, HAI must continue to labour in the pharmaceutical field in developing countries, along with taking a comprehensive approach for fighting poverty, social injustice, and the asymmetrical relationships between countries, as well as for fostering development and democratic societies by promoting solid coordination with other social organisations at international, national, and regional levels.

**Roberto Lopez Linares**

shifted from health issues to a myriad of other consumer concerns, came to rely on HAI to represent its interests in health at WHO. That continues, though the close organisational relationship between IOCU and HAI Europe gradually ended in the late 1980s. Meanwhile HAI and WHO have worked successfully together in many ways, most recently on a major drug pricing project, and on the drug promotion website ([www.drugpromo.info](http://www.drugpromo.info)).

Andrew has also been a link between drug bulletins and HAI, especially after the International Society of Drug Bulletins was founded in 1986. This is in a sense a parallel more specialised network, which shares many of HAI's interests and offers many opportunities for collaboration. Major issues occupying members of both networks in the last few years are drug promotion, especially direct-to-consumer advertising (DTCA), and the provision of reliable non-commercial information about medicines to the public. Since the pharmaceutical industry has a highly developed policy of funding 'friendly' patients' organisations to use them as allies in lobbying politicians and regulators, HAI is one of the few independent participants in debates on these matters.

### *HAI'S Relevance Today as a Global Network*

Along with its partners in other world regions, HAI Africa is working towards a world where all people, especially the poor and disadvantaged, are able to exercise their human right to health. This right to health requires equitable access to affordable quality healthcare and essential medicines.

A scandalously high number of people in Africa are not able to enjoy their right to health. In the poorest parts of the continent, half of the population lacks access to essential medicines. Many factors contribute to this lack of access. These include high prices, irrational use of medicines, inadequate health systems and a lack of new medicines that address the needs of developing countries.

HAI Africa's role in remedying this situation is clear. Its goal is to see policies and practices established that increase people's access to quality medicines, which are correctly prescribed and appropriately used, particularly for the poor and marginalised in Africa. Within the philosophy of health as a human right, HAI Africa works to achieve a more balanced structure of power within the medicines sector. It aims to achieve this as a consequence of stronger medicine-related civil society organisations and activists who empower consumers and promote competent providers, well-informed donors and governments.

In today's world, globalisation is a potent force. The factors that affect access to medicines in one part of the world - both negatively and positively - are heavily influenced by circumstances originating in other regions. Decisions taken by a few in global bodies such as the World Trade Organisation have an impact all over the world.

The HAI global network has been engaged in working together at the global policy level, such as ongoing advocacy work at the annual World Health Assembly meetings.

From the community-based to the national level, regional and international, the HAI global network is engaged in interventions that will have an impact on the complex causes of barriers to access to essential medicines.

As we celebrate 25years of HAI's existence, we should be cognizant of the different dynamics and changes within the NGO world and other key stakeholders. We should take stock of these changes and adapt so as to sustain the HAI Global network.

Long Live HEALTH ACTION INTERNATIONAL

*Patrick Mubangizi*

Individual work goes ahead in tandem with collective work, drawing in many different people and organisations in a constant ebb and flow, linked by the mechanism of networking (once described by Catherine Hodgkin as “the strength of the cobweb”). When we stop to count the people who received their initial inspiration from HAI, it is clear that it has been an early training ground for a host of activists who are now working in public health worldwide.

The nature of networking has been captured in a phrase - “fast, furious and flexible.” But, of these, it is surely the flexibility that is the defining advantage. It is this quality that has - after 25 years - seen a surprising consistency and permanence. Many of the original HAI partner organisations are still working effectively, defying the difficulties of finding resources year after year. Many of the individuals are still actively contributing. Networks (as opposed to organisations, where staff rapidly come and go and focuses of interest change) preserve a constant evolution of a necessary body of work, and are the curators of its history. They cross vertical barriers to shape and modify global and national policies, and they dig deep to reach the specifics of local practice. No network better exemplifies these achievements than HAI.

### *SMON Tragedy in Japan*

One of history's most horrifying cases of pharmaceutical-related corporate negligence involved the Swiss multinational giant Ciba Geigy and its drug clioquinol (also known as mexaform, enterovioform, enteroquinol). Ciba started marketing clioquinol in 1934 to fight amoebic dysentery. By the time the company entered the lucrative Japanese market in 1953, it was pushing clioquinol worldwide for all forms of dysentery. Ciba was permitted to market the drug in for all types of abdominal trouble, with no limitation as to dosage or length of treatment. Ciba promoted the drug throughout the 1950s and 1960s as being safe and effective, even for children, and as having no adverse permanent side effects. Clioquinol is known to cause Sub-Acute Myelo-Optic Neuropathy (SMON), a serious side effect affecting the nervous system, causing damage to the spinal cords and the nerves, including the optic nerve.

Andrew Chetley, in his *Problem Drugs*, explains what happened in Japan in the 1970s: “When 19-year-old Mieko Hoshi came down with diarrhoea... she was eventually given a halogenated hydroxyquinoline drug called iodochlorhydroxyquin (or clioquinol). Shortly afterwards, she suffered from a temporary paralysis of facial muscles... When that problem disappeared, she began to suffer from a growing numbness in her legs which spread to an almost complete paralysis of her body...she also lost her eyesight... It was clear that she was one of more than 11,000 victims of a disease called sub acute myelo-optic neuropathy (SMON).” Chetley then states: “Japanese scientists reported that clioquinol was the probable cause. Within a month, the Japanese government banned all of the 186 halogenated hydroxyquinolines products on the market... Japanese victims began to take legal action against Ciba- Geigy, but it was not until six years later that the company both apologised to them, and paid substantial damages.”

SMON litigation began in May 1971 in Tokyo. In response, Ciba-Geigy stated: “the SMON problem is a peculiarly Japanese one and they are not responsible to Japanese patients.” However, Ciba-Geigy Japan, was a subsidiary of the Swiss multinational giant.

Further, a worldwide study of clioquinol, its brand names and information sheets accompanying the drug, by IOCU, found critical differences in drug information being supplied in different countries. For instance, drug information accompanying Enterovioform, manufactured in Switzerland and sold also in Greece, Portugal, Kenya,

South Africa, Hong Kong, Malaysia and Singapore, limited the maximum dosage to 750 mg; listed the four main contraindications - hyperthyroidism, iodine allergy and impaired liver or kidney function; mentioned the side effects - peripheral and optic neuritis; and warned that the drug must be stopped at the first signs of abnormal sensations and visual disturbances. However, when exported from Switzerland to Thailand and Indonesia the instructions specified a maximum dose of 1500 mg, omitted malfunctioning of liver or kidneys from the list of contraindications, and failed to warn the user to stop the drug at the first signs of neuritis. Similarly, Entero-Vioform manufactured in U.K., and sold there and in Bahamas, Belize, and New Zealand, limited the course of treatment to a total of 3 g (1000 mg for 3 days). On the other hand, when exported to Tanzania their instructions specified a maximum of 15 g.

The Clioquinol campaign, initiated by Dr. Olle Hansson and the Japanese victims, soon built up as a global campaign. As Ciba-Geigy continued to market clioquinol in spite of known hazards and doubtful hazards, 3000 Swedish doctors boycotted Ciba-Geigy products, causing the company to lose 25% of its market in Sweden. Clinicians from England, Australia, Switzerland, Sweden, Denmark, the Netherlands, and the United States described patients who developed neurological symptoms while taking clioquinol. Their clinical symptoms were similar to those noted in the histories of Japanese patients with SMON.

In August 1978, the Tokyo District Court ruled in favour of the SMON victims and ordered Ciba-Geigy to make a settlement, which will adequately compensate for their sufferings and to submit an apology to the SMON victims. The Court noted:

"The Ciba Geigy head office in Basel investigated reports that dogs given Entero-Vioform or Mexaform often developed epileptic seizures and died, and the company circulated a warning among veterinarians not to use these drugs in veterinary treatment. However, although 'these drugs were produced for human use', they not only did not take any measures to warn about the dangers of use by humans, but also, they continued to stress thereafter the safety of Entero-Vioform and Mexaform in Japan, which can be considered deplorable.

"If Ciba Geigy had taken the appropriate measures at that time, it is probable that the suffering of most or at least a considerable number of SMON patients could have been avoided. Under such conditions, this must be considered as a matter of deep regret with respect to the Defendant Ciba-Geigy."

Under intense pressure, Ciba-Geigy finally announced in November 1982 its intention to 'phase out' the production and sale of clioquinol oral preparations over a three to five year period. The company still maintained the decision was not related to the drug's toxicity, but reflected new developments...

In November 1984, Ciba-Geigy announced it would 'accelerate' its original policy and stop the supply of the products 'by the end of the first quarter of 1985'. Dr. Andrew Herxheimer stated: "Withdrawal of the drug would have weakened the company's legal position. This was probably a major reason for the company's policy of persistent denial of the drug's hazard and continued assertion of its value." Chetley, pp.62-64.

Ciba Geigy finally gave a written apology to the Japanese victims; the apology states "... [the plaintiffs'] grievances were all earnest expressions of their pain, distress, and anger; appeals were made for redress. They were heart rending cries that made us realise anew that SMON has caused the patients and their families unimaginable suffering...In view of the fact that medical products manufactured and sold by us have been responsible for the occurrence of this tragedy in Japan, we extend our apologies, frankly and without reservation to the Plaintiffs and their families... We have also realised, with regret, that when recently asked the court to act as mediator we neglected to adequately express our sincerity. Again, we deeply apologise to the plaintiffs and their families."

*- edited excerpts from Andrew Chetley's Problem Drugs and  
Locost's Lay Person's Guide to Medicine, [www.locostindia.com](http://www.locostindia.com)*



# RELIVING THE 25 YEARS WITH HAI

Mira Shiva

Twenty-five years is a major milestone for any organisation, but probably for us in HAI it is extra special. It is special because it is associated with memories of working together with conviction; with some of the finest people I've known - for a shared goal.

## LEARNING THROUGH ACTION

I remember advocating for the various HAI moments in my life - the first pharmaceutical workshop in Penang in the early 80s, Dr. Olle Hanson's visit to India, the first public meeting I organised for him in 1983 on Clioquinol at the All India Institute of Medical Sciences, the International Consultation of Experts on Rational Drug Use in Nairobi in 1985, followed by the World Health Assembly of 1986 as part of HAI lobby team. It was here that, when the resolution of Rational Drug Use was to have been passed, the US threatened to walk out of the WHO as it had from UNESCO; it was here that I witnessed for the first time what North-South politics meant and it was here that the need for an alternative People's Health Assembly was contemplated with Goran Sterky and Dr. Zafrullah Chowdhury. Five years of HAI celebration in Bogevé, the launching of Action for Rational Drugs in Asia (ARDA) and Educators for Rational Drug Use (ERDU) in Manila, the Drug Policy meeting in Colombo and the privilege to be able to enter and be in Dr. Seneka Bibile's room - what a flood of emotions! I recall feeling deep gratitude for the inspirational value of Dr. Bibile, the realisation that it was in this small room great thoughts were thought and outstanding work done. Dr. Bibile must have been a great teacher, and Dr. Bala, his student, carries on the legacy left by him.

## LEARNING FROM PEOPLE

I remember with fondness several individuals who have been part of HAI family who have influenced me deeply, or crossed my life's path, leaving fond memories and deep insights - Dr. Olle Hansson probably being the most important. I still recollect his detailed handwritten response to my query about the SMON case of Japan. That letter reflected humility, the desire of sharing, the clarity of the technical scientific arguments with references to material and people as well as passion for the work. The people

he put me in touch for the EP (fixed high dose combination of oestrogen and progesterone) case - Dr. Milton Silverman and Dr. Andrew Herxheimer, became dear colleagues and friends.

It was the HAI meeting in Lunde that I met Dr. Olle Hansson for the last time. When I had earlier visited him in Gothenburg he had already been diagnosed with cancer and was undergoing treatment. At Lunde, we discussed drugs and the Indian situation while he cooked lunch. Culturally for me it was deeply touching. A meal cooked for me by a man, that too, a senior Professor, while discussing intensely the work that needed to be done - what a privilege!

Dr. Olle Hansson was to have had a bone marrow transplant from his sister; however he passed away a day before. What a deep sense of loss we all felt. For me I lost a mentor and a friend. Receiving the first Olle Hansson Award thus meant so much to me. We have dedicated all five editions of *Banned and Bannable Drugs* to him, to his memory, to his contribution.

In life's thorny path HAI has been like an oasis with so many wonderful people. Dr. Andrew Herxheimer, Diana Melrose, Charles Medawar, Ingemar Rexed, Eva Lachkovics, Noriaki Mizuma, Virginia Beardshaw, Catherine Hodgkin, Philippa Saunders, Joel Lexin.

Where HAIAP is concerned Bala has been like a rock through all the ups and downs. Anwar Fazal's vision, Dr. Zafrullah Chowdhury's energy, Prof. Dato Dzulkipli Abdul Razak's presence in the Poison Centre in Penang, have been very important and helpful.

The capable young team of the HAIAP Secretariat and all the members and associates; Sumlee, Jiraporn, Niyada, Delen, Michael Tan, Ken Harvey, Dr. Tariq Bhutta, Mohamed Idris, Martin Khor and Evelyn Hong make HAIAP special.

## HAI'S RELEVANCE TODAY

HAI continues to be very special because it is needed much more today than ever before. Today's global socio-economic and political challenges are of an unprecedented nature, as are the concurrent marginalisation, delegitimisation and trivialisation of the

### *Prescription for healthy consumers*

Patients have the right to:

1. Appropriate and accessible healthcare
2. Freedom from discrimination
3. Information and education
4. Choose a doctor or other health worker
5. Choose a healthcare establishment
6. Informed consent about treatment
7. Participate in their own healthcare
8. Respect, privacy, confidentiality and dignity
9. Complain
10. Redress in the event of injury

*The  
Rights  
of  
Patients*

Source: "Lay Person's Guide to Medicine", [www.locostindia.com](http://www.locostindia.com)

voices of concern. As international trade regimes increasingly influence health and pharmaceutical policies, as voices of concern are snuffed and censored while those willing to comply with creating and enlarging the health 'market' are promoted as the voice of the consumers, HAI provides the counterforce that truly and collectively represents the poor, the marginalised and the needy. It is this collective voice, raised because of the strong sense of social justice and equity in healthcare, which makes HAI so special. This voice has also been an energiser for many drug activists working in their region, witnessing greater build-up of the forces of exploitation.

### *Remembering Olle Hansson*

One of the greatest health campaigners of our time, who believed in the patient's right to information and firm adherence to medical ethics, Dr. Olle Hansson passed away on May 23 1985.

Dr. Olle Hansson was a Swedish Paediatric Neurologist based in Gothenberg. His name is closely linked with his fight against clioquinols (mexaform-like drugs). Not merely did he provide scientific proof, about absorption of the drug, from the gut, when ingested, (even when this was being systematically denied) but he was the first to report blindness associated with the drug. Dr. Olle Hansson wrote in scientific medical journals and in the lay press persistently for several years, warning the medical community and consumers about drug related hazards.

He stood as an expert witness in Tokyo District Court on behalf of the SMON (Sub-acute Myelo Optic Neuropathy) victims and their relatives - to support their fight for compensation against the giant multinational, Ciba-Geigy.

He fought a long, lonely battle against needless, drug induced suffering, and for "the patient's right to information".

Affected with cancer, he continued his fight against the Swiss giant Ciba-Geigy to ensure withdrawal of Mexaform, Entero-vioform and Butazones (Oxyphenbutazone, Phenylbutazone) - publishing information related to the deaths and disability of more than thousand victims who had consumed these drugs.

Although he died of cancer on May 23, 1985, at the age of 49, he remains a continuing source of inspiration for public interest workers everywhere. May 23 is commemorated each year as 'Olle Hansson Day'.

Dr. Olle Hansson had all the elements of a great health campaigner - scientifically sound facts and arguments, persistence and perseverance, honesty and integrity coupled with humility.

His greatest attribute was his ability to inspire others with his incredible courage. He was the leading light in the consumer and health movement as he fought for truly rational and socially just use of drugs with humility that is a feature of truly great men.

Olle Hansson Award recognises the work of an individual from a developing country who best demonstrates the qualities of Olle Hansson in promoting the rational use of drugs. The award, which is given annually, carries a price of US\$2,000 and a commemorative certificate. The Olle Hansson Award Fund is managed by Health Action International Asia-Pacific (HAIAP) that is the Asia-Pacific arm of the HAI global network.

The Award was first given in 1987. The recipients included Dr. Mira Shiva of India, Dr. Alfredo Bengzon of the Philippines and Prof. Dato Dzulkifli Abdul Razak of USM, Malaysia, and more recently, Dr. K. Balasubramaniam of Sri Lanka.

As we celebrate 25 years of HAI I think one of the most admirable things is the fact that there are still so many of us who were and are very much a part of it, from the beginning of the journey, very much there to work together and to celebrate our working together. Happy Silver Jubilee everyone!

### *A Case Study of a Successful Health Campaign*

High-dose estrogen-progesterone (EP) combination drugs contain the same female sex hormones as the combined oral contraceptive pill but at a higher level. These drugs were used in 1950s as a treatment for missed periods since they were thought to start menstruation in women whose periods were delayed and who were not pregnant. A woman whose periods did not start after taking EP drugs was presumed to be pregnant, and hence EP drugs were used for pregnancy testing. But because the drug could apparently bring on menstruation, EP drugs were misused to induce abortion. Although no pharmaceutical company has ever claimed that these drugs will induce abortion, there was evidence in India that they were prescribed by doctors for this purpose and were also sold over the counter. About 20 years later research uncovered evidence that the EP drugs were unreliable as pregnancy tests and ineffective as treatment for missed periods. In fact, evidence showed that the drugs were associated with birth defects. Those women who used this drug for pregnancy testing and continued with their pregnancy exposed their unborn babies to the possibility of birth defects. Those women who took the drug to induce abortion but did not abort, also ran the same risk. The World Health Organisation alerted its Member States on the dangers of these drugs. Many countries began to withdraw/ban this drug since 1970.

In India EP drugs continued to be marketed by the pharmaceutical industry and by 1982, an estimated 180,000 were using the drug each year. The drugs were grossly misused by pharmacists and prescribed by doctors for pregnancy testing and as abortifacients in India, even though their efficacy for such indications was not established.

In 1982, as a result of a nation-wide campaign, the drug was banned by the Drug Controller of India (DCI). However, the pharmaceutical companies obtained a stay on this order on technical grounds. One of the petitioners was Infar, the Indian subsidiary of the Dutch multinational company Organon, which was not allowed to manufacture and market the drug in the Netherlands. Following this, a campaign was launched by health, consumer and women's organisations and it was sustained till the ban was re-enforced in 1988.

The campaign was led by the All India Drug Action Network (AIDAN) coordinated from Delhi. Non-governmental organisations involved in health, consumer and women's issues, journalists, academicians, lawyers and other concerned individuals including doctors and health practitioners were actively involved in the campaign. It started with the collection, compilation and dissemination of information including listing of brand names of EP drugs. The network also reviewed the medical literature on EP drugs and collected scientific data. This information was widely disseminated through the media. The media played a crucial role in influencing public opinion. Newspapers gave good coverage to latest developments on the EP case, numerous features written by AIDAN activists were carried and letters arguing the pros and cons of the drug kept the issue alive for six years. Network members used all possible forms to publicise the issue, giving television interviews, and took advantage of the various fora to increase public awareness, including street corner meetings, addressing meetings of women's committees, Rotary and Lions clubs and such like.

As a result of such high-pressure campaign, the Supreme Court directed the DCI to hold public hearings to seek the views of consumers and health groups in four metropolitan cities of Delhi, Calcutta, Madras and

Bombay. This struggle was also supported by international organisations like the Health Action International, IOCU, WEMOS (a Dutch NGO), and the Australia-based Medical Lobby for Appropriated Marketing (MaLAM). Finally in 1988, a year after the public hearings, the Indian government banned the manufacture and sale of high-dose combinations of EP drugs.

Though the EP product is not important in economic terms to the drug industry, the industry went to such extreme lengths to oppose the ban. This is the first time in the history of the drug industry in India that the industry has been forced to face a public inquiry to defend its products. So, it wanted to scuttle the movement before it snowballed and became too powerful. Despite knowing fully well that the drug was not allowed to be marketed in several countries, it obtained a stay order on the ban in 1982. Moreover, it used deceit, falsehoods and even threats of violence to oppose the ban. What is disturbing is that the industry could persuade highly-qualified Endocrinologists and Gynecologists to use questionable and possibly unethical tactics. Their opposition is a sad commentary on the status of the Indian medical profession and an indication of the highly disturbing stranglehold of the drug industry on the medical profession.

The industry perceives any argument or inquiry, however scientific and rational it may be, as a threat to profitability and will go to any extent to thwart it. Under such circumstances, the ban on the high-dose drug was a great achievement. Despite the powerful industry's stranglehold, the people's movement proved strong as they stood united for one single cause.

*From: Menon, Lakshmi. "Till We Have Won: Campaign to Ban High-dose Oestrogen-Progesterone Drugs", in Organising Strategies in Women's Health: an Information and Action Handbook. Manila: Isis International, 1994. pp. 117-120, reproduced from: "Lay Person's Guide to Medicine", [www.locostindia.com](http://www.locostindia.com).*



'It is time to act! It is time to act for all of us who believe in human dignity and justice'.

**- Olle Hansson**

### *Proud to be with HAI*

I am, perhaps, the newest member of staff to join the HAI network, and only took up my post in January 2006, so to be engaged at such an auspicious time is truly wonderful. It gives me great personal pleasure to be contributing to the HAI-Asia Pacific 25 year Anniversary publication, and would like to add my best wishes to those of the other HAI regional offices.

The HAI network has much to be proud of in its first 25 years, and the contribution, and often lead, that HAI has taken in propelling the global debate on medicines and health has been crucial. However, when we review the successes of last 25 years we might also reflect on the fact that the very principles on which HAI was founded are as relevant today as they were in 1981. The current global market in medicines still reflects a bias that puts commerce before health, economic considerations before therapeutic innovation, products before treatments and profit before patients. The question is - where in this conceptualisation are the voice of the consumer and the interests of those taking medicines protected? The answer is that the consumer perspective is rarely presented. Consequently, on the one hand, we see the over-consumption of profitable drugs, beyond any sensible assessment of benefit and harm and often as a result of aggressive promotion. On the other hand, R&D and innovation ignores real health needs, and access to even essential drugs is denied to the many that need them.

It is into this vacuum of consumer interest representation that HAI must step and it is clear that HAI still has much work to do. But HAI is more than up to the challenge and by building on the successes of the past, exploiting the extraordinary wealth of expertise of HAI members and taking strength from being a part of the HAI global network, I am sure we can look forward to the future with ever-greater optimism.

Even though I have been at HAI only a very short time, I recognise the dynamic and strategic advantage of being part of a global network, and wish all the members in HAI Asia-Pacific all the very best for the next twenty-five years.

*Tim Reed*

# HOW DID I FIRST GET INVOLVED WITH HAI?

**Ken Harvey**

In the early 1980's, while working at the Royal Melbourne Hospital, I had published articles in the Medical Journal of Australia on antibiotic-resistant microorganisms and the inappropriate promotion of new antibiotics by the pharmaceutical industry. A young policy officer of the Australian Consumer's Association came from Sydney to talk to me about medicinal drug policy; she also introduced me to the work of HAI, HAIAP and Dr. Bala. Her name was Yong Sook Kwok. An invitation from Bala to attend a HAIAP regional meeting in Penang soon followed.

My wife and I had worked as medical officers in Papua New Guinea. However, until this time, like many Australians, I had usually flown over Asia and the Pacific Islands on my way to medical meetings in Europe or the USA. My first HAIAP meeting drastically changed my subsequent travel focus! In Penang I met an inspiring group of health activists from many countries who were all working to make the HAI slogan. "Health for all - Now!" a reality.

## WHERE HAVE I BEEN WITH HAIAP?

I have been involved with HAIAP in Bangladesh, China, India, Indonesia, Laos, Malaysia, Pakistan, Philippines, Sri Lanka and Thailand. In addition, I have valued HAI support in Geneva in the late 1980's when I was a member of a WHO expert panel that formulated the WHO "Ethical Criteria for Medicinal Drug Promotion". Furthermore, with the assistance of AusAID and the Australian Health Insurance Commission, I have spent more time working on medicinal drug policy issues with colleagues in the Philippines, Croatia and Jordan. This work was informed by experience gained through HAI. Finally, back in Australia, our own national medicinal drug policy has been greatly assisted by local HAI activists, especially Yong Sook Kwok, Mary Murray, Beverley Snell and Peter Mansfield, supported internationally by Bala, Alfredo Bengzon, Andrew Herxheimer, Goran Tomson and many others.

## WHAT DO I BEST REMEMBER FROM WORKING WITH HAI?

- Eating with my hand for the first time in India, wishing I had had not asked what I was eating in China, sleeping under mosquito nets and trying to fit a large Australian frame through small doorways at Gonoshasthaya Kendra, Bangladesh.

- The American FDA delegate to the WHO Ethical Criteria expert panel who continually blocked suggestions for additions to the ethical criteria on the grounds that, “my government [the US pharmaceutical industry] would be opposed to such ideas.” My first [but not my last] introduction to the noxious but pervasive influence of Big Pharma.
- Stirring speeches from Anwar Fazal, battle stories from Zafrullah Chowdhury and Alfredo Bengzon, passionate advocacy from Mira Shiva, social analysis from Michael Tan, persistent advocacy from the Thai Drug Study Group, Nordic enthusiasm from Goran Tomson, valued international support from Andrew Chetley, Catherine Hodgkin and Charles Medawar, passionate debate among the group who organised the first People’s Health Assembly and, above all, the humility, dedication, organisational and analytical skills of Bala and his HAIAP team.

## **FINAL THOUGHTS**

The role of a health activist is often isolating and lonely. It is never easy. It inevitably takes a ton of effort to get an inch of movement. But the task is important. Under these circumstances it is crucial for activists to come together, to learn from each other, to support each other, to celebrate success, to commiserate the difficulties and to strengthen each other’s resolve to continue the battle. This has been the key role that HAIAP has played over the first 25 years of its existence.

It has been a privilege to be involved, it has been most satisfying to see the network expand, and the results achieved are a fitting tribute to the original vision of Anwar Fazal and Bala. I have no doubt that a younger generation, inspired by those who have gone before them, will ensure that the next 25 years will be even more productive.



# HEALTH ACTION INTERNATIONAL ASIA-PACIFIC

*The World Health Report 2002 describes the ten leading risk factors for human health as underweight, unsafe sex, high blood pressure, tobacco consumption, alcohol consumption, unsafe water, sanitation and hygiene, iron deficiency, indoor smoke from solid fuels, high cholesterol and obesity. At least 30% of all disease burden occurring in many developing countries such as those in Sub-Saharan Africa and South East Asia results from fewer than five of the ten risks.*

*In a world which is richer than ever before today, and that has the means to prevent most of the deaths due to ill health through the provision of the most basic health services, a health catastrophe that kills more people than ever before is allowed to continue. This health catastrophe is poverty, inequity and injustice. Globalisation, liberalisation and privatisation in the health and the provision of basic services sectors are deepening the catastrophe.*

*As the People's Charter for Health says in its preamble, "Health is a social, economic and political issue and above all a fundamental human right. Inequality, poverty, exploitation, violence and injustice are at the root of ill health and the deaths of poor and marginalised people. Health for all means that powerful interests have to be challenged, that globalisation has to be opposed, and that political and economic priorities have to be drastically changed." Health Action International Asia-Pacific focuses on actions to defend this fundamental right.*

## ABOUT HAIAP

In March 1986, Action for Rational Drugs in Asia (ARDA) network was founded at the Planning Meeting for the Asian Drug Campaign held in Penang, Malaysia. ARDA, hosted by Consumers International Regional Office for Asia and the Pacific (CIROAP) was to function as the Asian arm of the HAI network. In 2001, the founder members decided to move ARDA out of CIROAP and relocate to Sri Lanka. Following this in March 2002 ARDA was registered as a non-governmental organisation called Health Action International Asia-Pacific (HAIAP) with its own legal entity.

HAIAP works with members and allies towards achieving its goals. A seven member governing council is the highest policy making body for HAIAP.

HAIAP consists of a network of organisations and individuals involved in health and pharmaceutical issues. One of the first successes of ARDA/HAIAP was the forging

of a new level of partnership among health activists, medical and pharmacy educators, officials from the Ministries of Health and International Trade and the media.

ARDA/HAIAP upholds health as a fundamental human right and aspires to build a just and equitable society in which there will be, among others, regular access to essential medicines to all who need them irrespective of their ability to pay for them. ARDA/HAIAP actively promotes the concept of essential drugs, their rational and economic use through advocacy research, education and action campaigns.

The main objectives of HAIAP are:

- To promote the concepts of essential drugs and their rational use.
- To campaign for the removal of harmful, irrational and unnecessarily expensive drugs.
- To provide objective drug information for prescribers and consumers in order to increase their awareness of the concepts of essential drugs and their rational use.
- To encourage governments to implement national drug policies.
- To ensure the availability of quality healthcare and safe and effective drugs of good quality at affordable prices to all who need them.
- To call upon governments to adapt to their own needs the criteria listed in the WHO document “Ethical Criteria for Medicinal Drug Promotion”. This will assist national drug regulatory authorities to control drug marketing in their respective countries.

HAIAP conducts its advocacy through:

- Publishing *HAI News*,
- Organising consultations/seminars/workshops,
- Producing publications,
- Access to information through HAIAP website, and
- Providing advisory services.

Apart from reports, newsletters, press releases and briefing papers, HAIAP has also produced four position papers (with inputs from three working groups consisting of its members) on *Access to Medicines*, *Rational Use of Drugs*, *Traditional Medicine* and *Undergraduate Medical Education* respectively, reflecting its position on these issues.

## **HAI NEWS - THE GLOBAL NEWSLETTER OF THE HAI NETWORK**

*HAI News* is the communicational tool of the global network Health Action International. It is published quarterly by HAIAP and provides a forum for HAI partners to share their experiences and learn from one another. A lead article examines and analyses in-depth selected current topics relevant to health, pharmaceuticals and development. In the section ‘Network News’, contributions from HAI members/partners on various projects, campaigns, events and their activities are featured. The section ‘Journal Scan’ reports on developments in the international campaigns for more rational and fairer health and pharmaceutical policies. The ‘Resources’ section carries reviews of selected publications of interest to health and development activities.



# HAI News

THE NEWSLETTER OF HEALTH ACTION INTERNATIONAL

## Healthcare - who cares?

By K. Balasubramanian

### HAI in Madrid

10th April 1995



Transforming Policy into Practice: Involving African Consumers in RDP



Health for all now

## Cost Effective Use of Drugs in Hospital

Dr. A. K. Balasubramanian



Transforming Policy into Practice: Involving African Consumers in RDP

Health for all now



## When industry ignores health: The impoverished struggle to get essential medicines to those who need them

By Jane Howell & Sue Van der Meer

During the last year, consumers have been hearing about the need for essential medicines. The World Health Organization (WHO) has been urging governments to ensure that essential medicines are available to all who need them.

However, getting essential medicines to those who need them is a complex task. It involves ensuring that the medicines are available in the right quantities, at the right prices, and in the right places. It also involves ensuring that the medicines are of the right quality and that they are used correctly.

### In This Issue

- Health for all now
- Cost Effective Use of Drugs in Hospital
- Transforming Policy into Practice: Involving African Consumers in RDP
- Free Trade Agreements: a boon or a bane?
- EP drugs: The bigger battle
- Historic Day for...



## EP drugs: The bigger battle

Dr. A. K. Balasubramanian

Essential medicines are those medicines that are needed to meet the basic health needs of the population. They are the medicines that are used to treat the most common diseases and to prevent the most common injuries.



The battle for essential medicines is a long and difficult one. It involves ensuring that the medicines are available in the right quantities, at the right prices, and in the right places. It also involves ensuring that the medicines are of the right quality and that they are used correctly.

### Patients' Rights

Dr. A. K. Balasubramanian

Patients have the right to be treated with respect and dignity. They have the right to be informed about their condition and to participate in decisions about their care. They have the right to refuse treatment if they so choose.



## Free Trade Agreements: a boon or a bane?

Passionate Contributors: A. K. Balasubramanian

## Historic Day for...

On 10th April 1995, the World Health Organization (WHO) celebrated the 50th anniversary of its founding. The WHO was established in 1948 and has since then been working to improve the health of the world's population.

The WHO has achieved many successes in its 50 years of existence. It has helped to reduce the incidence of many diseases, to improve the health of many people, and to bring about many other positive changes in the world's health.

The WHO is a unique organization. It is the only international organization that is dedicated to the health of the world's population. It is a source of pride for all who are committed to the health of the world.

The WHO is a source of inspiration for all who are committed to the health of the world. It is a source of hope for all who are struggling with health problems. It is a source of strength for all who are fighting for a better world.

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Currently, *HAI News* is circulated among 500 subscribers in 102 countries worldwide. A reader survey is conducted among the subscribers to seek their views and suggestions for further improvements on the newsletter. HAIAP receives several requests from students, health professionals, health activists, journalists from all over the world to subscribe, contribute or for permission to reproduce certain articles.

*HAI News* is accessible electronically on <http://www.haiap.org/publications.html>.

## **HAIAP WEBSITE**

HAIAP's website [www.haiap.org](http://www.haiap.org) provides information on the latest publications including the global newsletter, activities, events of HAIAP and relevant news and events on health, pharmaceuticals and development issues shared by our members and partners. It contains seven pages including the home page, history of HAIAP, publications, activities, news and events, contact details and links to the regional offices and a contact us page. According to web statistics, it had on average approximately 6500 visitors per month during 2005.

We still continue to receive a number of requests via the feed back form on the website from individuals and organisations interested in working with HAIAP, students for internships and block placements, grass root level organisations writing in for funding and from people seeking information on various issues.

## **HAI POSITION PAPERS**

In 2004 four position papers titled, *Access to Medicines: Drug Pricing and Patents*, *Rational Drug Use*, *Traditional Medicine* and *Undergraduate Medical Education* were produced by HAIAP and disseminated among local and regional media organisations, HAI Regional Coordinating offices, list-servs and to HAIAP members for further dissemination in their individual countries. HAIAP had several requests from postgraduate students, academia, health professionals, International Non-Governmental Organisations from countries in Asia, Europe, the Americas, Australia and Africa.

The position papers were reproduced in some of the local newspapers and in the *HSC News* published by the Health and Social Campaigners Network International, a network designed to support individuals who work as campaigners in health and social care.

The press releases and the position papers are available in full on the HAIAP website.

### *From the Health and Social Campaigners' News International*

*Clive Nead, Editorial Director, Health and Social Campaigners' News International...*

We feel that HAIAP's four position papers provide a superb overview to their subject matter. We would therefore like to feature them as a one-page article in the next issue of our monthly briefing, *Health and Social Campaigners' News International*, in the hope of further publicising them. The briefing currently goes out to about 1000 members of the Health and Social Campaigners' Network International (one of which is HAI Europe). HAIAP was also offered one year's honorary membership with HSC Network International.



# THE ROADS WE HAVE TRAVELLED TOGETHER

**Prem Chandran John**

In the early eighties, the world was a different place, not a better place surely but different. As the old song says, it was a time of innocence. The pressures and pulls, the disparities between nations and within nations existed but the processes of globalisation had not widened them yet. Neo-colonialism and neo-liberal economic policies had not yet made their pervasive influence felt. The wide gaps between the rich and the poor as evidenced by the ill-health statistics were shameful to say the least. The health situation of large tracts of the globe was cause for concern. Governing classes of the day were pursuing their own paths while their citizenry languished. But not enough voices were being raised and very little analysis of the situation was being done. In such a milieu was born Health Action International in 1981 with the International Conference of Pharmaceuticals and NGOs in Geneva.

The original aim of HAI was to act as a watchdog over the activities of multi-national pharmaceutical companies, increase access of the poor to essential drugs and to promote the rational use of drugs. This is still largely true of HAI but its offshoots such as HAI Asia-Pacific (HAIAP) have moved on to addressing larger and more basic issues such as the fundamental question of poverty that causes inequities in health as also in other livelihood situations of the poor.

Historically speaking, in 1984, Asian Community Health Action Network (ACHAN) convened a workshop - Pharmaceuticals and the Poor of Asia - in Madras, India to which we invited Dr. Balasubramaniam, known as Bala which, in the tongue of his ancestors (and mine), means the Younger, much like Pliny the Younger. At that time Bala - I have been given the licence to call him Bala though he is older and by far the wiser - was with UNCTAD and was and still is, recognised as the foremost expert on the issue of pharmaceuticals and the poor, not in the Third World alone but globally. Knowing his exalted status, we still had the temerity to invite him to come back to Asia.

By March 1985, ACHAN along with IOCU (now CIROAP) began the process of forming an entity that would effectively support the activities of Bala. This resulted in the formation of ARDA (Action for Rational Drugs in Asia), a separate entity that would use the umbrella of CIROAP but with its own programmes, budget and staff structure.

In May 1986, Bala, still in UN service, was invited to the World Health Assembly in Geneva. Following this, a meeting of HAI took place in Bogeve, France where some of us from the so-called Third World - Anwar Fazal, Zafrullah Chowdhury, Mira Shiva and I - had discussions with Bala about Asia and the need to focus on issues other than pharmaceuticals. Bala gave us wise counsel and thus came about the transformation in the entire outlook of CIROAP in favour of the poor of Asia.

Bala retired from the UN in September 1986 and joined ARDA that October. Like Pliny the Younger, since then, his wisdom and prolific analytical and advocacy skills have led ARDA that subsequently became HAI AP thus providing a lot of synergy.

The 1992 Asia-Pacific workshop on Pharmaceuticals in Colombo, Sri Lanka formalised the mandate for the focus on poverty as a cross cutting and fundamental issue; this was reiterated in the Regional Consultation held in 1994 in Madurai, India. When TRIPS came into being in 1995 threatening the poor of the world, HAIAP was there to start a high profile advocacy role to fight against it.

## **PEOPLES HEALTH ASSEMBLY**

Out of the first planning meeting of ARDA in Bangkok in April 1987, emerged the seed of a People's Health Assembly (PHA). Successive World Health Assemblies where the health decision makers of the world congregate each year had failed to address the needs and aspirations of the poor of the world. Health decision-making was not only taking a different route altogether in conformity with neo-liberal economics but was being concentrated in the hands of a few nations and institutions. Consider the fact that the health budget alone of the World Bank is bigger than the entire budget of WHO.

Bala, being in the thick of things as it were and still within the UN structure, floated the idea of a PHA which would act as a forum where people's voices would be given pride of place. It took thirteen years for the idea to germinate, take root and flower, resulting in the first PHA in December 2000, in Savar, Bangladesh. The 1,500 people from 90 countries present - activists, academics, professionals, health workers, midwives - all spoke in one voice, demanding that they be heard at the global health decision-making processes.

Out of PHA 2000 grew the People's Health Movement (PHM), now a worldwide movement and geographically significant enough to be recognised by the powers that be. PHA 2, which took place in Cuenca, Ecuador, July 2005, further strengthened this. To give an example, as a result of this strengthening, PHM played a crucial role in pushing WHO to set up the Commission on Social Determinants of Health - CSDH. In fact, one of the Commissioners is a PHM member, as are all the Regional Facilitators for Civil Society, and thus, PHM continues to have its foot in the door. Hopefully, in course of time and hopefully within the lifetime of CSDH, WHO's decision-making will become more people-centred. PHM, therefore is one tangible and effective entity that came about largely due to Bala's vision and commitment to the poor of the world.

The Governing Council of HAIAP consists of some of the most respected names in the Asian non-governmental activist scene, each one an expert in one or several of the issues confronting Asia. But it is Bala who makes us focus on issues and harnesses the synergy that comes about.

This compilation of some of his learned writings is but a small and inadequate salutation to Bala and his prescience. Over the years, his contribution has been

immense and this is only a small part of his expressed anguish on the plight of the poor of Asia and the mechanisms that cause and perpetuate it, which is being published. He has, truly, been a prophet!

It is my pleasure, privilege and honour to commend Bala on the 25th Anniversary of HAI and his singular contribution to the poor of Asia. By honouring such a person of eminence, we are actually honouring ourselves.

### **MILES TO GO AND PROMISES TO KEEP**

The task is not over yet. The governing classes worldwide and the structures that they have built up to prop themselves up are getting stronger. The corporations, as David Korten says, are beginning to rule the world, from Bangkok to Bogotá and from Norway to Nairobi. The dark clouds gather but the voices that are being raised and the solidarity that is being built up have come to such a pitch that they cannot be ignored any longer. In such a situation, Bala has played and will continue to play a crucial role for we are dealing with evidence-based research of which he is a postmaster. The woods, as they say, are still dark and deep but Bala, with his physical problems and advancing years, still would say that he has promises to keep. That is a challenge to the younger generations.

If, as Chairperson of HAIAP, I say that we have been on the cutting edge of the struggle against the hegemony of transnational pharmaceutical corporations and have been primarily responsible for keeping this issue alive in the public eye, it is solely due to the foresight, vast knowledge, scholarship, international reputation, global recognition and a prolific output of learned papers of Bala that this has been possible.

*- Prem Chandran John*

# MEMBERS NARRATE THEIR HAIAP STORIES

## AFGHANISTAN

*Some statistics on Afghanistan from the Human Development Reports*

Total population (millions), 2003	27.2
Life expectancy at birth (years), 2003	46.2
Population with sustainable access to improved sanitation (%), 2002	8
Population with sustainable access to an improved water source (%), 2002	13
Children underweight for age (% under age 5) 1995-2003	48
Children under height for age (% under age 5), 1995-2003	52
Malaria cases (per 100,000 people), 2000	937
Tuberculosis cases (per 100,000 people), 2003	671
One-year-olds fully immunised against tuberculosis (%), 2003	56
One-year-olds fully immunised against measles (%), 2003	50
Births attended by skilled health personnel (%), 1995-2003	14
Health expenditure per capita (PPP US\$), 2002	34
Public health expenditure (% of GDP), 2002	3.1
Private health expenditure (% of GDP), 2002	4.9
Physicians (per 100,000 people), 1990-2004	19

The NGO - Afghan Children Centre (ACC) - of which I am the Executive Director focuses on health and rights-related issues of children and on issues maternal health. In addition we are trying to improve access to drugs and promote rational use of drugs. We work in close collaboration with the Ministry of Health and other relevant institutions on these issues. The ACC has affiliated with International Children Center that is located in Turkey.

Our activities include:

- Training of health staff for numerous programs of ministry of health with regard to child and mother health.
- Conducting researches for various health related institutions.
- Participation in any activities with regard to rational use of drugs at the country level.
- Celebration of national and international occasions with regard to child, mother and drug related issues.



- Participation in international conferences and workshops with regard to child, mother and drug related issues.
- Providing of any kind of support to HAIAP in Afghanistan.

ACC is also working towards creating a national network for ensuring that people's, especially children's health rights are met adequately.

*Abmaduddin Maarij*

## **CAMBODIA**

The Department of Drugs and Food of the Ministry of Health of the Kingdom of Cambodia, especially the Essential Drugs Bureau, has been actively involved in improving the supply system of the essential medicines in Cambodia, the rational use of medicines and improving the Cambodian people's access to essential medicines. Our activities include: regular supervision and monitoring on drugs use and drugs management the production of manuals for logistic supply management of pharmaceuticals, production distribution and airing of education (IEC) materials, survey, training and workshop.

For activity related to the implication of the Intellectual Property Rights on pharmaceuticals, only few workshops or trainings have been organised in Cambodia to improve awareness among government officials. However, following the Doha Declaration containing Article 6, Cambodia reacted immediately by mentioning in Article 136 of our Law on Patent, Model Utilities and Industrial Design that "Cambodia will exclude the patent protection of pharmaceuticals until 2016".

I am very proud to have been selected as Associate Member of HAIAP. Despite my limited involvement in HAI activities, I appreciate their work in the areas of the rational use of medicines and the accessibility to essential medicines, especially the implication of the international treaties on national public health and healthcare systems. My special appreciation is also due to Dr. Bala and all of his HAI colleagues for their valuable efforts to improve the health situation of many developing countries including Cambodia.

*Chroeng Sokhan*

## **CHINA**

In the early 1990s, we found problems with antibiotic use in China and we published an article in an international journal (Yang Y. H., et al. "Abuse of antibiotics in China and its potential interference in determining the aetiology of paediatric bacterial diseases." *Pediatr Infect Dis J*, 1993,12:986-988) to bring this to the attention of international scientists. In 1994, with the support of Consumers International, we successfully held the 1st National Workshop on Rational Use of Antibiotic in Beijing, organised by the Chinese Society of Paediatrics. International experts, Dr. Bala from CI, Drs. Harvey and Primrose from Australia and Dr. Dzulkifli from Malaysia joined us and shared their experience.

In 1995, Dr. Shao Mingli from the Ministry of Health (MOH), Dr. Fan Maohuai from our hospital and I were invited to attend an International Conference on National Medicinal Drug Policies in Sydney, Australia organised by the Australian Government and the WHO. Subsequently, Dr. Harvey visited Beijing for two months in 2000, supported by the WHO and sponsored by myself, to exchange information on rational

antibiotic use. I was also invited to translate the Australian booklet *Therapeutic Guidelines: Antibiotics* (Ed. 10) into Chinese. Subsequently, the Chinese Sub-Society of Paediatric Pulmonology (I am the Chairman of the Sub-Society), prepared the *Guideline of Antibiotic Use in Respiratory Infections* which was published in Chinese journals.

In 1997, we collaborated with the Centre for Disease Control, USA to survey the antibiotic use in rural areas of China.

Over the past 15 years, we have organised and/or joined several national meetings concerning with rational use of antibiotics and antibiotic resistance of bacteria in China.

In 2004, with support from the Chinese Government (Ministry of Health and the Ministry of Sciences Technology - MOST), we commenced a very important project, *The use of antibiotics and the resistance of common pathogen*, along with the Shanghai Children's Hospital (affiliated to Shanghai Transportation University), Paediatric Hospital (affiliated to Fudan University in Shanghai) and Chongqing Children's Hospital (affiliated to Chongqing Medical University). Along with other national experts, I am also preparing a booklet, *The Principle of Antibiotic Use* for the MOH and Chinese Medical Association. Our government is clearly paying attention to the severe problem of antibiotic abuse and the resistant microorganisms that this causes.

Given this growing interest in rational drug use, we felt it was time to organise a second workshop on this subject in order to review the current situation and discuss strategies that might further improve antibiotic use in China. The workshop was successfully held in Beijing, from 28th to 30th November 2005. Representatives from the WHO Beijing office, Chinese Ministry of Health and Ministry of Science and Technology, State Food & Drug Administration, China CDC and Beijing City Health Bureau attended the meeting. Australian speakers came from La Trobe University, the National Prescribing Service and Medicare Australia. The aim of the workshop was to provide an opportunity for university and hospital clinicians, pharmacists, opinion leaders and policy makers to contribute and learn from Chinese and international initiatives that promote rational antibiotic use. In addition to lectures, small group sessions gave all participants many opportunities to put forward their own views and discuss the conference recommendations. Chinese data on antibiotic resistance and antibiotic use were summarised, educational initiatives were shared, barriers to rational antibiotic use were explored, and an action plan, including policy suggestions, were formulated.

Dr. Harvey, along with his colleagues Drs. Judith Mackson, Janet Mould and Ms. Michelle Sweidan, shared the Australian experience in rational drug use. We appreciate very much the support of the Australian government, the Australian National Prescribing Service, and Australian academia, which made their visit possible. In addition, I would like to record our sincere thanks to HAIAP, especially Dr. Bala, their Advisor and Coordinator for this workshop.

*Yonghong Yang*

## **INDIA**

While my formal association with HAI Asia-Pacific started after its reorganisation a few years back, memories of HAI as one of the few global organisations that have consistently located health in a people-centric context stretches much further back. In

the eighties HAI was synonymous with the global campaigns for access to essential drugs and right to healthcare. I still have copies of *HAI News* published decades back, and for many of us it was a window into the wide world outside our immediate concerns.

Of course, in the ultimate analysis, organisations stand for what the people who shape them make of them. So memories of HAI are linked with the people who have nurtured it – and one cannot but think of Bala and Zafrullah in association with HAI Asia-Pacific. Bala as Coordinator of HAI Asia Pacific is an extension of Bala who was such an inspiration for many of us. I still remember how once we changed the dates of a national event at a fairly advanced date to accommodate Bala and Zafrullah's commitments. Several papers or ideas for campaigns that we have pursued have had their origins from picking their brains.

Above all HAI has been a platform at a global level to exchange experiences, learn from each other and join hands for shared concerns. That it today celebrates its 25th anniversary is testimony to the efforts of those who have nurtured HAI. Swimming against the tide is never easy, and in today's climate that encourages cut-throat competition and values of unbridled consumerism through the medium of the market, HAI stands for basic human values and compassion.

*Amit Sen Gupta*

Way back in 1981 FMRAI met HAI friends in Moscow at an international seminar on Pharmaceutical Industry and Role of the Multinational companies. We appreciated the film shown by HAI friends on the effect of Clioquinols and SMON among the Japanese population. Our friends, who later founded HAI, were then working against the baby food industry. They were glad to know that the Trade Union Organisation of the Sales People, despite being victimised, was also fighting the multinational companies. Since then, we have maintained bilateral relations with HAI, and have been considered as a key HAI contact in India.

Later, after being invited to a HAI meeting in Geneva in 1992, we, for the first time met our HAI friends. In the meantime, we were trying to construct a small-scale pharmaceutical company for which we were guided by UNCTC to contact Dr. Bala, who was working towards developing such efforts in the Caribbean. In no time, Dr. Bala became the source of our knowledge for technology. We also, for the first time, gathered basic ideas about pharmaceutical patents and the mischief being done by certain multinational companies. In the meantime, in 1988, together with Indian pharmaceutical companies like Cipla and Ranbaxy, we had founded the National Working Group of Patent Laws, an effective lobby to protect Indian Patents Act 1971.

At the 1992 meeting, HAI gave priority to issues like the irrational and hazardous medicines and unethical promotion of medicines. We, too, were working on the last issue, and exchanged many documents with HAI. At the meeting, I proposed that the price of medicines and abnormally high profit earned by the multinational medicine companies should be taken up as a priority in the agenda, as also IPR issues emerging out of the Uruguay Round. This was not accepted, though a post dinner session outside the official agenda was allowed. During the sessions Dr. Bala described the fundamentals of the patent issue, which many were hearing of for the first time and so could, not understand the impending danger.

Some time later, Chirag and Pascal met us in the Peoples Health Assembly held in Dhaka in 2000. They candidly told me that when I had insisted on discussing patent and policy issues at the 1992 meeting, I had been disrupting the meeting. Now both pharmaceutical pricing and TRIPS have become priority issues of HAI, which I am very happy about.

When HAIAP was formed, FMRAI decided to associate with it. FMRAI initially was hesitant to work with so many important persons and specialists but friends in HAI expressed clearly that our work is that of a social scientist. This has inspired us to continue working happily with HAI and HAIAP.

*Amitava Guba*

My association with Health Action International dates back to the early 1980s when HAI was formally launched in Geneva. Many of us in India were already active in the campaign to promote the essential medicine concept and the fight against irrational and dangerous drugs. There was a convergence of objectives and concepts between the health groups in India and organisations like HAI that were functioning in Europe at that time. The publications and documents prepared by HAI were the resource materials for us to expose the unethical marketing practices and the double standards followed by multinational drug companies in marketing drugs in the developed and developing countries. We were also partners of the ARDA network, which later became HAIAP.

*HAI News* and other publications are still used extensively by the health groups in India for building up the campaign for rational drug use and access to essential medicines.

It may be mentioned here that Dr. Balasubramaniam, who has played and continues to play a central role in ARDA and HAIAP, is a source of inspiration and guidance to the health groups in India. He has visited India several times and participated in a number of seminars, conferences etc on drug and health related issues. The papers prepared by Dr. Bala are used as essential reading materials by all the health groups in India.

The People's Health Movement India (Jan Swasthya Abhiyan) looks forward to more closer cooperation and linkages with HAI Networks especially HAIAP.

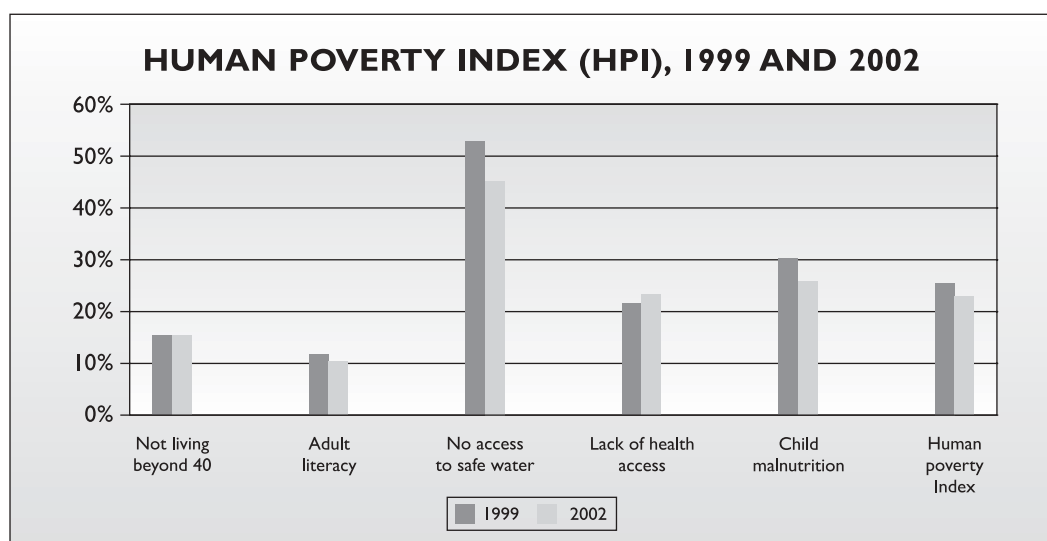
*B.Ekbal*

## **INDONESIA**

Yayasan Lembaga Konsumen Indonesia (YLKI) has worked with HAIAP since the establishment of HAIAP. Though YLKI did not play an active role in its development, it has almost always been involved in its activities such as capacity building, surveys, or research.

Among many issues raised by HAIAP, there were two issues that had quite a significant effect on our work. HAIAP has provided us with support and assistance in our advocacy on drug price policy and TRIPS.

With some other HAIAP members, we were involved in the HAIAP drug price surveys on generic and patented drug. The results showed that for the same brand, the price in Indonesia was higher than in other countries. We have used this finding successfully in our drug policy advocacy.



*Source: National Human Development Report 2004*

We also proposed that, as physicians have a tendency to prescribe branded and patented drugs, the generic names of drugs should be clearly written on the labels, along with the prices. Pharmacies usually charge higher prices. We raised these issues at every opportunity: seminars, talk shows, hearings, among pharmaceutical students, association of pharmacists, government institutions, etc. Because of our advocacy, pharmaceutical companies are now obliged through a regulation, to print the generic name of the drug on the packaging. However, we have not been as successful with regard to including the price on the packaging, as there are too many interests in the drug distribution.

In the drafting of the national patent law, YLKI focused on the health and drug issues. YLKI got support and assistance from HAIAP and Wemos Netherlands. After intensive advocacy, we succeeded in including 'health' as an emergency situation, in addition to military emergencies. A high level officer in WHO Indonesia sent us a card to congratulate us on this success.

*- Husna Zabir*

## IRAN

GDP per capita value (PPP US\$) 2003	6995
Life expectancy at birth 2003	70.4
Total population (thousands) 2003	68.2
Infant mortality rates (per 1000 live births) 2003	33
Under-5 mortality rates (per 1000 live births) 2003	191

*Source: HDR 2004*

I had the opportunity to meet Dr. Bala for the first time in Bangalore in a poverty alleviation meeting in 1999, and then again in Savar, Bangladesh, during PHA 1.

We met once again at a pre-World Health Assembly meeting in 2003, where both of us were fighting for the revitalisation of the Alma Ata approach to Primary Health Care, which was later unanimously passed at the 57th WHA. It was during this meeting

that Dr. Bala introduced HAI to me, and I became a member of HAIAP. Since then I have participated in numerous HAIAP programmes, including review and planning meetings. Also, as poverty is the main root of ill health, HAIAP has approved of a seed grant to assist us in advocacy for poverty alleviation.

I believe that HAI is one of the foremost successful international NGOs to challenge the dominant healthcare system, to ensure HEALTH FOR ALL, by working to make Essential Drugs more accessible and affordable. I congratulate all members of HAI Foundation, HAIAP Governing Council, Dr. Bala, all the members and very friendly staff of HAIAP on the silver jubilee of HAI, and wish that in future, they meet with success in achieving their goals.

*M.A.Barzegar*

## **MALDIVES**

Life expectancy at birth (years) (HDI), 2003	66.6
Maternal mortality ratio adjusted (per 100,000 live births), 2000	110
Infant mortality rate (per 1,000 live births), 2003	55
Under-five mortality rate (per 1,000 live births), 2003	72
Tuberculosis cases (per 100,000 people), 2003	39
Infants with low birth weight (%), 1998-2003	22
Births attended by skilled health personnel (%), 1995-2003	70
Physicians (per 100,000 people), 1990-2004	78
Public health expenditure (% of GDP), 2002	5.1
Private health expenditure (% of GDP), 2002	0.7

*Source: HDR 2004*

HAIAP is an important organisation whose work globally and in the Asia-Pacific region spans the areas of health and human rights.

In 2003, I was invited by HAIAP to a regional consultation on TRIPS in Colombo as a representative of the Ministry of Health, Maldives. The opportunity provided me with insight into the complex issues surrounding intellectual property protection and how agreements like TRIPS and other multilateral agreements have an impact on people's access to essential medicines. I was able to advocate to my colleagues on the need for national capacity building in this area, including formulating relevant legislation with stakeholders, so as to minimise the negative impact of multilateral agreements. At present, the Ministry of Trade and Development, Maldives is preparing, with inputs from stakeholders, a draft intellectual property legislation that will be presented before the Parliament. The technical knowledge and ideas received from my association with HAIAP have been valuable in providing input from my Ministry to such documents.

The HAIAP experience has also widened my understanding of how health, trade, development and poverty issues impact one another. In fact I realised that much needs to be done to advocate the latter issues and I hope to build on the understanding I gained from HAIAP and the work of its member organisations. As an associate member, I plan to work closely with local organisations that are involved in a similar

line of work as HAIAP. In April 2005 I also participated in the HAIAP Asian Health Forum held in Penang, Malaysia

I take this opportunity to congratulate HAI on its 25th anniversary. I hope that, in the years to come, HAI, with its numerous achievements, continues to grow as a strong organisation.

*Ubeydulla Thoufeeq*

## **NEPAL**

Although my association with HAIAP has been short, it has definitely been quite enriching and fruitful. It started when I met Dr. Paranietharan, former Project Officer of HAIAP during the second ICIUM in Chiangmai, Thailand in 2004. He suggested that I apply for membership, which I did. Later I was offered associate membership, which I accepted. Nevertheless, I was familiar with the name of HAI for a long time before my association with the network.

By training, I am a Pharmacist and have been working as a faculty in the Department of Pharmacology at the Manipal College of Medical Sciences in Pokhara, in the western region of Nepal, since 1994. We follow an integrated, problem-oriented, and student-centred curriculum prescribed by Kathmandu University. Undergraduate medical education is one of the priority areas of HAIAP as well, and recently our Dean, Dr. S.K. Dham, was invited to attend the 2nd International Consultation on Undergraduate Medical and Pharmacy Education, convened by HAIAP in Sri Lanka.

Besides being in academia, I am also associated with a Drug Information Centre (DIC) in our 750-bedded teaching hospital, which is a tertiary care hospital. The DIC provides objective, unbiased and authentic information about drugs and therapy to physicians, pharmacists, nurses, other paramedical staff, medical officers, medical interns and patients since November 2003. It works round the clock throughout the year. We publish the *Drug Information Bulletin* quarterly, which is a member of International Society of Drug Bulletins. We also have a full-fledged Pharmacovigilance cell in the DIC, where spontaneous reporting of adverse drug reactions (ADRs), their analysis, and documentations are being done. This centre is working as a regional centre in Nepal for the Pharmacovigilance programme. In addition, we run a medication counseling centre, through which we educate and counsel patients who have been prescribed complicated dosage regimens like inhaler, insulin pen, etc., where skills need to be developed for proper and rational use of drugs and about how to use the drugs with a narrow margin of safety. I am also associated with Drug and Therapeutics Committee of our hospital, which is responsible for the inclusion and exclusion of drugs being used in the hospital. We have been reporting regularly about our activities in different issues of *HAI News*.

By becoming a part of the HAI AP network, we have gained a lot - the opportunity to come in contact with individuals and organisations who are working in the field of healthcare, expanding the horizon of camaraderie and co-operation among the members. My participation in the HAIAP Social Health Forum in April 2005 in Penang, Malaysia provided a great opportunity for networking, especially in the field of drug utilisation, drug information, pharmacovigilance and undergraduate medical and pharmacy education. Thanks to HAIAP for sponsorship and giving me the opportunity to attend the forum.



Our close liaison with the HAIAP secretariat in Colombo, Sri Lanka also helps us to keep up-to-date with recent developments in the field of rational use of drugs, for which thanks are due to Dr. Bala, Prasadini, Passanna, and Dihani. This association has also been of tremendous significance in developing research protocols, especially community reporting of ADRs. We look forward to working more intensely and closely with HAIAP in future. I would like to congratulate HAI for completing its silver jubilee and I wish personally and from my organisation, a great success for HAIAP in all its endeavours in reaching out to the people.

*Pranaya Mishra*

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## **PACIFIC REGION**

### **HAIAP AND THE PACIFIC**

The Asia-Pacific area of the globe has long been referred to as one word – ‘Asia-Pacific’. However, the Pacific region could not be more different from the Asian Region. Asian countries are characteristically densely populated with vibrant and complicated economic sectors and infrastructure. The Pacific countries are mostly remote island countries sprinkled throughout the entire Pacific Ocean. They are characterised by very small populations, in most cases widely dispersed among many islands. The largest nation - Fiji - has a population of around 1 million. Tokelau has around 600, and the populations of most other nations range between 2000 and 100,000.

The logistic difficulties are exemplified in the Republic of Kiribati where 5000 km separate the extreme islands from east to west and 2000 km separate the extreme islands from north to south. The total population is around 80,000.

The tiny populations, remoteness and extreme isolation from the rest of the world and from each other mean that these Pacific Island countries and territories have unique problems and issues to address. Their needs cannot be addressed inclusively in an Asia-Pacific context.

Dr. Bala recognised the problem and brought it to the notice of participants at the 1995 WHO Conference on National Drug Policies in Sydney. It was at this meeting that Dr. Bala raised the possibility of organising a meeting that would bring together people working in the pharmaceutical sector with consumer representatives to look at the pharmaceuticals situation in the Pacific region. He secured funding for the participation of 15 of the 22 Pacific Island countries that would be held in Fiji the following year.

Jonathan Dartnell and I, acting as a Melbourne-based secretariat, developed questionnaires for the proposed participants so they would be armed with issues to discuss at the meeting. To contact participants, we had to use fax, as email was not available. But there seemed to be very few fax machines available and in some cases they were located in locked offices with the key held by a specific, but absent, person. In a few cases, the fax had been cut off and in others they were turned off at night. Arranging flights to Fiji was another major problem, one that was enormously expensive as well. But the meeting did happen and it happened successfully.

### **SUMMARY OF ISSUES IDENTIFIED IN COUNTRY REPORTS AND DISCUSSIONS**

Many countries have some of the components of a national drug policy or are using essential drug concepts, but these components need to be developed further. Logistics also need to be strengthened. We noted some common factors:



- With education and empowerment, consumers can become advocates for NDP.
- Donated drugs are a problem. Both donors and recipients need drug donation guidelines.
- Pharmacists are not receiving adequate training in drug management in their undergraduate courses. It is important to explore strategies to help strengthen all aspects of pharmaceutical management.
- There is no private sector in many Pacific Island Nations but where there is a private sector, it is important to look at drug pricing and insurance issues.
- Traditional medicine is an important issue.

We believe that HAI, under Dr. Bala, put the Pacific on the map in the pharmaceuticals area with the 1996 meeting. The Essential Medicines Department of WHO, WPRO, has built on that meeting and has conducted periodic Pacific consultations and provided significant support. Networking has also improved, although it remains very costly.

*Beverley Snell*

## **PAKISTAN**

It was in 1990 that I first heard of HAI. I was receiving a number of children in my department with diarrhoea, as is common in most of the paediatric units in the developing world. But I noticed that a large number of children had developed paralytic ileus soon after they were given treatment at home or by General Practitioners. This was alarming. There was one common thread: all of them had received Imodium as part of their treatment at home, or by the general practitioner. In many of these infants and children, the paralysis was so severe that it led to respiratory failure and eventually death. So I wrote to the company manufacturing this medicine and said that they should stop making this dangerous drug as it is causing serious complications and death. The company responded that it was not their fault; instead the fault lay with the parents or the health professionals who prescribed this drug. Needless to say, this response stunned me. So I collected all the data about these unfortunate children and sent it to the *Lancet*, which published it. The company immediately promised to withdraw the drug. Almost all countries banned or withdrew Imodium for use in children. A TV network from the UK made a documentary about the child victims in Pakistan, which WHO has been using as a teaching aid for the course on diarrhoeal disease management to be used in nearly 140 countries.

Soon after, we set up an organisation with the help of some like-minded people and Save the Children Fund, UK, to create awareness about medicines and its appropriate use amongst the health professionals and the public. A second objective was to help the drug regulatory authority in its work of promoting rational drug use. Finally, the organisation also wanted to keep an eye on the drug marketing practices of the pharmaceutical industry in the country. It is at that time that I first came across HAI as an organisation already working in the field. HAI Europe and HAI Asia-Pacific were already doing commendable work in the field of rational drug use under the leadership of Catherine Hodgkin and Dr. Bala respectively. Since then my association with both the groups have been close and strong.

HAIAP has done a great job in creating awareness about various issues relating to pharmaceuticals and health in the region. In the 1970s, WHO gave us the slogan,

HEALTH FOR ALL, at Alma Ata and identified active participation by people in health policy planning and implementation as key to achieving this. Unfortunately, the Alma Ata Declaration was not translated into reality; in fact, it was ignored by most of the developing country governments. One of HAIAP's greatest achievements has been the People's Health Assembly, which provides a forum for people's voices, so that HEALTH FOR ALL may become a reality.

HAIAP also supports various organisations in the Asia-Pacific region on issues relating to pharmaceuticals. Access to Essential Drugs, Traditional Health Practices, Herbal Medicines are some of the areas where HAIAP has developed great expertise.

Now, in the era of globalisation and the WTO, HAIAP is not only providing leadership to its member organisations but also expertise to the ministries of health in the region. This has helped in formulating policies and position papers to protect people's health.

Dr. Bala and his team are doing amazing work and we in the region are fortunate to have his wisdom and experience in these turbulent times. I hope HAIAP continues to work with the same zeal and commitment in the coming years as it has been doing during the last quarter of the century.

*Tariq Bbutta*

## **NEW INTERNATIONALIST REPORTS ON THE CAMPAIGN AGAINST ANOTHER ANTIDIARRHOEAL DRUG: LOMOTIL**

### ***Multinational backs down***

LAST June we reported on a campaign to stop US pharmaceutical giant Searle promoting the anti-diarrhoeal drug Lomotil for Third World infants. According to the British Social Audit, Lomotil does nothing for diarrhoea except 'stop the stuff coming out', leaving untreated the infection that caused it and masking potentially fatal fluid losses.

Lomotil is at best useless as a cure (the WHO says it has 'no value') and at worst poisonous to young children even in relatively small doses. "This is not an innocuous drug," warns the US Food and Drug Administration. "Dosage recommendations should be strictly adhered to, especially in children." Yet Lomotil is sold over the counter in many developing countries and recommended by Searle for infants as young as three months old.

Claiming that "you can take it anywhere", advertising leaflets circulated exclusively in the Third World boast that Lomotil was used by astronauts of the Apollo moon flight and was taken on the 1975 British Everest expedition. While conceding that both weightless and deer-frozen diarrhoeas are undesirable, Social Audit maintains that promotion to Third World countries is downright irresponsible.

In their new book *Drug Diplomacy* Social Audit give a blow-by-blow account of their efforts to get Searle to take responsibility for their product. The main thrust of the book — apart from a carefully-documented restatement of Lomotil's dangers — is to highlight an interesting and disturbing facet of the corporate personality.

Freud would have dubbed it "hysterical blindness". Social Audit's Charles Medawar calls it "the pursuit of ignorance in the search for corporate bliss." Either way, *Drug Diplomacy* chronicles a stubborn reluctance by Searle's scientists and executives to accept that their product is lethal.

The story began back in January 1981 with a letter asking Searle for more information about the drug. The request was ignored. Social Audit then published their leaflet *WHO says Lomotil has no value?* outlining

the main dangers of the drug. There followed an exchange of letters, phone-calls, and meetings between the giant and the watchdog.

In most of these exchanges, Searle refused to face Social Audit's main accusation — that to market a dangerous drug in countries lacking the usual consumer safeguards is irresponsible. Instead, they attempted to sidestep the accusation by searching for loopholes in the scientific evidence marshalled by Social Audit. At the same time, they refused to see the weaknesses in their own experimental data.

For months, the battle degenerated into a duel of statistics until in December Searle at last conceded defeat and agreed to change their marketing policies.

The watchdog won. But Charles Medawar is not satisfied, because this was just victory in one battle of statistics. And it is the establishment of a principle that he and co-author Barbara Freese are seeking. They point out that Lomotil is just one instance of abuse — just one of “thousands of other drugs whose effect in developing countries is mainly to turn things from very bad to very much worse.”

And until the World Health Organisation institutes a pharmaceutical marketing code with teeth, companies like Searle will continue to turn a blind eye to potentially harmful effects of their products and systematically misinterpret scientific evidence in order to add noughts to that all-important bottom line.

*Source: New Internationalist, vol. 112, June 1982, <http://www.newint.org/issue/112/update.htm>*

## PHILIPPINES

It is with great pride and pleasure that the Health Action Information Network (HAIN), the Philippine Drug Action Network (PDAN), and I congratulate Health Action International (HAI) on its twenty-fifth anniversary. Indeed, HAIAP has gone a long way in its advocacy for pharmaceuticals and health. HAIN, PDAN, and I are surely proud to have been a part of this.

I still remember in the early years, how HAIAP members and associates (known then as ARDA), persistently advocated for rational national drug policies. We constantly lobbied and focused on educating people in all venues, be it in WHO, Congress, Ministries/Departments of Health, of Trade, academe, communities, and even in the streets, despite the harassment and threats some of us received from the affected sectors such as the pharmaceutical companies and medical societies.

Hosting the 2nd International Meeting of ARDA meeting in Manila in August 1988 was very important for us since we had just enunciated a National Drug Policy and the Generics Act was being deliberated in Congress. Dr. Bala and other ARDA members such as Dr. Mira Shiva, Dr. Zafrullah Chowdhury assisted Dr. Michael Tan, Dr. Romeo Quijano and myself in crafting strong position papers that were presented in Congress by PDAN and the Health Alliance for Democracy (HEAD), to counter the arguments of the multinational drug companies. The campaign for essential drug policies continues because of the weak implementation by government of the Generics Act of 1988, and the National Drug Policy of 1987.

HAIAP's projects on Traditional Medicines have complemented our campaign for understanding and using traditional medicines rationally. We have used HAIAP publications to advocate for the recognition of this important aspect of health as part of the essential health services, as well as the medical and pharmacy curriculum. Researches done by community-based health programmes, which are members with

the Council for Health and Development (CHD), an affiliate member of HAIAP, on traditional medicine have also enriched this campaign.

The manner by which HAIAP addresses pharmaceutical issues - not merely as a consumer issue but rather as a health issue anchored in the principles of Primary Health Care - is what really inspired me along with millions of others to continue supporting these actions.

As health concerns become more global, HAIAP becomes more challenged to be relevant and appropriate in its response. Being one of the eight founding networks, which organised the People's Health Assembly in December 2000 held in Dhaka, HAIAP continue to support the People's Health Movement, which is now a growing movement in almost a hundred countries. I know that this has been one of Dr. Bala's dreams since the late 80's that has now become a reality.

With the WTO assuming a wider influence on people's lives, HAIAP's campaign against the TRIPS Agreement on extended patent protection for medicines, and its advocacy for compulsory licensing and parallel imports is laudable in that it truly puts HEALTH and SERVICE as a primary concern over trade and profit. HAIAP is a staunch supporter of this dictum and this is indeed commendable.

The recently concluded second consultation workshop for educators of colleges of medicine and pharmacy on teaching rational use of drugs is again a manifestation of HAIAP's continuing and sincere commitment to the cause of rational use of pharmaceuticals and health.

In the lobby campaigns of PDAN, we also got strong support from HAI Europe - Anita Hardon, Catherine Hodgkin, Ellen t'Hoen, Barbara Mintzes, and Rose de Groot. The *Problem Drugs Pack* produced by HAI has been widely distributed and discussed throughout the country and HAIN reproduced it to make it more accessible and affordable to people.

The feature articles in *HAI News* have been photocopied and distributed and used as important references by faculty when discussing rational drug use.

HAIN, PDAN and those of us who have been associated with HAIAP are indeed proud to be part of this laudable, commendable and honourable organisation.

Congratulations on your silver jubilee and we wish you more years of genuine service to the people who need you most: the poor, the marginalised, the oppressed and the exploited peoples of this world.

*Edelina Padilla de la Paz*

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## **SRI LANKA**

Eva Lachkovics, who was the editor of *HAI News*, first introduced me to HAIAP in 1983. At that time, as a regular reader of *HAI News* I took up pharmaceutical issues such as the adverse effects of medicines, promotion and irrational use of medicines, with community leaders, women's groups and youth in rural Sri Lanka, while working with Gamisawiya - an NGO working towards empowerment of the rural poor.

I attended my first HAI meeting in Universiti Sains Malaysia, Penang in November 1983. At this meeting we identified a common agenda to campaign on behalf of patients to ensure that they receive proper healthcare and are prevented from using irrational medicines. The network newsletter kept us informed about happenings in the global pharmaceutical scene and activities of network partners in Asia. Dr. Mira Shiva's work in India on banned drugs and Dr. Zafrullah Chowdhury's work in Bangladesh on drug

policy provided useful campaign material for us in Sri Lanka to carry out our health actions.

In 1986 I represented Gamisawiya at a two-day summit meeting, where groups from 10 Asian countries launched ARDA, a more focused campaign. The solidarity among Asians generated by this campaign enabled Gamisawiya to engage in activities related to issues such as non-implementation of the essential medicines concept, banning of harmful drugs, curbing unethical drug promotion, rational use of medicines and patients rights.

In 1988 Gamisawiya's women's groups participated in the UNICEF children's medicines project coordinated by HAIAP. We presented the findings at another international gathering of health activists and medical academics, which later formed the network ERDU (Educators for Rational Drug Use). Sri Lanka ERDU members were a valuable resource for our campaign for a national drug policy based on the essential drugs concept.

In 1991 HAIAP local partners together with the Government Medical Officers Association and the Independent Medical Practitioners Association organised a national workshop on the concept of essential drugs and rational drug use. The recommendations emerging out of this workshop were accepted by the Presidential Task Force on Formulating a National Health Policy and were fully incorporated in the final official publication. However, vested interests in the pharmaceutical industry, supported by a section of the medical profession representing specialists, managed to stall the implementation of these recommendations.

During the 90s there was a rapid decline in public sector health services, while the private sector, dependent on private practice of public sector health professionals, grew larger. Health activists became more involved in patients rights and policy issues. A national workshop on quality of healthcare was organised by HAIAP local partners in collaboration with the Ministry of Health in September 1998. Policy makers, administrators, providers and users of healthcare discussed issues related to quality of healthcare both in the public and private sectors and identified measures needed to improve the quality of patient care. The workshop findings were presented and discussed with the Presidential Task Force on National Health Policy in January 1999.

In 2000, 40 health activists including HAIAP partners participated in PHA 1 in Bangladesh. The post PHA scenario of health activism in Sri Lanka saw the emergence of better networking among individuals and groups engaged in health actions and also the birth of the People's Movement for Rights of Patients.

The first decade of the 21st century will engage HAI activists in campaigning on issues such as globalisation and its impact on health, privatisation and its effects on healthcare services, equity and health financing which are matters of grave importance to the health of millions in the developing countries. We in Sri Lanka are also concerned with global escalation of organised violence against human beings such as child abuse, ethnic wars, terrorism and counter-terrorism, which undermines the health of millions. We expect HAIAP will focus on violence and health and a campaign to contain and eradicate violence from our societies.

We are confident that HAI network partners will learn from their successes as well as failures and make HAI a powerful global movement campaigning for HEALTH FOR ALL - NOW.

*Joel Fernando*

# ACTIONS FOR HEALTH IN ASIA-PACIFIC

**K Balasubramaniam**

## PERSONAL REMINISCENCES

At the International NGO seminar on Pharmaceuticals, held in Geneva in May 1981, where HAI was formed, I represented UNCTAD and presented a paper on “Drug Policies in Third World Countries”. My background was academia and UN. This conference introduced me to a new world - the NGO world. I was amazed and much impressed by a group of motivated and knowledgeable persons from different organisations who had come together to share their experiences and to plan for the future. It was a very pleasant experience.

HAI was created “to resist the ill treatment of consumers by multinational drug companies”. The fact that the pharmaceutical corporations have been able to make scandalously huge profits, engage in unethical marketing and double standards in labelling (and get away with this most of the time) is because they are multinational networks. Such corporate multinational networks can only be challenged by a countervailing multinational force. And HAI, now representing about 200 NGO groups from 70 different countries, is such a force.

The participants recommended that the network, among other activities, should have a clearinghouse and a newsletter. IOCU Regional Office for Asia and Pacific (now CIROAP) agreed to serve as the clearinghouse and publish HAI News, the newsletter of the global coalition.

I shared HAI’s philosophy since my work was based on the same philosophy. In the early 1970s I had the opportunity of working with the late Prof Seneka Bibile when he introduced the innovative and pioneering pharmaceutical reforms in Sri Lanka and setup the Sri Lankan Pharmaceuticals Corporation. In 1978 I joined the Technology Division in UNCTAD and worked on pharmaceutical issues. My work in UNCTAD was to campaign for the promotion of the concept of essential drugs and their rational use.

In 1984, the Asian Community for Health Action Network (ACHAN) convened a seminar on ‘Pharmaceuticals and the Poor’ in Madras (now Chennai), South India. I was in Caribbean Community Secretariat (CARICOM), Guyana, South America. Dr. Prem Chandran John invited me to participate at the seminar. While in Madras he requested me to consider leaving the United Nations and joining HAI Asia. I agreed to think about it. In 1986 IOCU ROAP invited me to be a member of the IOCU lobby team

to the World Health Assembly, Geneva in May. Following the Assembly, HAI convened an international meeting in Bogeve, France. Several long-term plans for the growth of HAI in the region were taken up. One was the setting up of HAI Asia-Pacific. It was at that meeting that my friends from Asia including Anwar Fazal, Prem Chandran John, Zafrullah Chowdhury and Mira Shiva finally convinced me to join them. They also had set up the Asian arm of HAI in March 1986 in Penang, and given it an action-oriented name: Action for Rational Drugs in Asia (ARDA).

I joined IOCU ROAP in Penang, Malaysia, as the Co-coordinator of the ARDA Programme in October 1986. Then followed the most productive and satisfying period in my working career. Anwar Fazal and Foo Gaik Sim introduced me to the NGO World. Working with motivated, socially conscious network partners from different countries within Asia-Pacific region has been a pleasant and also challenging experience.

## **HAIAP'S ACTIONS FOR HEALTH**

What has HAIAP achieved? Its goal is to ensure regular access to essential medicines to all who need them. How successful has HAIAP been in achieving its goal? It will not be possible to answer this neatly with a number of bullet points.

Let me explain by examining the achievements of the Action Programme for Essential drugs in the World Health Organisation, Geneva. I shall quote from the *WHO Medicines Strategy: countries at the core 2004-2007*.

Vision: "Our vision is that people every where have access to the essential medicines they need (p3)

Goal: WHO's goal in medicines is to help save lives and improve health by ensuring quality, efficacy, safety and rational use of medicines, including traditional medicines and by promoting equitable and sustainable access to essential medicines particularly for the poor and disadvantaged. (p4)

25 years of experiences - The essential drug concept emerged in the 1970s with a definition of essential drugs in 1975 and the publication of the first WHO Model list of Essential Drugs in 1977 followed by 1978 Declaration of Alma Ata that identified "provision of essential drugs" as one of the eight elements of Primary Health Care.

1980 saw the operationalisation of the essential drug concept with the establishment of the Action Programme for Essential Drugs in Geneva. A number of NGOs such as HAI and INRUD (International Network for Rational Use of Drugs) were formed to support the implementation of the concept. (p4)

Yet today, almost 2 billion people - one third of the global population - do not have regular access to essential medicines. In some of the lowest - income countries in Africa and Asia more than half the population have no regular access to essential medicines. (p3)

According to the WHO in 1975 about 50 per cent of the global population did not have regular access to essential medicines.

Twenty-five years of enormous efforts and resources put in by the WHO head quarters and six regional offices supported by a number of NGOs have been able to improve regular accessibility from 50 per cent to about 67 per cent. And in Africa there seems to have been no change.



## RATIONAL USE OF DRUGS

The *World Medicine Situation* (WHO 2004) reports “World wide, it is estimated that half of all medicines are inappropriately prescribed, dispensed or sold and half of all patients fail to take their medicines properly”.

Twenty-five years of work to ensure safety and the rational use of medicines seems to have had very little impact in the rational use of medicine.

It is in this context that achievements of health NGOs need to be assessed. Dr. Ken Harvey has succinctly put this in his message, “It inevitably takes a ton of effort to get an inch of movement.”

At the annual review and planning meetings, HAIAP members have always expressed their satisfaction that HAIAP is achieving its objectives in the context of an environment which has changed and is changing politically, epidemiologically and pharmaceutically. As the pharmaceutical corporations have formed themselves into corporate multinational networks, they can only be effectively challenged by a countervailing multinational network, such as HAI.

A major battle between the multinational network of the pharmaceutical industry and the WHO supported by NGOs such as HAI is on the concept of essential drugs and national drug policies. Formulation and implementation of national drug policies based on the concept of essential drugs and generic names will end the monopoly that multinational drug corporations have on the pharmaceutical supply system. And hence the battle between the multinational drug corporations and HAI. What is the situation in Asia-Pacific?

The *World Medicine Situation* (WHO 2004) in figure 6.2 gives the geographical distribution of countries that have adopted national drug policies. The Asia-Pacific region, which includes the WHO South East Asian and Western Pacific regions, comes out best. All the countries in the region except New Zealand have national drug policies.

### *Total Health: HAIAP'S Concern*

One of HAIAP's objectives is to demystify medicine and encourage consumers to talk to doctors and pharmacists and become active members of the health team. In June 1992, HAIAP convened an Asia-Pacific workshop on Pharmaceuticals for Health Ministry Officials in Colombo, Sri Lanka, which was also attended by senior ministry drug policy makers from 16 countries in the region, all of which had formulated NDPs and implemented several components.

The participants unanimously recommended that HAIAP, while continuing its work on pharmaceuticals, should also initiate programmes on the broader aspects of health including Poverty and Health, Healthcare Financing, Primary Health Care, Traditional Medicine, Pharmaceutical Patents, Drug Pricing.

In 1996 the Malaysian Medical Association (MMA) requested HAIAP to prepare a background document on healthcare financing for Malaysia. This paper was presented at a National Seminar. The MMA presented this to the Ministry of Health, Malaysia. Few more meetings were convened by the Ministry of Health and the MMA to discuss healthcare financing. Now the Government has announced the setting up of a social health insurance scheme based on the model originally presented by HAIAP.

Members of HAIAP in a number of countries in the Asia-Pacific region have been invited by the respective Ministries of Health to sit in official committees. HAIAP's voice is heard at the Ministerial level.

One tangible evidence of success is the Malaysian Parliament accepting the proposal of the Ministry of Health to setup a National Health Financing Scheme. This is based on the model initially presented by HAIAP to the Malaysian Medical Association.

Several medical and pharmacy schools in the region have curriculum development units to continuously develop the undergraduate curricula. HAIAP has played a role in this.

The seeds of the Peoples' Health Assembly and the Peoples' Health Movement emerged out of the first planning meeting of ARDA in Bangkok, April 1987. Dr. Prem Chandran John describes this in his message.

Most of HAIAP's activities are based on advocacy. HAIAP is regularly invited to present resource papers on the different aspects of health and pharmaceuticals at national, regional and international conferences. Selected papers presented between 1987 and 1995 were published by Consumers International - *Health and Pharmaceuticals in Developing Countries : Towards Social Justice and Equity*. The book was widely circulated in the Asia-Pacific Region. Executive Summaries of selected papers presented since 1996 have been included in this publication.

## **RESEARCH-BASED ADVOCACY**

HAIAP has invested considerable resources in this kind of advocacy for the following reason. These papers are read by academics, researchers, government officials, health activists and research students. We believe that when they read any article, certain important key points get embedded in their memory. At any point of time afterwards, whenever they are faced with problems or issues related to the subjects they have earlier read, the key points embedded in their memory come back. They will naturally feel that the ideas are their own.

This is our justification in presenting our papers to as wide an audience as possible.

## **TAKING ON TRIPS AND THE WTO**

Since 1995, when WTO was established, HAIAP has initiated a programme on TRIPS and Public Health and works in close collaboration with Third World Network (TWN) Consumer Project on Technology (CPTech) and Médecins Sans Frontières (MSF) on this issue.

In April 2003 HAIAP in collaboration with TWN organised the "Regional Consultation on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses" in Colombo, Sri Lanka. The Consultation was hosted by the Ministry of Health, Sri Lanka. Government representatives from the Ministries of Health and International Trade from 18 countries in the Asia-Pacific region together with health activists participated in the Consultation. A centrepiece of the Consultation was the presentation of TWN's publication- *Manual of Good Practices in Public Health Sensitive Policy Measures and Patent Laws*. The Manual provided useful guidelines to developing member states of WTO to enact public health sensitive patent laws in conformity with the TRIPS Agreement. The Manual is being used by policy makers in the Third World in their work.

## *Undergraduate medical and pharmacy education*

The International Consultation on Medical and Pharmacy Undergraduate Education in Manila, Philippines August 1988 was the first major conference organised by HAIAP. Dr Alfredo Bengzon, Secretary Health in the Aquino Government in Philippines, gave the keynote speech. Vice-Chancellors, Professors and Senior Lecturers in medicine and pharmacy worked together with health activists in small groups discussing the social, economic, political and cultural aspects of therapeutics. The consultation culminated in the formation of an informal network - Educators for Rational Drug Use (ERDU) - to continue the work initiated at Manila.

Medical educators in India followed up actively with the regional meetings and agreed on curricular changes to introduce the aspects of social, economic, political and cultural aspects of therapeutics in undergraduate medical curricula. HAIAP convened national training workshops on undergraduate medical education in the Philippines, Indonesia, Thailand and Bangladesh.

The Second International Consultation on Undergraduate Medical and Pharmacy Education was convened by HAIAP in collaboration with the World Health Organisation 19-23rd September 2005 in Negombo, Sri Lanka. Over sixty participants including Vice Chancellors, Deans, Deputy Deans, Professors and Senior Lecturers representing 35 medical and pharmacy schools in 18 countries shared their experiences, success and failures, developed ideas for model curricula in undergraduate medical and pharmacy education and took them back as useful guidelines in strengthening their own respective curricula. The Medical Faculty, University of Peradeniya, Sri Lanka followed up with two training workshops and has developed a curriculum for an undergraduate pharmacy programme. The first batch of students for this programme will be taken in late 2006.

In 1987-88 HAIAP coordinated studies on the treatment of common childhood illnesses - upper respiratory infections and diarrhoeal diseases - in seven countries. In each of the seven countries a team of the HAIAP member, a Pharmacology Lecturer and a Paediatrician was set up to study how mothers managed their infants and young children suffering from diarrhoeal diseases and upper respiratory infections. The reports were presented at the Asia - Pacific workshop on Consumer Information, Education and Media in August 1990 in Penang, Malaysia with Senior Paediatricians acting as resource persons. All the studies revealed the mothers' conception that doctors should treat episodes of these common illnesses. The results showed polypharmacy, with antibiotics given in almost all cases, and anti-diarrhoeals for all children with diarrhoea. The irrationality of the treatment was made clear to the health activists and media personnel and appropriate treatment guidelines were explained. This was followed by national training workshops on consumers, medicines and media in several countries of the region. National newspapers in the countries of the region carried reports of the workshop.

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- Swedish International Development Agency (SIDA)
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HAIAP does not accept industry sponsorships under any circumstances.



*Padma Prakash, Dr Imrana Quadir, Dr Zafrullah Chowdbury, Dr Mira Shiva and Sunita Narayan engaged in an informal chat after the Public Meeting on Rational Drug Use, New Delhi, India, 1983*



*Dr Mira Shiva, Dr Zafrullah Chowdbury, Charles Medawar, Dr Andrew Herxheimer, and others with Dr Halfdan Mahler, former Director General of the WHO during the International Consultation on RDU, Nairobi, Kenya, 1986*





*Participants of the Regional Consultation on WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses organized by HAIAP in collaboration with TWN and SEARO/WHO pose for a group photograph at the Colombo Plaza, Colombo, Sri Lanka in April 2003*



*Participants of the Regional Consultation on WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses during one of the sessions*



*The HAIAP team meeting with Sushma Swaraj, Honourable Minister of Health, India after the World Health Assembly in 2003*



*The HAIAP team including Dr Ken Harvey, Dr Tanveer Ahmed, Prof Dató Dzulkifli Abdul Razak, Prof Qasem Chowdbury, Dr K Balasubramniam, Amitava Guba, Prof Tariq Iqbal Bhatta, Dr Niyada Kiatying-Anguslee, Dr Edelina P de la Paz, Dr Mira Shiva at the John Knox during the WHA in Geneva, Switzerland, 1992*





*The lighting of the traditional oil lamp by HAIAP Members at the Asia Pacific Seminar on Traditional Medicine organized by HAIAP in April 2003 in Colombo, Sri Lanka*



*Dr Prem Chandran John, Chairperson HAIAP Governing Council, The Minister of Indigenous Medicine and Disaster Relief of Sri Lanka, Hon. Sarathchandra Rajakaruna, MP, the chief guest for the seminar and Dr Balasubramaniam, Advisor/Coordinator, HAIAP at the inaugural session of the Asia Pacific Seminar on Traditional Medicine organized by HAIAP in April 2003 in Colombo, Sri Lanka*

# HIGHLIGHTS OF ACTIVITIES OF ARDA/HAIAP, 1987 - 2005

The activities of ARDA and HAIAP include the following:

- a. Continuous activities
- b. Advisory Services
- c. Special Activities

## **a. Continuous Activities include**

- Editing and publishing *HAI News*, the quarterly newsletter for the Global HAI.
- Networking with members and partners.

The first issue of HAI News was published in October 1981. Since then it has been regularly published. It provides relevant information on pharmaceuticals and health to readers in 102 countries in all five continents.

## **b. Advisory Services**

These are services provided by staff of ARDA/HAIAP when invited as resource persons to national, regional and international meetings and to information seekers who contact us.

## **c. Special activities include meetings convened at national, regional and international levels.**

The following is the list of meetings convened from 1987 - 2005.

### **1987**

1. International Seminar on Pharmaceutical Patents for Developing Asian Countries, in collaboration with Drug Study Group, Bangkok, 4<sup>th</sup> April, Bangkok, Thailand.
2. ARDA First Planning Meeting, 5 - 6 April, Bangkok, Thailand.
3. Three international workshops were convened during the 12th IOCU World Congress Madrid, 15-20th September.
  - Rational Drug Policies: Responding to Critics.
  - Patients, Health Workers and Drug Information.
  - Drug Utilisation studies.

### **1988**

1. The Second International Meeting of Health Action International, 28-31 January, Penang, Malaysia.

2. International Consultation on Rational Drug Use in Undergraduate Medical and Pharmacy Education, 13-16 August, Manila, Philippines.
3. International Consultation on Children's Medicines, 17-18 August, Manila, Philippines.
4. Second ARDA Review and Planning Meeting, 19-20 August, Manila, Philippines.

#### **1990**

1. National Workshop on the Rational Use of Drugs, 9-13 June, Dhaka, Bangladesh.
2. The Third Review and Planning Meeting of ARDA, 9-10 August, Penang, Malaysia.
3. International Workshop on Consumer Health and Drug Information, 12-16 August, Penang, Malaysia.
4. Regional Seminar on Drug Regulation, in collaboration with the Ministry of Health, Malaysia, Universiti Sains Malaysia and the German Foundation for International Development, 5-10 November (Kuala Lumpur) and 12-17 November, Penang, Malaysia.

#### **1991**

1. Regional Seminar on Rational Drug Therapy, in collaboration with CDMU and VHAI, 12-15 March, Digha, West Bengal, India.
2. National Workshop on Concepts of Essential Drugs and Their Rational Use in collaboration with the Ministry of Health, 4-5 May, Sri Lanka, Colombo.
3. National Workshop on Rational Use of Drugs, in collaboration with Universiti Sains Malaysia, 28-30 September, Penang, Malaysia.
4. Regional Workshop on Rational Use of Drugs: Challenge to Medical Schools, in collaboration with Christian Medical College, Vellore, 28-30 November, Vellore, India.

#### **1992**

1. Asia-Pacific workshop on Pharmaceuticals for Health Ministry Officials, 8-12 June, Colombo, Sri Lanka.
2. The Fourth ARDA Review and Planning Meeting, 13-14 June, Colombo, Sri Lanka.
3. National Workshop on Role of Mass Media Towards Consumer, Health, Drug Education and Rational Use of Drugs, 2-3 December, Savar, Bangladesh.

#### **1993**

1. National Workshop on Rational Use of Drugs in Children and Role of Mass Media, hosted by the College of Physicians and Surgeons in Pakistan, 6-7 February, Karachi, Pakistan.
2. National Workshop on Consumer Education, Medicines and Media, in collaboration with Universiti Sains Malaysia, 29-31 October, Penang, Malaysia.
3. National Workshop on Medicines, Media and Consumer Education, in collaboration with Society of Educators for Quality Update of Indian Physicians (EQUIP), 20-22 November, Pondicherry, India.

#### **1994**

1. National Workshop on Teaching of Clinical Pharmacology to Undergraduates and Post Graduate Students, in collaboration with the college of Physicians and Surgeons, Pakistan and WHO, 28-30 March, Karachi, Pakistan.

2. National Workshop on Consumer Education, Medicines and Media, hosted by the Association for Consumers Action on Safety and Health (ACASH), 3-5 April, Bombay, India.
3. Three International Workshops were convened during the 14th IOCU World Congress held in Montpellier, France 26-30 September.
  - Drug Promotion.
  - The AIDS Epidemic: The Challenge Ahead.
  - Reform and Privatisation of Healthcare: Defending Consumer Rights.
4. National Workshop on Rational Use of Drugs, China in collaboration with the Chinese Society of Paediatrics and the Beijing Children's Hospital, 8-12 October, Beijing.

## **1995**

1. International Seminar on Rational Use of Drugs, in collaboration with CDMU, 22-24 April, Siliguri, India.
2. Regional Workshop on Health and Health Related Issues, in collaboration with the Federation of Consumer Organisations - Tamil Nadu, (FEDCOT), 20-22 May, Kodaikanal, India.
3. Olle Hansson's Day, in collaboration with FEDCOT, 23rd May, Madurai, India.
4. Asia Pacific Seminar on Implementing National Drug Policies, in collaboration with the Dag Hammarskjöld Foundation, Sweden and the Commonwealth Department of Human Services and Health, Australia, 3-7 October, Sydney, Australia.

## **1996**

1. Regional Seminar on National Drug Policies for the Pacific Island Nations, in collaboration with Ministry of Health, Fiji, 8-11 September, Nadi, Fiji.
2. Asia-Pacific Regional Consultation on Quality Health Care Services, 11-14 December, Madurai, India.
3. Fifth ARDA Review and Planning Meeting, 15th December, Madurai, India.

## **1997**

1. Regional Workshop on National Health Policies, 21st January, New Delhi, India
2. Regional Workshop on Health for all: An Elusive Goal, 23rd January, New Delhi, India

The two workshops were convened during the Asia-Pacific Members Meeting and an International Conference on Consumer Protection organised by CIROAP, 21-24 January, New Delhi, India

3. International Workshop on Health Care Financing, 4 November, Santiago, Chile.
4. International Workshop on Protecting the Health of Consumers, 5 November, Santiago, Chile.

These two workshops were convened during the 15th World Congress of Consumers' International in Santiago, Chile, November.

## **1998**

1. National Workshop on Health Care Services, in collaboration with YLKI, 17-20 June, Jakarta, Indonesia.
2. National Workshop on Quality of Health, 18-20 October, Kandy, Sri Lanka.

3. First International Planning Meeting for the People's Health Assembly, 10-15 November, Penang, Malaysia.

#### **1999**

1. Second Planning Meeting for the Peoples' Health Assembly, 2-4 March, Penang, Malaysia.
2. Third Planning Meeting for the Peoples' Health Assembly, in collaboration with GK, 4-7 September, Savar, Bangladesh.
3. Training Seminar on Rational Drug Use, in collaboration with HAIN and Visayas State University College of Medicine, 8-9 November, Iloilo City, Philippines.

#### **2000**

1. Fourth Planning Meeting for the Peoples' Health Assembly, in collaboration with GK, 10-13th March, Savar, Bangladesh.
2. Fifth Planning Meeting for the Peoples' Health Assembly, 28-31st July, Savar, Bangladesh in collaboration with GK.
3. National Seminar on Health Care Services, in collaboration with the Federation of Malaysian Consumers Association (FOMCA), 21 October, Kuala Lumpur, Malaysia.
4. An International Workshop on Intellectual Property and Pharmaceuticals, convened during the 16th World Congress of Consumers International 14 November, Durban, South Africa.

#### **2001**

1. National Workshop on Health and Food, in collaboration with Cambodia NGO Alliance for Cooperation (CNAC), 27-28 June, Phnom Penh, Cambodia.
2. National Workshop on Health and Food, in collaboration with Foundation for Consumers, 30-31 October, Thailand.

#### **2002**

1. Planning Meeting for HAI Asia-Pacific, 18-20 February, Colombo, Sri Lanka.

#### **2003**

1. Regional Consultation on WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Changes, Sri Lanka, in collaboration with WHO/DAP Geneva, WHO/SEARO, New Delhi and Third World Network, 17-19 April, Colombo. Hosted by the Ministry of Health, Sri Lanka.
2. Regional Consultation on Traditional Medicine, in collaboration with Ministry of Indigenous Medicine, Sri Lanka, 20 April, Colombo, Sri Lanka.
3. First HAIAP Planning Meeting, 21 April, Colombo, Sri Lanka.
4. National Seminar on TRIPS Agreement, the Intellectual Property Bill and Public Health, in collaboration with the Ministry of Health, Sri Lanka and Department of Commerce, 4 July, Colombo, Sri Lanka.

#### **2004**

1. National Workshop on Integrated Pharmacotherapy Teaching for Medical Undergraduates, in collaboration with WHO and hosted by the Centre for Clinical Pharmacology and Medicinal Policy Studies, Gaja Mada University, 9-10 February, Yogyakarta, Indonesia.

2. National Workshop on Free Trade Agreement between Thailand and the US: Impact on Access to Drugs and Healthcare, hosted by Drug Study Group, 27-28 February, Bangkok, Thailand.
3. Regional Seminar on Healthcare Financing, in collaboration with the WHO Collaborating Centre for Drug Information at Universiti Sains Malaysia and SEARO/WHO, 15-17 April, Penang, Malaysia.
4. Regional Seminar on Traditional Medicine, 18 April, Universiti Sains Malaysia, Penang, Malaysia.
5. The Second Review and Planning Meeting - HAIAP, 19 April, Universiti Sains Malaysia, Penang, Malaysia.
6. The First Meeting of the Governing Council - HAIAP, 20 April, Universiti Sains Malaysia, Penang, Malaysia.
7. Sub Regional Workshop on Pharmaceuticals and Health for Health Ministry Officials and NGOs from Cambodia, Laos PDR, Myanmar and Vietnam, hosted by Drug Study Group, 23-25 October, Bangkok, Thailand.
8. Second Regional Workshop on WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses, in collaboration with WHO/SEARO, Third World Network, MSF, Consumer Project on Technology and supported by UNDP, 28-30 November, Kuala Lumpur, Malaysia.

## **2005**

1. Asia Social Health Forum, in collaboration with the WHO/SEARO hosted by the WHO collaborating Centre for Drug Information, Universiti of Sains, Malaysia, 25-27 April, Penang, Malaysia.
2. Third Review and Planning Meeting - HAIAP, 28 April, Penang, Malaysia.
3. Second Meeting of the Governing Council - HAIAP, 29 April, Penang, Malaysia.
4. Second International Consultation on Undergraduate Medical and Pharmacy Education, in collaboration with WHO/SEARO and WHO/EMRO, 19-23 September, Negombo, Sri Lanka.
5. Second National Workshop on Rational Use of Antibiotics, hosted by Beijing Children's Hospital, 28-30 November, Beijing, Peoples Republic of China.

## **2006**

1. Regional Seminar on the Future of Health Services: Who Will Live and Who Will Die, PHA Building, Gonoshasthaya Kendra, 10 -12<sup>th</sup> April, Savar, Dhaka, Bangladesh.
2. Fourth Review and Planning Meeting – HAIAP, Gonoshasthaya Kendra, 13<sup>th</sup> April, Savar, Dhaka, Bangladesh.
3. Third Meeting of the Governing Council – HAIAP, Gonoshasthaya Kendra, 14<sup>th</sup> April, Savar, Dhaka, Bangladesh.



# CHALLENGE TO NGOS

**K. Balasubramaniam**

Twenty-eight years after Alma Ata and after enormous resources that have gone into the various interventions in the name of Primary Health Care, we do not see any dent made in the incidence of global poverty and ill-health.

*“One in five people in the world - more than 1 billion people - still survive on less than \$1 a day, a level of poverty so abject that it threatens survival. Another 1.5 billion people live on \$1 - \$2 a day. More than 40% of the world’s population constitutes, in effect, a global underclass, faced daily with the reality or the threat of extreme poverty”.*

*“More than 1 billion people lack access to safe water and 2.6 billion lack access to improved sanitation.... Every two minutes four people die from malaria alone, three of them children. Most of these deaths could be prevented by simple, low cost interventions. Vaccine-preventable illnesses - like measles, diphtheria and tetanus - account for another 2-3 million childhood deaths. For every child who dies, millions more will fall sick or miss school, trapped in a vicious circle that links poor health in childhood to poverty in adulthood. Like the 500,000 women who die each year of pregnancy related causes, more than 98% of children who die each year live in poor countries. They die because of where they are born”.*

***Human Development Report 2005***

The reasons for the total failure of the existing international system were well explained by Dr Halfdan Mahler in his address to the Peoples Health Assembly (PHA), December 2000, held in Savar, Bangladesh. He confirmed the failure of the international system to deal with the interaction of poverty and health. “In my 50 years of working as an “international gypsy” it has been clear to me that, within the UN system, we cannot reach the poor. We hear the excuse that it is too difficult, too expensive. This is an in-built discrimination against the poor. We have betrayed the Primary Health Care approach so badly. Who is speaking out against all the obscenities caused by poverty? We are very badly betrayed by the health profession, which has become so commercialised. Governments cannot be counted on to make radical change. You, the NGOs, forced my hand to present to the World Health Assembly a report on Primary Health Care. And now, thanks to you, you still think it is proper to take a look at what has been happening.”



The report that this health visionary was referring to, was the 1978 Alma Ata Declaration on Primary Health Care. The report argued that Primary Health Care (PHC) formed an integral part both of the country's health system and of the overall social and economic development of the community. The Alma Ata Declaration was based on the fact that ill-health and malnutrition among the poor are biological manifestations of a socio-economic disease.

What happened to the Alma Ata Declaration? Five years later, the fact that developing countries were not implementing PHC prompted Mahler to issue them a challenge:

"If you take a group of doctors from medical schools throughout the developing countries and put them through an examination on PHC then the overwhelming majority will fail."

He added a postscript to this challenge: "In theory you can have PHC in spite of doctors. But in reality we, the doctors, will always win if we decide to fight PHC. Because we have developed this conviction that we are God's chosen representatives on earth".

Medical schools in developing countries took the easy way out and ignored the challenge. No one seemed to have read the postscript.

Dr Mahler gave additional reasons why PHC was not introduced in any country. "PHC, as conceived in Alma Ata, failed because of doctors - too many doctors - and because doctors practice inappropriate medicine. The health of millions may be at risk because of doctors. Doctors may be one of the main factors holding back progress in the health of poor countries".

WHO's *Progress in Primary Health Care: A Situation Report*, published in 1983 on the fifth anniversary of the Alma Ata Declaration, besides informing of these startling facts, also brought together information from 70 countries containing 64 per cent of the world population. The report had this to say about doctors in India, "...In India, doctors' inability to understand the importance of prevention, and hence their lack of interest in the various health programmes, is to a large extent responsible for the inadequacy of rural services".

According to Mahler the UN system cannot reach the poor; therefore, there is an urgent need for Non-Governmental Organisations (NGO's) to mobilise the interests, commitments and resources of a broader constituency to support the poor.

We now see a new and interesting development that is taking place all over the world. Socially conscious people from different walks of life, disillusioned with the apathy of their governments in tackling urgent problems, are organising at the grassroots level to plan and implement development strategies to improve the lot of the underprivileged. Substantial contributions to health and well-being have already been made by this non-governmental sector.

Many NGOs in the South have pioneered several health-related development projects, which meet the needs and enhance the participation of the communities they seek to assist, and which recognise the role and needs of women in the development process. More importantly, these programmes are all sustainable. Their major thrust is to alleviate poverty by empowering people to improve their own lives.

Literally thousands of socially oriented indigenous groups exist in the South. All these groups provide some form of PHC to vast numbers of people who have no other

sources of help. These groups are waiting for additional ways and means to apply their energies and leadership. Social and political activism is not new, but it can be put to new use at local, national, regional and international levels. This will enable concerned individuals and groups to bring their views and the power of the people to bear on ineffective, misguided and exploitative officials and agencies.

HAIAP had the honour and privilege of initiating the process which brought together socially conscious people from the developing and developed worlds, hundreds of socially oriented indigenous groups from Africa, Asia and Latin America and providing them with an international forum to share their experiences and plan future strategies. The forum was the Peoples Health Assembly in Savar, Bangladesh December 2000 and the outcomes were the Peoples Health Movement and the *Peoples Charter for Health*.

Dr Halfdan Mahler's words at the People's Health Assembly are still very relevant for NGOs. Given the floor to end the session, he reflected on a question he was often asked: What was the finest hour of the World Health Organisation? Most people expected him to reply that it was the successful global eradication of smallpox. With a rueful smile, and a shake of his head, he said there were three moments: 'The first was when you NGOs pushed WHO to develop an essential drugs policy - painful for many of us - but you were steady in your pressure.

'And the second is the follow up to Primary Health Care. Again, you NGOs have been challenging WHO to engage in much more dialogue. Some of the things that we should learn from you are what people have been doing over the past few years, because they have the guts to protest.

'And the third, you will not believe how complex it is for someone like me when I was Director-General of WHO, to come to terms with the issues around breast milk substitutes. You mobilised, you talked to delegates, and you supported an international code. It was a great moment of power of the NGOs, of the people's organisations, to get companies like Nestle down on its knees.'

He added there were no recipes for how to get power, but it was certainly time that more people's organisations, more representatives from civil society organisations were on the national delegations to UN bodies where decisions were being made that affected the lives and health of the poor.

As NGOs, we are very pleased that Dr Mahler appreciates the work NGOs have done so far. Nothing succeeds like success. Let us therefore commit ourselves to provide:

1. A political statement to the world that the agenda for better health lies in the hands of the people and peoples' organisations and that governments and the International Agencies have, by and large, failed to meet peoples' needs.
2. Opportunities for national, regional and global NGO health communities to analyse and evaluate the accepted and frequently pronounced health strategies. Based on this critical analysis, to campaign and lobby national governments and international agencies to change stream and promote HEALTH FOR ALL - NOW, as outlined in Alma-Ata.
3. Opportunities for national, regional and global NGO health communities working on various aspects of healthcare to act in cohesion.

Finally NGOs need to campaign for a change in the existing world order in global health.

- \* Bring WHO back as the leading agency in global health.
- \* Let WHO and not WTO processes determine access to drugs so that public health interests take precedence over commercial interests in international trade agreements.
- \* Let WHO and not the World Bank, Global Fund or PEPFAR allocate financial resources for public health programmes in poor countries.

# CHALLENGES FACING THE NEXT GENERATION OF HAI ACTIVISTS

An Australian perspective

**Ken Harvey**

## PAST CHALLENGES

HAI was created in 1981 out of concern about the unethical marketing of drugs, especially in the Third World. Poor people often wasted what little money they had on an abundance of heavily promoted irrational, inappropriate, sub-standard and counterfeit products. At the same time, they (and half the world's population) lacked access to essential drugs. This inequity with respect to medicinal drugs mirrored the inequity of development both within and between countries. In addition, right across the world there was a profound imbalance between institutional based, disease-orientated healthcare and community based, preventative-focused Primary Health Care. These inequities and imbalances were primarily a result of profit being put before ethics, of self-interest coming before community interests and the perceived interests of nation states being put before those of the international community. HAI, international agencies and many NGOs and individuals have worked hard over the years to improve this situation.

Twenty-five years later, there has been some progress. More of the world's population has access to essential drugs (although a third still miss out). The worst pharmaceutical marketing excesses have been moderated (although there is still plenty to complain about). Infectious diseases have been brought under better control (although new pathogens have emerged). Economic development has lifted many people out of poverty (although many have missed out, some countries have gone backwards and the gap between the rich and the poor has increased).

## NEW PROBLEMS

Meanwhile, new problems have emerged. Medical diagnosis and treatment has become increasingly sophisticated and can now cost more than most people (or health systems) can afford, even in wealthier countries. National health insurance schemes can moderate healthcare costs by purchasing cost-effective services yet current fashion advocates "small government" and the use of more expensive, less efficient, private health insurance funds. In more and more countries, traditional culture is being

destroyed and increasing affluence, coupled with more sedentary lifestyles, has produced new epidemics such as obesity, diabetes, coronary heart disease, depression, unhappiness and alienation. Over-consumption (of food and many other things) is promoted as the pathway to economic prosperity, health and a happy life. In reality, it drains our prosperity into avoidable healthcare expenses, it threatens our health and well-being, and shortens our lives. Indeed, in many parts of the world, this generation of affluent, obese, sedentary children may be the first to have a shorter lifespan than their parents. Furthermore, unbridled consumption and unrestrained pollution are threatening the very ability of planet earth to sustain mankind. Meanwhile, in obscene contrast, more than 1 billion people survive in abject poverty on less than \$1 a day and 10.7 million children every year do not live to see their fifth birthday.<sup>1</sup>

## **FUTURE CHALLENGES**

The challenge for the next generation of HAI activists (and the current ageing ones) is to move the debate (and action) from specific problems, such as those associated with medicinal drugs (important as they still are), to exposing the general contradictions of neo-liberal ideology and its dogma that economic growth is the key to continued social progress. To spell out that the consequence of a constant barrage of commercial messages promoting instant gratification, conspicuous consumption and self-deception is an increasingly selfish and superficial society. To reiterate that a money-driven society is the root cause of disposable relationships, a decline in values, corporate greed and loss of civic culture.

The People's Health Movement (PHM)<sup>2</sup> and People's Health Assemblies (PHA) were created to address this challenge. The PHA vision is:

*"Equity, ecologically-sustainable development and peace - a better world - a world in which a healthy life for all is a reality; a world that respects, appreciates and celebrates all life and diversity; a world that enables the flowering of people's talents and abilities to enrich each other; a world in which people's voices guide the decisions that shape our lives."*

The task for the next generation of HAI activists is to progress this broader PHA agenda;<sup>3</sup> to think globally and act locally and, by so doing, forge a new politics and a new and better society.

## **AUSTRALIAN RESPONSES**

The PHM has received support from Australians.<sup>4</sup> In addition, there are several related initiatives that are attempting to forge a new politics and a new and better society. *Labor First* is a grass-roots renewal movement of the Australian Labour Party working to strengthen a social democratic party that has lost the last three Federal elections. They want to provide the Labour Party with new ideas, stronger membership, better candidates, structural reform and better campaigning.<sup>5</sup>

<sup>1</sup> <http://hdr.undp.org/reports/global/2005/>

<sup>2</sup> <http://www.phmovement.org/en>

<sup>3</sup> <http://www.phmovement.org/files/phm-pch-english.pdf>

<sup>4</sup> <http://phmoz.org>

<sup>5</sup> <http://www.laborfirst.com.au>

The Australian Greens<sup>6</sup> are part of the Global Greens network. Their vision is for a fair, independent and sustainable Australia based on a respect for all life, human and non-human. They recognise the mutual interdependence between humanity and the rest of nature and they seek to move down an ecologically sustainable path. They are slowly gaining more elected representatives in the Australian Senate.

The *Well-being Manifesto* is an initiative of the Australia Institute.<sup>7</sup> It notes that while material comforts are essential up to a point (and pockets of poverty remains a serious problem in Australia) for most Australians more money adds little to their well-being. Rather, collective well-being is improved by living in a peaceful, equitable, flourishing and supportive society in which all people can develop their potential and feel their lives are fulfilling and worthwhile. The Australia Institute argues that wellbeing comes primarily from having a web of relationships and interests. That family and friends, meaningful work, leisure activities and spiritual beliefs can all increase our wellbeing. That intimacy, sense of belonging and the support offered by close personal relationships are of greatest value.

While governments cannot legislate to make us happy, many things they do affect our wellbeing. Industrial relations laws can damage or improve the quality of our working lives; government policies can protect the environment or defile it; our children's education depends on the quality of schools; equitable access to health services can be facilitated or denied by health policies; tax policies can make the difference between a fair and an unfair society; and the cohesiveness of our communities is affected by city design and transport plans.

The *Wellbeing Manifesto* proposes nine areas in which governments could and should enact policies to improve national well-being (and for which people should agitate). These are aimed at:

1. Providing more work-place flexibility and more fulfilling work;
2. Limiting working hours to improve quality of life;
3. Protecting the environment;
- 4 Rethinking education (especially preserving the independence of universities);
5. Investing more in early childhood education and care;
6. Discouraging materialism and promoting responsible advertising;
7. Encouraging loving and supportive relationships;
8. Encouraging a fairer society by increased public spending (including more overseas aid) financed by cutting back on business and middle-class welfare and cracking down on tax avoidance;
9. Measuring what matters by using indicators such as the genuine progress indicator (GPI)<sup>8</sup> rather than the GDP.

Polls of Australian citizens show increasing disquiet with the results of neo liberal policies implemented by the current conservative coalition government. However, many people (including health activists) feel alienated from the political process; the main parties seem too alike, policies appears poll-driven rather than value-driven and even party members interested in reform feel impotent in the face of the party machine and apparatchiks.

<sup>6</sup> <http://www.greens.org.au/>

<sup>7</sup> <http://www.wellbeingmanifesto.net/>

<sup>8</sup> <http://www.rprogress.org/newprograms/sustIndi/gpi/index.shtml>

## SUMMARY

In my view, the final challenge for HAI activists is to support, strengthen and maintain democratic processes, engage and reform political processes and encourage others to do the same. As a famous health activist said many years ago, “*Medicine is a social science and politics is nothing more than medicine practised on a larger scale*”.<sup>9</sup>

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<sup>9</sup> Rudolph Ludwig Karl Virchow, 1847, <http://www.pathguy.com/virchow.htm>



The United Nations Industrial Development Organisation (UNIDO) has classified countries in the following categories depending on the stage of development of the pharmaceutical industry.<sup>1</sup>

Sophisticated pharmaceutical industry with a significant research base. No developing country in Asia has attained this stage

*Innovative capabilities.* This means that at least one molecular entity was invented and marketed by these countries. China and India have “innovative capability”.

*Technological capacity to produce raw materials from chemical intermediates.* Bangladesh, Indonesia, Korea, Pakistan, Philippines and Thailand have this capacity.

*Countries formulating dosage forms from imported raw materials.* Almost all countries in the region except Maldives and Laos PDR have this capacity.

*Source: Robert Balance, Jairos Proganj and Helmut Forstner, The World Pharmaceutical Industries: International Perspective on Innovation, Competition and Policy, UNIDO, 1992*

## PATENT POLICIES AND PHARMACEUTICAL PRICES

*Lecture delivered to Post Graduate Diploma in Health Development, 16th October 2004, Faculty of Medicine, University of Colombo*

### INTRODUCTION

The late Prof Seneka Bibile first put the negative impact of pharmaceutical patents on the prices of essential drugs on the international agenda. The Fifth Summit Meeting of the Non-Aligned Movement (NAM) took place in Colombo in 1976. This Summit Meeting unanimously adopted a special resolution on pharmaceuticals, based on the pharmaceutical reforms introduced by Bibile in 1972, who also prepared the preliminary draft of the resolution. The Resolution urged developing countries to formulate and implement national drug policies (NDPs) based on the concept of essential drugs and to exclude pharmaceuticals from patent protection.

Three international agencies, the WHO, UNCTAD and UNIDO had been mandated, among others, to assist developing countries to strengthen their pharmaceutical industries and the pharmaceutical supply systems in order to ensure the regular availability of good quality essential medicines at affordable prices. These three

agencies working with their member developing countries recommended that they should use the Sri Lankan reforms as a model to formulate and develop their own national drug policies. A survey by UNCTAD during the 1970s showed that about 90 developing countries and a few developed countries including France, Germany, Italy, Japan, Switzerland and Sweden had enacted national laws on patents that excluded pharmaceutical products from patent production.

## **WHAT IS A PATENT?**

A patent is an intellectual property right (IPR). An IPR is a creation of the mind. This will include artistic and literary works, inventions and trademarks. An invention is a product or process that is new, useful and capable of manufacture. A patent is an IPR given by a government for an invention for a limited period of time, giving the owner exclusive monopoly rights to manufacture, import, distribute and offer for sale the patented product; it prevents third parties from manufacturing, importing, distributing or offering for sale the patented product. A patent can be granted to a product - product patent, and to the process by which the product is manufactured - process patent.

## **TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)**

Exclusion of pharmaceutical products from patent protection was in conformity with the international agreement - the Paris Convention that was in force until 1994. This enabled several Member States to exclude pharmaceutical products from patent protection in their national laws on patents. Unfortunately the global scenario changed with the beginning of the Uruguay Round of Negotiations on the General Agreement on Tariffs and Trade (GATT) that began in 1986.

GATT, which came in to force in the late 1940s, was confined to trade in goods only. There had been a number of revisions of GATT. The last revision, which began in 1986 in Uruguay, introduced, for the first time, multilateral negotiations on “trade-related intellectual property rights.”

Developing countries led by Brazil and India argued against this introduction. But under strong pressure by the industrialised countries, led by the US, a specific agreement on the availability and enforcement of IPRs became part of the Final Act of the Round of Negotiations. This was the TRIPS Agreement.

Governments of industrialised countries introduced the TRIPS Agreement in order to obtain worldwide protection for the innovations and technologies generated by their corporations.

The TRIPS Agreement has several serious and adverse implications for developing countries, as many of its provisions could place higher obstacles to these countries being able to procure essential medicines at affordable prices and for transfer, of technology to develop and strengthen their pharmaceutical industry.

The TRIPS Agreement, which came into force in 1995, has removed the flexibility given to member states in the Paris Convention. Under the Paris Convention Member states were allowed the freedom to determine the areas of:

- Patentability;
- Duration of patents; and
- The set of exclusive rights conferred on patent holders

Both developed and developing countries used these provisions to enact their national legislations on IPRs to serve as policy instruments for developing and strengthening their pharmaceutical industries and pharmaceutical supply systems. These provisions enabled developing countries like Argentina, Brazil, China, India and Mexico to develop and strengthen their pharmaceutical industries to very high standards and compete with multinational drug companies (MNCs) based in industrialised countries. The large number of small developing countries, with no pharmaceutical industries, was able to import generic drugs of good quality at much lower prices compared to the brand forms from MNCs.

Using the flexibilities allowed in the Paris Convention, these countries had the following provisions in their national laws on patents.

- Pharmaceutical products were excluded from patent protection;
- Process protection was granted for periods of seven to 10 years;
- The patent holder was obliged to manufacture the drug in the country that granted the patent right using the patent process protected. This is referred to as working the patent. Imports of the patented product and marketing in the country do not qualify as working the patent; and
- Governments could grant compulsory licensing.

On the other hand, the provisions in the TRIPS Agreement include the following.

- All member states have to provide a minimum of 20 years patent protection to pharmaceutical products and processes.
- Patent holders are not obliged to manufacture the patented product in the country granting the patent. They can import the patented product and have the monopoly of the market.

### **THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES: IMPACT OF PATENTS ON PRICES OF MEDICINES'**

- According to a World Bank economist, the minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) would amount to a minimum of US\$ 3.5 billion and a maximum of US\$ 10.8 billion, while the income gains by foreign patent owners would be between US\$ 2.1 billion and US\$ 14.4 billion (Nogues, 1990).
- A “national health disaster” has been anticipated by the Indian Drug Manufacturers Association as a result of the implementation of the TRIPS Agreement in the country, where only 30 per cent of the population can afford modern medicines in spite of the fact that drug prices in India are one of the lowest in the world. Comparisons of prices of drugs between India and countries where patent protection exists indicate that in some cases they are 41 times more than in countries with patent protection (National Working Group on Patent Laws, 1993).
- Similarly, the IMF economist A. Subramanian noted that drug prices in Malaysia, where patent protection existed, were 20 - 760 per cent higher than in India, which did not grant product patents; this reflected a profit-maximising behaviour based on “what the market can bear” (Subramanian, 1990). Annual welfare losses for India (the biggest market) ranged between US\$ 162 million and US\$ 1,261 million, and annual profit transfer to foreign firms between US\$ 101 million and US\$ 839 million (Subramanian, 1995a and 1995b).

- Price increases of drugs resulting from the introduction of product patents in Egypt were estimated at five-to six-fold as compared to non-patented product (EI Shinnawy et al., 1997).
- A study conducted in Argentina (Challu, 1991) estimated that the introduction of pharmaceutical product patents in the country would imply an annual additional expenditure of US\$ 194 million with a reduction of 45.5 per cent in the consumption of medicines, as a result of a price increase of around 270 per cent. The increase in remittances of foreign firms abroad would reach US\$ 367 million. Fiscal expenditures would have to increase by around US\$ 200 million annually in order not to affect the current public health level.
- Another study for Argentina - based on Subramanian's methodology - concluded that significant price increases (71 per cent) and fall in consumption (50 per cent) will take place in the case where monopoly follow a competitive situation.

## **DEVELOPING COUNTRIES' RESPONSE: THE DOHA DECLARATION**

With increasing evidence of the negative impact of the WTO/TRIPS Agreement on access to drugs: developing countries, with support from NGOs including TWN, CPTech, OXFAM, MSF and HAI developed a carefully elaborated strategy, with assistance and support from the WHO, and went to the WTO Ministerial Conference in Doha, Qatar in November 2001. The outcome of their strategy was the adoption of the Doha Declaration on the "TRIPS Agreement and Public Health". This was a significant achievement for the developing countries.

### **THE DOHA DECLARATION**

The Doha Declaration adopted by Trade Ministers at the WTO Ministerial Conference in Doha, Qatar in November 2001:

- Recognised the gravity of public health problems afflicting many developing countries.
- Affirmed that TRIPS Agreement does not and should not prevent Members from taking measures to protect public health;
- Recognised the Ministers' concerns about its effect on drug prices;
- Confirmed that the TRIPS Agreement has left room for flexibilities at the national level;
- Stated that pressures to impede the use of flexibilities run counter to the spirit and purpose of the TRIPS Agreement.

The Doha Declaration is a strong political statement that makes it easier for Sri Lanka and other developing countries to adopt measures necessary to ensure access to healthcare without fear of being dragged into a legal battle.

Compulsory licensing and parallel imports are two flexibilities referred to in the Doha Declaration. Incorporating these two provisions in the Sri Lankan Intellectual Property Bill will ensure access to quality drugs at affordable prices. Compulsory licensing is a critical policy tool to promote competition and access to lower priced generic equivalents. It brings the benefits of generic competition before patent expiration. Even when a government does not actually employ the provision, the mere prospect that a compulsory license may be issued, enhances a government's negotiating power with patent holders.

## WHAT IS A COMPULSORY LICENSE?

The provision of compulsory licensing in the law on patents will enable Sri Lanka to license a local generic company to manufacture a life saving drug manufactured and/or marketed by a brand name company in Sri Lanka. The local generic company would then manufacture the drug for sale in Sri Lanka under the generic name and pay a reasonable royalty to the brand name company.

Compulsory licensing is permissible under the TRIPS Agreement. Sri Lanka has the freedom to determine the grounds for compulsory licensing. The Trade Ministers reiterated this in the Doha Declaration. But there is a catch!

There are no local companies in Sri Lanka that can use a compulsory license to manufacture a patented drug. This is when paragraph 6 of the Doha Declaration comes to our rescue.

We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Unfortunately, the Council for TRIPS could not find the solution requested from them. A viable solution to the problem is to allow for export of drugs manufactured under compulsory license. For instance, the Sri Lankan Government can issue a compulsory license and transfer the right to an offshore manufacturer for example, in India. This is the only way a country like Sri Lanka with no manufacturing capacity can make use of compulsory licensing.

There is a subset of compulsory licensing called government use provisions - "Public Non-Commercial Use" or "Crown Use". The TRIPS Agreement permits government use provisions that make it simple and easy for governments to make use of patents without the authorisation of the patent owner. Many advanced countries, including the UK and USA have government use provisions in their national laws.

## PARALLEL IMPORTS

Parallel importing is permissible under the TRIPS Agreement and involves the import and resale in a country, without the consent of the patent holder, of a patented drug that has been put on the market of the exporting country by the patent holder or in any other legitimate manner. The justification for allowing parallel imports is that since the inventor has been rewarded through the first sale or distribution of the patented drug, the patent holder has no right to control the use or resale of the drugs put on the market in a legitimate manner. In other words the inventor's rights have been exhausted.

A multinational company markets its brand form *Zantac* (ranitidine) in Sri Lanka at Rs 13.85 per 150 mg tablet. The same company markets ranitidine as *Zinetac* at the equivalent of Sri Lankan 1.36 rupees per 150 mg tablet in India. In 1995, the State Pharmaceutical Corporation was forced to shelve its plans to import *Zinetac* from India through parallel importing due to threatened legal action by the patent holder.<sup>2</sup>

Parallel imports are legally justified under the principle of exhaustion of IPRs on an international scale. Articles 6, 28, 30 and 51 of the TRIPS Agreement are particularly relevant to this issue. Although parallel importing is unknown in developing countries

including Sri Lanka, many European countries have significant trade in pharmaceutical parallel imports particularly within the European community itself but also from outside the EU. In some countries efforts to discourage parallel imports are considered violations of antimonopoly laws.

## PATENTS AND PRICES: SOME EXAMPLES FROM SRI LANKA

The following tables clearly show the negative impact of patents on prices. The retail prices of brand forms of the innovator drugs are much higher than the retail prices of generic equivalents.

**TABLE I**

Comparison of retail prices in US dollars of 100 tablets or capsules of nine commonly used drugs in Sri Lanka and India. The prices of the innovators brand forms and the generic equivalents are given for 1995, 1998 and 2002.

Drug and Strength in mg	1995				1998				2002			
	Generic		Brand		Generic		Brand		Generic		Brand	
	India	Sri Lanka	India	Sri Lanka	India	Sri Lanka	India	Sri Lanka	India	Sri Lanka	India	Sri Lanka
Amoxycillin 250	9.0	4.0	10.0	24.0	10.0	3.0	8.0	8.0	6.2	1.8	6.6	10.3
Cimetidine 200	5.0	2.0	-	23.0	4.0	1.0	2.0	28.0	n.a	0.67	n.a	n.a
Co-trimoxazole 480	3.0	1.0	3.0	9.0	2.0	0.3	4.0	9.0	1.3	0.83	2.4	9.6
Diazepam 05	3.0	0.14	3.0	3.0	2.0	0.1	2.0	9.0	2.6	0.073	3.3	8.2
Diclofenac 50	2.0	2.0	2.0	29.0	2.0	2.0	2.0	28.0	1.3	0.60	2.5	25.7
Erythromycin 250	12.0	5.0	11.0	9.0	9.0	6.0	9.0	10.0	7.4	4.2	6.7	7.5
Frusemide 40	-	0.6	-	5.0	2.0	0.6	1.0	2.0	0.62	0.36	0.86	1.8
Propranolol 40	3.0	0.6	4.0	5.0	3.0	0.6	3.0	5.0	1.9	0.42	3.2	3.9
Ranitidine 150	3	-	3.0	63.0	2.0	9.0	2.0	61.0	1.4	1.70	1.4	14.6

Source : 1995, 1998 - Data presented in HAI News Dec 1995 & April 1998,

2002 - Prices collected from Rajya Osu Sala, Colombo 4 and Monthly Index of Medical Specialties (MIMS) India, Vol. 22, No 7, July 2002

**TABLE 2**

Comparison of the average retail prices in US dollars of a basket of selected number of drugs listed in Table 3.1 in Sri Lanka and India in 1995, 1998 and 2002.

Year of Survey	1995		1998		2002	
Generic or Brand	Generic/ branded generic	Innovators' Brand	Generic/ branded generic	Innovators' Brand	Generic branded generic	Innovators' Brand
Number of drugs in basket	6	6	6	6	6	6
Average prices in Sri Lanka US\$	2.12	13.17	2.0	11.5	1.32	10.77
Average prices in India US\$	5.33	5.50	4.67	4.67	3.45	4.12

Source: Table 1

The above tables make it clear that

- The retail prices of brand forms are higher than generic equivalents in Sri Lanka
- The retail prices of brand forms are higher in Sri Lanka than in India
- The retail prices of generic drugs are lower in Sri Lanka than in India except for ranitidine
- The average retail prices of a basket of innovators' brands are very much higher than corresponding basket of generic equivalents in Sri Lanka.
- The average retail price of a basket of generic drugs is lower in Sri Lanka than a corresponding basket in India.
- The average, retail prices of a basket of innovators' brands are higher in Sri Lanka than in India.

**TABLE 3**

Comparison of retail prices of the innovators' brands of nine essential drugs and their generic equivalents in July 2002. The differences in retail prices between the generic and the brand forms expressed as a per centage of the generic prices are given.

Drug	Retail Prices		Difference in prices expressed as a per centage of the retail price of generic
	Generic	Innovators brand	
Amoxycillin	1.75	9.90	465
Cotrimoxazole	0.80	9.19	1050
Diazepam	0.07	7.84	1020
Diclofenac	0.58	24.70	4160
Erythromycin	4.00	7.23	80
Frusemide	0.35	1.68	380
Propranolol	0.40	3.75	840
Ranitidine	1.64	13.98	750

Source: Rajaya Osu Sala, Bambalapitiya

Table 3 shows wide differences in retail prices between innovators' brands and generic equivalents. The price differences expressed as a per centage of the generic prices are given. They range from 80-4160 per cent with a mean of 1093 per cent.

## CONCLUSIONS AND RECOMMENDATIONS

MNCs and their governments are threatening to deny access to essential medicines to the poor in developing countries through TRIPS. The only way to break the monopoly and promote generic competition is by including provisions for compulsory licensing and parallel imports in the national laws on patents.

The provisions for compulsory licensing should be specifically designed to allow exports of drugs manufactured under compulsory licensing. This is the only way that Sri Lanka and the vast majority of developing countries, which have no industrial capability to manufacture drugs, can make use of compulsory licenses. For example Sri Lanka can issue a compulsory license and transfer the right to an offshore manufacturer for example in India. The Indian manufacturer will have legal support for exporting the drugs manufactured under compulsory license.

<sup>1</sup> Carlos Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Third World Network, Penang, Malaysia 2000

<sup>2</sup> Personal Communication – Prof. Krishantha Weerasuriya



## WIPO PATENT AGENDA II

### TECHNICAL ASSISTANCE AND ACCESS TO MEDICINES: CONSUMER PERSPECTIVE

*Paper presented at a conference on the WIPO work Programme and How to Involve consumers - Consumer International World Congress, 13-17 October 2003, Lisbon, Portugal.*

Over two billion consumers have no regular access to medicines. This inaccessibility is due to high prices of medicines. Strong patent protection is a major cause of the high prices. The Fourth WTO Ministerial Conference recognised the concerns about the effects of the TRIPS Agreement and patent protection on access to medicines. The Conference solution to this concern was the Doha Declaration.

The Doha Declaration on the TRIPS Agreement and Public Health reaffirmed the right of WTO Member States to make full use of the safeguard provisions in the TRIPS Agreement to protect public health and enhance access to medicines.

The technical assistance that consumers request from WIPO is for the Secretariat to assist developing and least developed countries operationalise the Doha Declaration. The Secretariat is mandated to provide technical assistance, on request, to Member States in the development of their legislative systems.

In order to provide the assistance that developing countries really require, the WIPO Secretariat should initiate activities to carry out the proposals of the Director General of WIPO. According to the Director-General of WIPO, the international patent system should:

- Become more user friendly and accessible.
- Provide an appropriate balance between the rights of inventors and the general public.
- Ensure that the system itself and the technical assistance given allowed developing and least developed countries to use the intellectual property system to their benefit.

## **WIPO'S PATENT AGENDA**

The Assemblies in 2001 mandated the WIPO Secretariat to prepare a study to examine the effects of the international patent system on developing and least developed countries. It was proposed that the findings and analysis of this study would be taken into consideration in the development of a Patent Agenda. Unfortunately this study has not been carried out. The Patent Agenda, which is described in the WIPO document A/37/6, has completely ignored the rights and interests of consumers and governments and has, instead, focused all attention on solving problems faced by the patent owners and administrators.

Delegations from developing Member States have put forward very good reasons and effectively argued that they were unable to begin consideration of any of the recommendations contained in the WIPO Patent Agenda document until their concerns and views are taken fully into consideration. These include the following:

- i. There is a clear need for adopting a balanced approach for the initiation of discussions of a possible International Patent Agenda in order to take into account the different interests and levels of development of WIPO Member States, particularly those which are developing and least developed.
- ii. It is clearly not in the interests of developing countries if they are forced to deal with an international system which imposed even greater obligations on them while denying them the flexibility to address their legitimate public policy concerns.
- iii. Any discussion on the International Patent system should in no way be detrimental to the achievements in other international fora that recognised the sovereign right of the Member States to protect public health and promote access to drugs;
- iv. The document A/37/6 is not balanced since it focuses primarily on the interests of users of the Patent System - the patent owners. The needs and concerns of a broader constituency should have been taken into account for example the interests of governments, consumers and civil society, which are crucial to the consideration of the potential negative impacts of higher level of patent protection.
- v. The agenda of the International Patent System and progress in the work of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore should not in anyway be linked nor should they be treated as trade offs. Each is an independent issue on its own.
- vi. A comprehensive patent agenda should not confine solely to strengthening intellectual property offices and harmonisation with a view to an "international patent" but should also necessarily take into consideration other critical issues such as public health including compulsory licensing and parallel importation, nutrition, traditional knowledge, transfer of technology and development. This is the way forward towards a balanced approach in the evolution of an international patent system acceptable to all Member States. More studies, more expertise and more consultations are necessary in order to evaluate the impact of the patent agenda on developing countries particularly in areas, which have ethical dimensions such as biotechnology.

- vii. Harmonisation that proposes a one-size-fits-all model is not workable and therefore not acceptable. It would accentuate the degree of commitment to more stringent provisions thereby placing an additional burden on developing and least developed countries.
- viii. An international patent system should always maintain a proper balance between the private interests of the patent owner and public policy interests such as public health, access to medicines, nutrition, food safety and transfer of technology.
- ix. The WIPO argument that patents provide incentives for investments and development of new technologies should be critically examined and analysed. These incentives work differently depending on the supply response. There will be much more costs than benefits for developing and least developed countries which are solely dependant on knowledge generated elsewhere to satisfy their basic needs and faster development.
- x. Great concerns were expressed by some delegations that the Patent Agenda document completely failed to take into a number of well-researched contributions by representatives of civil society at the WIPO Conference on the international patent system in March 2002, e.g. Médecins Sans Frontiers (MSF), Oxfam, Third World Network (TWN) and others.
- xi. Reference was made to the report of the Commission on Intellectual Property Rights (CIPR) appointed by the United Kingdom. This report analysed various aspects of the effects of intellectual property rights on development policy. Among others it was indicated that developing countries should not be required to provide higher standards of intellectual property protection without serious and objective analysis of what the impact on the development process would be. The report also highlighted several times the need to not limit the flexibility which the TRIPS Agreement provided to these countries and argued the need to tailor national intellectual property systems in developing and least developed countries appropriately.

## CONCLUSIONS

- There should be a balancing mechanism in WIPO policy making. WIPO has argued the necessity for those who represent the thinking of the users of the institution of intellectual property (the patent holders) also to participate in exchange of views. Consumers argue that those who represent the thinking of consumers and governments should also participate in exchange of views and policy making. These will include the WHO and non-profit NGOs such as MSF, TWN, OXFAM and HAI.
- WIPO should carry out a study to examine the effects of the International Patent System on developing and least developed countries.
- The data and analyses of this study together with those of other well-researched studies referred to by the Delegations of Member States should be taken into consideration in the development of the WIPO Patent Agenda. These studies include the Report of the Commission on Intellectual Property Rights UK and contributions by MSF, OXFAM, TWN and others to the WIPO Conference on the international patent system in March 2002. Consumers believe that this is the only way forward to develop a Patent Agenda that will:

- i. Provide an appropriate balance between the rights of patent owners and public interest;
- ii. Ensure that the systems and the technical assistance given allow developing and least developed countries to use the intellectual property system to their benefit. The technical assistance consumers request from the WIPO Secretariat is the development of a 'Handbook on Public Sensitive Patent Legislation.'

The proposed Handbook should contain the following:

- A discussion and description of TRIPS consistent policy measures Member States can use for purposes of producing, importing and exporting patent protected medicines they need at affordable prices.
- Model legal provisions as to how governments may give effect in their national laws on patent to each of the following.
- Compulsory Licensing;
- Parallel importation;
- Government use; and
- Exception to patent rights
- Discussion and description of the domestic administrative and institutional framework required for the equitable and effective implementation of their provisions, which are TRIPS consistent and reiterated in the Doha Declaration.

# ACCESS TO MEDICINES AND PUBLIC POLICY SAFEGUARDS UNDER TRIPS

*Executive summary of paper presented at the Multi-Stakeholder Dialogue on Trade, Intellectual Property and Biological Resources in Asia, 19-21 April 2002, Rajendrapur, Bangladesh.*

This dialogue is on access to medicines. It needs to be underscored that access to medicines is one of the means to an end and not an end by itself. The end is Health for All. It is therefore imperative that access to medicines is discussed, not in isolation, but in the wider context of health for all, which is our final goal.

The Doha Declaration is the first Ministerial acceptance of the negative impact of the TRIPS Agreement on public health when the Ministers recognised the concerns about the effect of intellectual property protection on drug prices.

Patents and high prices are among several constraints to access to medicines. Factors affecting access include: a country's wealth, distribution of income within a country, public and private health spending, commitment to national drug policy, national insurance schemes, and price controls.

Poverty is the world's deadliest disease and also the commonest cause of ill health. Infant, maternal and under-five mortality rates and prevalence of malnutrition are unacceptably high in the majority of countries in the South and Southeast Asia Region. There are at present seven least developed countries (LDCs) in South and Southeast Asia. In 1971 when the list was first prepared there were only four. The UN has identified India, Indonesia, Pakistan, Sri Lanka and Viet Nam as countries which meet some but not all the criteria to be included in the list of LDCs. If the economies of these countries continue to deteriorate, the ranks of LDCs in the region will continue to grow in the next decade. Poverty eradication measures are the only ways to improve and promote health and to ensure regular access to essential medicines.

**SELECTED KEY INDICATORS IN 15 DEVELOPING COUNTRIES IN SOUTH AND SOUTHEAST ASIA**

Developing Asian country	Population in million 1999	Population below national poverty line % latest available	Population below \$1 a day % latest available	Per Capita GNP		Total health expenditure as a per centage of GDP	Public health expenditure as a per centage of total health expenditure	Private health expenditure as a per centage of total private health expenditure
				US\$ 2000	US \$PPP 2000			
Bangladesh	128	35.6	29.1	380	1650	3.5	46.7	54 (53.3)
Bhutan	0.78	30	n.a	550	1350	10.6	48	52
Cambodia	12	36.1	n.a	260	1410	6.9	9	91
India	998	35.0	44.2	460	2390	4.8	12.5	87.5
Indonesia	207	20.3	15.2	570	2840	1.4	43	57
Lao PDR	5	46.1	n.a	290	1530	2.5	48	52
Malaysia	23	15.5	n.a	3380	8360	2.3	57	43
Maldives	0.278	40	n.a	1460	4880	10.6	48	52
Myanmar	45	n.a	n.a	n.a	n.a	1.8	11	89
Nepal	23	42.0	37.7	220	1360	5.5	24	76
Pakistan	135	34.0	31.0	470	1960	4.0	23	77
Philippines	77	40.6	n.a	1040	4220	3.7	46	54
Sri Lanka	19	35.3	6.6	870	3470	3.1	45	55
Thailand	62	13.1	<2	2010	6330	5.8	29	71
Vietnam	78	50.9	n.a	390	2030	4.8	08	92

Source: (i) *World Development Report 2001*, World Bank

(ii) *Asian Development Bank Key Indicators of Developing Asian and Pacific Countries, 1998*, Volume XXIX

(iii) *Human Development Report 2001*, UNDP.

n.a - not available

As the above table shows, South and South-East Asia have about 30 per cent of the world's population but approximately 50 per cent of the world's poor live here. Public health expenditure is very low. Six countries (40 per cent) spend less than one per cent of their GDP on public health. Thirteen countries (87 per cent) spend less than two per cent of the GDP on public health. The total health expenditure in 10 countries (67 per cent) is less than five per cent of the GDP. The very low public health expenditure on health is the major constraint to access. For example in India, where drug prices are the lowest in the world, only 30 per cent of the population has access to drugs.

There are no universal national health insurance schemes. Except in India, there is no price control policy.

The WHO has initiated a collaborative process to monitor and analyse the impact of multilateral trade agreements on access to drugs, to answer the following questions:

- How is patenting affecting drug prices?
- How are patents and enhanced intellectual property protections affecting the rate of introduction of generic drugs?
- Are TRIPS and expanded intellectual property protections spurring the development of drugs for neglected diseases?

- Are TRIPS and expanded intellectual property protections contributing to an increase or decrease in transfer of technology and direct foreign investment in developing countries?

## **TRIPS AND COMPULSORY LICENSING**

Technical assistance given by WIPO and WTO to developing countries to create national legislation on intellectual property seems to be an instrument of regulatory policy more concerned with how to comply with TRIPS rather than how to best make use of the safeguards provided in TRIPS and to choose the most appropriate strategies within the multilateral framework.

The economic and demographic profiles and the science and technology capacities clearly indicate that a large number of developing countries do not have the resources to implement and enforce an efficient and effective intellectual property regime. Moreover TRIPS is an agreement on a legal framework. Its implications will be decided by settling disputes. That makes case law and the power of the parties involved of great importance. The high costs of disputes with the world's leading nations are very frightening. This discourages developing countries from asserting their rights. For example not a single developing country has included compulsory licensing in its national law since TRIPS. Several industrial countries have included compulsory licensing and parallel importing in their national laws.

## **TRADITIONAL MEDICINE**

According to the World Health Organisation, traditional medicine serves the healthcare needs of about 80 per cent of the world's population, majority of who live in South and Southeast Asia.

TRIPS Agreement has been developed to meet the needs of inventors engaged in high technology R&D. But traditional healers have entirely different ways of owning and transferring technology related to genetic resources, traditional and community knowledge and expressions of folklore. However, the framework for intellectual property rights developed for the modern high technology R&D is being applied to genetic resources, traditional and community knowledge and folk medicine. By this process, they are easily patentable, become private property and enrich the new owners who have actually "pirated" the resource and the knowledge by using a legal framework quite irrelevant to what are "pirated". The world needs an entirely different legal framework to meet the needs of billions of people in developing countries who have been the keepers of genetic resources, traditional and community knowledge.

## **IMPACT OF TRIPS ON NATIONAL PHARMACEUTICAL INDUSTRY**

In the 1960s, the drug prices in India were one of the highest in the world. About two decades later, India had completely reversed this and had the lowest drug prices. The policy instrument responsible for this was the Indian Patent Law, 1970. This law followed the German system of allowing process patents but not product patents. Protection was granted for seven years.

The clauses of the TRIPS Agreement are forcing India to abandon this law. The Indian Drug Manufacturers' Association has warned of a national health disaster as a result of the implementation of the TRIPS Agreement.



The Doha Declaration gives clarification, which public health groups have been campaigning for. The Declaration enables members to use to the full compulsory licensing and parallel imports. The next step is to turn these provisions into feasible public policy options. This will require a legal structure suited to developing countries. In view of the limited resources in developing countries, a model legislation prepared by knowledgeable persons would serve as a guideline to formulate national legal provisions and procedures on patent and public health. While WIPO will not prepare model legislation on intellectual property system on the ground that countries have different legal systems, the HDR 2001 has prepared and proposed draft provisional legal structures.

The WHO initiative of a collaborative process to assess the impact of TRIPS on access to drugs confirms NGOs' position that the Doha Declaration is just the first short-term step towards countering the negative impact of TRIPS and improving access to medicines. Much more data and analysis are required to find long-term solutions. The long-term sustainable solution to ensure self-reliance and self-sufficiency involves building the pharmaceutical manufacturing capacity in all those developing countries that have adequate resources. This will promote generic manufacture and competition to ensure a truly competitive global market in pharmaceuticals, to serve particularly those smaller countries (about 60 of them) that have no resources to set up national pharmaceutical industry or enact and enforce an efficient intellectual property regime.

Establishing and strengthening the pharmaceutical sector in developing countries will need a supportive patent legislation. In this respect, the Doha Declaration does not address major problems developing countries face. These include:

- Faulty patent granting systems, which do not meet patentable criteria such as novelty, inventive step, prior art, etc.
- The inadequate capacity level in developing countries to ensure the application of patent criteria and examination of patent applications.

These are issues our negotiators may wish to take into consideration in calling for a review of TRIPS. In this context, it is encouraging to quote from the opening address to a WHO meeting by Dr. Supachai Panitchpakdi, the Director-General Designate of WHO. He clearly preferred that the review of the TRIPS Agreement commence before the launch of the next Round saying,

“So we are looking at implementation and I am sure that before the next Round which I will call the Development Round we would have some sort of agreement to look into some of the requirements of TRIPS, I am sure that there will also be some review of the requirements connected to patent rights and the protection of patent rights that must have some bearing on certain kinds of essential drugs”.

In light of the external perception of the WTO, he emphasised his desire to give it a human face by adding; “I would like to put a human face on the WTO which has always been called the rich man's club. I have to change that.”

## “HEADS - TNCs WIN, TAILS - SOUTH LOSES”

*Executive Summary of paper presented at the HAI Seminar: World Trade Organisation/GATT, Pharmaceutical Policies and Essential Drugs on the GATT/WTO/TRIPS Agreement, 4th October 1996, Builefeld, Germany.*

Goebbels, the propaganda chief in Hitler's Nazi regime, we have been told, held the view that when deliberate lies are repeated often enough, people will eventually believe and accept them as true.

A reverse phenomenon is now taking place. When a truth is repeated often enough, and no one takes any serious notice or people want to deliberately ignore it, the words used to describe the truth lose all their meaning and no one believes it although it is still true. Development workers in developed and developing countries have, for over 20 years, repeated that a patent-free environment is essential for the development of the pharmaceutical industry in developing countries. This is based on the empirical data obtained from countries such as France, Germany, Italy, Japan, Sweden, Switzerland and the USA. At a time when the pharmaceutical industry in these countries had not reached international competitiveness, the governments in these countries refused to protect pharmaceutical patents and allowed their pharmaceutical industries to grow in a patent-free environment.

The truth, therefore, is that a patent-free environment is essential for growth of the pharmaceutical industry in developing countries. And this has been repeated over and over again. But the very opposite has been written into the Trade Related Intellectual Property Rights (TRIPS) Agreement signed by member states of the WTO after seven years of so-called “negotiations”.

Proponents of the TRIPS Agreement state that strong protection of pharmaceutical patents will stimulate transfer and diffusion of technology, strengthen research and development capabilities and encourage foreign investment. However, no evidence has been given to substantiate these assumptions.

### THE EVOLUTION OF THE TRIPS AGREEMENT

Initially the developing countries refused to enter the negotiations when the major trading powers attempted to include services, investment and intellectual property, in addition to goods into the Uruguay Round of Negotiations. A compromise was reached to negotiate services and investment outside the jurisdictional framework of

GATT. Negotiations on intellectual property rights would follow the approach in the articles of GATT that ensured that Member States had the freedom to pursue their own regime of protection of intellectual property.

However, soon after the negotiations began in 1987, the US used threats of bilateral trade retaliation, forcing developing countries to change their national legislation on patents and go back to the negotiating table. Negotiations continued and the paper describes in some detail the asymmetry of the negotiations. These were dominated by the major powers. The Final Agreement has been described as the most non-transparent, non-accountable, anti-people, pro-TNC agreement in the history of international negotiations and agreements.

The TRIPS Agreement together with Trade Related Investment Measures (TRIMs) have taken away the powers of economic decision making from the national governments and handed them to the dominant actors in the international market place, namely the TNCs. The international economic order has been radically restructured by the Final Act, which encompasses virtually the entire economic spectrum.

The Final Act is not limited to inter-border trade issues but the very functioning of national economies and their accessibility to transnational corporations in terms of financing productive infrastructure and market outlets. It sets forth rules governing:

- Domestic agriculture;
- Intellectual property rights;
- Foreign investments;
- Infrastructural services - telecommunications, air transport, banking, finance and insurance;
- Professional services;
- Health and safety standards; and
- Entire trade in goods.

It has been suggested that developing countries should make use of three specific provisions in the TRIPS Agreement to achieve their objective of strengthening the pharmaceutical industry. These provisions are:

- The principle of exhaustion of rights;
- Compulsory licensing; and
- The transitional period.

## **COUNTERING THE LINKING OF LIFE TO TRADE**

The only way forward is for all developing countries to unite and develop a common South position on the GATT/WTO/TRIPS Agreement.

The good news is that the political agenda and a technical blueprint for a common South position are already available. (See boxes *Statement on the Uruguay Round* and *The Geneva Declaration, November 23, 1993*).

The next step forward is based on the hypothesis that developing countries cannot achieve the objectives stated in the TRIPS Agreement by implementing the provisions in the Agreement. On the other hand, it will be counter-productive, leading to the decline of the pharmaceutical industry; there will be no transfer of technology or foreign direct investment in the pharmaceutical industry. Drug prices will increase and accessibility to essential drugs will be drastically reduced.

## *Statement on the Uruguay Round*

*Adopted by the South Commission at its third meeting, Mexico, 5-8 August 1988.*

The political feasibility of a common stand by the South rests on the cohesive force of a set of principles, adherence to which is crucial in shaping the outcome of the negotiations. These principles are:

- (a) the close linkages between trade, money and finance already recognised should be fully respected, with particular attention to the impact of developed country trade policies and other macro-economic policies on the development prospects of developing countries. Determined efforts should be made to improve the functioning of the international monetary system and the flow of financial and real investment resources to developing countries. Normality cannot be restored to the international trading system until the world economic environment improves. The link between the restrictive measures that developed countries are applying to imports from developing countries and the ability of the latter to meet their debt obligations and their development needs are a key component of this interdependence.
- (b) the multilateral trading system should be reformed, incorporating as a central objective the promotion of sustained development in the Third World. The special problems of the least developed countries, already recognised, should receive particular attention. Trade policy can be a powerful instrument of economic development, and this aspect must not be lost sight of by narrowly focusing on import liberalisation;
- (c) confidence in a rule-based international trade system should be restored through a return to transparent multilateral non-discriminatory disciplines, improved adherence by the major developed countries to the spirit and letter of the agreed rules and disciplines, and the introduction of collective mechanisms for enforcement of the rights of the weak as well as of the strong;
- (d) renewed attention should be paid to the problems of stable and remunerative returns from commodity exports. The work already undertaken in various international institutions should be strengthened, and further attention should be given to new mechanisms, including expanded schemes of compensatory financing;
- (e) priority in the negotiations should be given to completing the unfinished work of previous rounds, notably on tropical products, safeguards, textiles, agriculture, tariffs, non-tariff measures and dispute settlement, before moving to new issues;
- (f) the commitment to the principle of differential and more favourable treatment of developing countries as reaffirmed in the Ministerial Declaration of Punta del Este should be fully honoured together with effective operational arrangements for its implementation. While recognising that as the economic development of these countries progresses and their trade situation improves, they should participate to an increasing degree in the rights and obligations of the trading system, this should not be unilaterally imposed by the industrialised countries;
- (g) as already agreed in the Punta del Este Declaration the concept of automatic reciprocity in trade agreements, whether bilateral or multilateral, should be rejected. The developing countries should not be expected to 'pay' for liberalisation by developed countries where the restrictions involved are not in conformity with the GATT. Moreover, developing countries should be given credit in the Uruguay Round for their unilateral trade liberalisation measures taken under IMF and World Bank programmes;
- (h) the need for a multilateral set of rules relating to trade in services is far from established. In any case, any such regime should explicitly provide for measures designed to promote the development of service industries in the Third World as well as exports of services. And as agreed at Punta del Este in 1986, it should fully respect the policy objectives of national laws and regulations.

There is some preliminary data to support this hypothesis; however, there needs to be a carefully planned and controlled prospective study to further test this hypothesis. To carry out this study, the developing countries may wish to use the provision of the “reversal of the burden of proof” in the TRIPS Agreement. According to this provision, it will be the responsibility of WTO to carry out the study that will examine the impact of the TRIPS Agreement on:

- Transfer and diffusion of technology;
- Foreign investment;
- R&D capabilities; and
- Drug prices.

in developing countries.

When the results of the study confirm the hypothesis that developing countries cannot achieve the stated objectives in the TRIPS Agreement by implementing the existing provisions in the Agreement, they can call for an early review and revision of the TRIPS Agreement.

The developing countries will present a united single position at this review and revision using the already accepted political agenda (see box *Statement on the Uruguay Round*) and the technical blueprint (see box *The Geneva Declaration, November 23, 1993*).

### *The Geneva Declaration, November 23, 1993*

Pharmaceutical patents are a privilege, not an absolute property right.

Given the increasingly important role that pharmaceuticals play in human health, private property rights must be balanced with the public good.

In formulating their pharmaceutical patent policies, countries must preserve their sovereign right to strike the most appropriate balance between the competing commercial and healthcare interests at stake.

Dunkel's proposals establish long term monopoly rights in the extremely sensitive area of healthcare, which will result in escalating health prices, putting modern healthcare beyond the reach of large segments of the world's population. The declaration maintains that prices will increase by “500-800 per cent in many cases”.

There should be unambiguous provision in the text for automatic license or licensing of right for commercial use of the patent in any form by domestic companies, compensating the patent holder by paying royalties.

There should be no provisions in the text for patenting of life forms.

Importation should not be considered as working the patent.

Transitional periods should be consistent with the state of development of the country's national pharmaceutical industry and domestic healthcare policies.

A non-official panel of retired judges has been set up in India to examine the constitutional aspects of the Dunkel draft. The National Working Group on Patent Laws, India, was instrumental in setting up this “People's Commission”.

*(This declaration was adopted unanimously at a meeting in Geneva, November 2, 1993, attended by representatives of the national pharmaceutical industry from developing countries and Canada.)*

# INTERNATIONAL DRUG POLICIES: CONSUMER CONCERNS

*Executive Summary of a paper presented at “World Bank Pharmaceutical Policies and Access to Essential Drugs”, 26 September 1997, Oslo, Norway.*

The title of this paper has changed from consumer priorities and international drug policies to consumer concerns and international drug policies.

## WHAT ARE THE CONCERNS OF CONSUMERS?

Whatever has happened in the early 1980s has reversed the health gains achieved by developing countries prior to this period.

For example, between 1946 and 1982, the total annual child deaths had dropped dramatically from 25 million to 14.5 million. This dramatic decline ceased in 1982 when 40,000 were dying everyday. It was 36,000 a day in 1992 as well as in 1996. This is unconscionable in a world that has mastered the means of preventing it

This paper divides the last 30 years into two distinct eras:

- International drug policies before the early 1980s, and
- International drug policies after the early 1980s.

## INTERNATIONAL DRUG POLICIES BEFORE THE EARLY 1980S

Prior to the 1980s, WHO, UNCTAD, UNIDO and the Non-Aligned Movement (NAM) played key roles in shaping international drug policies, which were first placed on the international agenda in August 1976 when the Fifth Summit Conference of NAM adopted a special resolution on pharmaceuticals.

During the 1970s it became clear that a national drug policy should be a component of a national health policy. Pharmaceuticals were a means to the end - the end is health.

At the request of NAM, WHO, UNCTAD and UNIDO set up an Inter Agency Task Force in Pharmaceuticals in 1978. This Task Force jointly organised an interregional mission that visited several developing countries in Africa, Asia and Latin America. The Report of the mission, entitled *Pharmaceuticals in the Developing World - Policies on Drugs, Trade and Production*, described in detail, comprehensive national drug policies and recommended strategies for implementing them.

The report underscored the urgent need for:

- The technological, economic and commercial development of the pharmaceutical sector in developing countries;
- The transfer of pharmaceutical technology under favourable conditions to developing countries;
- A leading role for the public sector in the pharmaceutical supply system; and
- Self-reliance in the pharmaceutical sector in developing countries.

Drug policies gathered momentum in the late 1970s. WHO published its first model list of essential drugs; UNIDO convened a series of Consultations in the Pharmaceutical Industry. These Consultations brought together representatives from transnational drug companies, Governments of Member States and national drug companies, both public and private, from developing countries. The objective of these consultations was to enable participants to engage in multilateral negotiations and reach agreements on the transfer of technology to developing countries.

UNCTAD published a series of documents on pharmaceuticals including guidelines, reports of regional workshops and country case studies.

These three agencies - WHO, UNIDO and UNCTAD - provided technical assistance, in their respective fields of expertise, to developing countries, to formulate and implement drug policies.

The historic conference in Alma Ata in 1978 came out with the declaration of Health For All and identified Primary Health Care (PHC) as the key to Health For All. All member states from developing countries agreed to formulate and implement national health policies on the concept of PHC. Provision of essential drugs is a major component of PHC. A national drug policy based on the concept of essential drugs should therefore be a component of a national health policy.

The first era came to an end during the early 1980s. Why did it end? What precipitated the need for a second era? What were the major thrusts in the second era?

Based on a critical analysis of available empirical data, I believe that drug policies accepted by the WHO and the developing countries in the first era cannot be implemented in the second.

## **INTERNATIONAL DRUG POLICIES AFTER THE EARLY 1980S**

The debt crisis and the entry of World Bank into the health arena were the reasons why the first era ended and the new era dawned. The World Bank took a leading role gradually displacing WHO as providing the lead in health policy thinking. For example, the annual health sector expenditure of the World Bank is more than twice the total annual budget of WHO.

The fundamental principles on which WHO, UNCTAD, UNIDO and NAM had developed drug policies, were completely reversed. In the new era after the early 1980s:

- Public sector had been relegated to the background. The private sector has taken the leading role.
- Pharmaceutical (and curative healthcare) has been left safely in the custody of the invisible and presumably thereby beneficial, market forces;



- The private sector considers drug policies developed during the first era irrelevant to its needs and has ignored them.

There are numerous examples of the adverse impact of Structural Adjustment Programmes (SAPs) forced upon indebted developing countries by the World Bank and the IMF. The health gains achieved by developing countries in sub-Saharan Africa during 1965-1970 have been completely reversed by SAPs in a short period of five years. The scope and extent of such reverses in health and human development in developing countries have been documented by, among others, *State of the World's Children 1992*, UNICEF and *Human Development Report 1996*, United Nations, New York.

Primary Health Care (PHC) was a strategy advocated by the world community in 1978 at the Alma Ata Conference. PHC was accepted as the only way the noble goal of Health for All can be achieved.

PHC was the first casualty when the World Bank entered the health arena. The Bank introduced the selective PHC approach, arguing that when implemented, it will reduce child morbidity and mortality. UNICEF data shows that more than 10 years of selective PHC has not had any impact on child morbidity and mortality.

Again, it is ironical that, in spite of the billions of dollars that the World Bank lends to developing countries for their health sector, there is a negative net transfer of billions of dollars from the developing countries to the World Bank. In 1990-1 developing countries transferred over US\$8 billion to the Bank.

These are the concerns of consumers, who reiterate that a national drug policy should be a component of a national health policy. Consumers are waiting to hear how international agencies will assist developing countries to implement drug policies when the public sector healthcare services in these countries have been relegated to the background and the private sector has taken a leading role in providing healthcare including pharmaceuticals. The private sector considers drug policies accepted by WHO and the developing countries, irrelevant to their scheme of things.

We cannot graft a bud on to a dying tree. However strong and healthy the bud is and however sophisticated the grafting technology is, the bud will never take. It will be a waste of time and resources; the priority task is to put the bud aside and concentrate our efforts to bring life back to the dying tree.

# DIMENSION OF RIGHT TO HEALTH IN RELATION TO GLOBALISATION

*Executive summary of a paper presented at the International Study Conference on Human Rights and Health, 14-16 October 2004, Department of Social Work, Madras Christian College, Chennai, India.*

## INTRODUCTION

"It is my aspiration that health will finally be seen not as a blessing to be wished for but as a human right to be fought for", said Kofi Annan, Secretary General, United Nations.

It would seem paradoxical that the UN Secretary General calls on us to fight for the Right to Health when several international treaties, conventions and declarations have included the Right to Health as a Fundamental Human Right.

By recognising the right to health as a fundamental human right, international human rights law removes health from the status of a marketable commodity. The paper argues that if health is ever to become a fundamental human right, it should cease to be a commercial product bought and sold in the market or a charity doled out by the rich.

Unfortunately, health is becoming more and more a marketable commodity in the developing countries. It is no longer a fundamental human right. The poor have no resources to purchase health in the market. This explains the reason behind the statement by the UN Secretary General that health should be considered as a human right to be fought for.

Globalisation and its impact on health: The World Bank, the International Monetary Fund and the World Trade Organisation.

The World Bank and the IMF were established in July 1944 by the UN Monetary & Financial Conference in Bretton Woods, New Hampshire, USA. The two IFIs are controlled by nine rich nations of the world, which hold 50 per cent of the quotas. The decision-making power in WB and IMF is divided through votes, which are in turn weighted according to the quotas for owning shares in the two IFIs.

Further power imbalances are evident from the fact that in the IFI's nearly 50 Sub-Saharan African Member States are represented by just two directors while eight rich countries are represented by one director each and USA maintains a veto power by holding more than 15 per cent of the votes. In addition to all these, is the unwritten law based on tradition that the post of the President of the WB is reserved for an American and that of the Managing Director of IMF is reserved for a European, unlike the practice in all other UN agencies.

The WTO was set up in January 1995. A description of WTO, as given in Para 15 of the report of the special Rapporteurs on Globalisation, ends with the following “... *The net result is that for certain sectors of humanity particularly the developing countries of the South - the WTO is a nightmare*”.

With the WB, the IMF and the WTO playing leading roles in globalisation, there has been a major change in the field of global players. In addition to these three institutions, transnational corporations (TNCs), which break down state borders, have emerged with their own systems of regulations. The TNCs are largely outside the jurisdiction of a given state and no international law applies to them.

The WHO has lost its leadership role in health to the WB, which has now become the leading international agency for health policy planning in the developing countries.

The economists in the WB have, quite naturally, adopted a market-oriented approach to human health. For them health is one of the means to an end (or the ultimate goal), which is rapid economic growth. Therefore the objectives of health policies advocated by the WB are economic growth and not health for all.

The WB took over leadership in health policy planning in the early 1980s. The developing countries were heavily indebted to commercial banks in the North. They were unable to service their debts, which led to the debt crisis. The WB and IMF presented a strategy whereby these countries could relieve their debt burden through adopting Structural Adjustment Programmes (SAPs), which would enable them to achieve rapid economic growth in order to be able to service their debts.

## **STRUCTURAL ADJUSTMENT PROGRAMMES**

The main policies or SAPs demanded by the WB and the IMF included the following.

- Cut back in government spending/subsidies on social sectors such as health, education and food.
- Successive devaluation of the local currencies in the name of achieving export efficiency and competitiveness; however in reality the retail prices of basic and essential consumer commodities like food and medicinal drugs have increased;
- Rollback or containment of wages and retrenchment of workers; deregulation of laws protecting job security;
- Deregulation of the economy; less restriction on the entry and operations of foreign investors;
- Elimination or reduction of protection for the local market;
- Liberalisation of trade, reduction of tariff rates;
- Removal of trade and exchange controls; and
- Abolition of price controls.

The SAPs provided WB and the IMF a tool to suck developing countries into the global market dominated by the TNCs. This was the beginning of globalisation in developing countries.

The overall impact of SAPs on human development and particularly on the fundamental right to health has been overwhelmingly negative, as the documentation by various NGOs and UN institutions shows. However, ignoring all the well-documented empirical data and analysis, the WB and the IMF demanded developing countries to continue implementing SAPs.

In the mid 1990s, a number of NGOs challenged the incoming WB President Wolfensohn to involve WB staff in an exercise with citizens' groups in the South in order to critically analyse the ground realities in the Third World so as to provide critically important perspectives and analysis into the formulation of WB's economic advice and policy making. In response to this request, the Bank established the Structural Adjustment Participatory Review Initiative.

### **STRUCTURAL ADJUSTMENT PARTICIPATORY REVIEW INITIATIVE**

The findings of the Structural Adjustment Participatory Review Initiative - SAPRI, a joint five-year multi-country participatory investigation into the impact of specific structural adjustment policies on a wide range of social and economic sectors and population groups, included the following:

1. Destruction of the domestic productive capacity particularly among the small and medium-sized enterprises that are the core of national economies and which employ the large majority of the work force.
2. Large increase in unemployment and a loss of income mostly among the poor unskilled workers.
3. Wages had declined and income distribution had worsened.
4. Reduced availability of productive farmland for cultivation to the domestic market, which led to food security being undermined.

The economists in the WB refused to take into consideration the findings and change their policies, arguing that the long term macroeconomic gains from the implementation of SAPs offset any short term losses among certain population groups and sectors, as the implementation set the path towards sustainable economic growth and development. Civil society rejected this argument for several reasons including the following:

1. The losses to the poor have not at all been short term.
2. After two decades of adjustment there was no evidence to show that adjustment policies will work their magic in the market, set the country on the path towards sustainable economic growth and development and reduce poverty and inequality. On the contrary, poverty and inequality had increased in all the countries where investigations were carried out. There was definite evidence of an adjustment - poverty connection.
3. The Bank refers to short-term losses among certain population groups. Who or what are these "certain population groups?" They are the poor, and in many developing countries, the majority of the people are poor and relatively poor. This means that the short-term losses affected over a billion poor people not "certain population groups".

Unfortunately the WB ignored the results of the joint SAPRI exercise for over a year. However, extensive media coverage and increased public awareness following the release of the SAPRI Report in Europe finally pushed the Bank and its President to re-engage the SAPRI Network (SAPRIIN).

## **POVERTY REDUCTION STRATEGY PAPERS**

As a result of the pressure of public awareness, the WB invented a new name for SAPs - Poverty Reduction Strategy Papers (PRSPs). In fact, the President of the World Bank put a proposal to involve SAPRIIN and other civil society organisations to join the Bank in the development of the PRSPs. The Bank sat on this proposal for a year and eventually rejected it. Instead, it insisted on continuing to base PRSPs and their implementation on its old philosophy - those long term macroeconomic gains from the implementation of PRSPs will offset any short term losses.

The developing countries were told that in the preparation of the PRSPs the WB/IMF economic framework should provide the parameters for any poverty reduction strategy, completely ignoring the SAPRI findings. The WB and its proponents claimed that PRSPs were an important tool for developing countries to reduce their debt burden. Unfortunately, this resulted in the continuance of economic globalisation and market liberalisation.

Civil society resistance to PRSPs increased across the Third World. It took various forms.

1. Civil society unrest had taken the form of “IMF riots”.
2. The process of the development of PRSPs reflects the ultimate mockery of the threadbare claim that PRSPs are based on “national ownership”.
3. Even the best African example of the PRSPs exercise, Uganda has been a little more than a way for the WB and the IMF to co-opt the activist community and civil society in Uganda into supporting the same old traditional policies.

## **CONCLUSIONS**

The enforced policy changes initiated by SAPs and PRSPs have adversely affected human development. The 1990s or the era of globalisation has represented both the best and the worst years for human development and economic growth, depending on the perspective from which it is seen. Data from *Human Development Report 2003* confirms this:

- The richest five per cent of the world's people receive 114 times the income of the poorest five per cent.
- The richest one per cent of the world's population receives an income as much as 3.42 billion people or 57 per cent of the world's population.
- The 25 million richest Americans have an income as much as almost 2 billion of the world's poorest people.
- In 54 countries there was a negative growth in the per capita GDP during 1990-2001.
- Of the 67 countries with data for poverty rates available, 37 countries saw an increase in poverty rates in the 1990s.
- In South Asia, home to almost 500 million poor people, the number has hardly changed during this period.

- In Sub-Saharan Africa the number of people living in poverty increased by 74 million during this period. The inequality revealed proves that the 1990s the decade of globalisation has been the “best of years and the worst of years”.

## RECOMMENDATIONS

The following recommendations are based on the critical analysis of the empirical data provided, and are divided into three groups: Global Governance, Conflict Resolution and Civil Society Activism.

### GLOBAL GOVERNANCE

It is becoming abundantly clear that global opportunities are not equally shared by all. The vast majority of the people in developing countries are excluded out of the global opportunities due to economic globalisation. Civil society argues that this has come about due to the dominant role played by the G7 group of the seven rich countries, and a few hundred TNCs supported by WB, IMF and WTO. The WHO, UNCTAD and UNIDO have been marginalised.

This brings us to an examination of global governance and the existing world economic order. Governance is not government. It is the framework of rules, institutions and established practices that lay down rules, set limits and give incentives for the behaviour of organisations and corporations.

Inter-governmental policy making in today's globalised economy is in the hands of the seven major industrial powers, the G7 and the international institutions they control - the WB, the IMF and WTO. Their rules create a very secure environment for open markets but an adverse environment for social and human development in the Third World. These three institutions and their rules and practices are designed to advance global markets and to ensure the growth and power of the 20 per cent of the population living in the OECD countries. It is therefore quite clear that the existing institutions are inadequate to meet the aspirations of all the people of the world. An essential aspect of global governance is transparency, accountability and responsibility to people - to equity and social justice. These are missing in the existing systems of institutions, rules and practices.

The *Human Development Report 1999* has identified some of the key institutions of global governance to put human development and social protection at the centre of international policy and action. They are:

- A stronger and more coherent United Nations to provide a forum for global leadership with equity and human concerns.
- A global central bank and lender of last resort.
- A World Trade Organisation that ensures both free and fair international trade, with a mandate extending to global competition policy with antitrust provisions and a code of conduct for multinational corporations.
- A world environment agency.
- A world investment trust with redistributive functions.
- An international criminal court with a broader mandate for human rights.
- A broader UN system, including a two-chamber General Assembly to allow for civil society representation.

## **CONFLICT RESOLUTION**

There is a clear conflict of interests between a country's obligations and commitments under international law on human rights and the country's need to conform to multilateral trade agreements and dictates of economic globalisation. How can this conflict be resolved? Does one set of obligations over ride the other? And if they do so, which takes precedence, and why? How to resolve this conflict should be a priority agenda item in every national, regional and international fora and various summit conferences where the critically important issues of human development, human rights and economic globalisation are discussed.

The Report of the Special Rapporteurs on Globalisation underscored the fact that the role played by WB, IMF and WTO had adverse impact on human rights. The Report stated that it was clear that the institutional mechanisms of globalisation had yet to seriously address the issue of human rights in a fundamental and democratic fashion.

Developing countries and civil society both in the North and the South should continue their protests and lobbying around the world. The three institutions should be forced to respond to human rights concerns in keeping with the International Bills of Human Rights as a way forward towards conflict resolution. Continued and focused lobbying, coordinated globally, will enable the voices of ordinary people of the world, so far unheard, to be heard in these three institutions that are the propelling forces of globalisation. Eventually they will have to listen to and respond to people's voices and take appropriate measures to seriously address the issue of human rights in a fundamental and democratic manner.

## **CIVIL SOCIETY ACTIVISM**

### **"WORLD BANK BOND BOYCOTT"**

The World Bank gets about 80 per cent of its resources from World Bank bonds purchased by Northern citizens and institutions that are the Bank's main shareholders. A good strategy will be to pressurise the IFIs through their main shareholders - Northern citizens via their governments.

This innovative strategy was developed by the World Bank Bonds Boycott. US groups like the Centre for Economic Justice and Global Exchange have been working with Jubilee South Africa and Brazil's Movement of the Landless. One of the action plans is to ask the shareholders the question "Is it ethical for socially conscious people to invest in the WB, by buying its bonds and earning dividends which represent the sweat of millions of suffering people?" The world's largest pension fund, (Teachers Insurance & Annuity Association - College Retirement Equities Fund) sold its World Bank bonds as campaigners made it a special target.

The global civil society should get civil society organisations in Belgium, Canada, France, Germany, Italy, Japan, Netherlands and the UK to set up national World Bank Bonds Boycott Campaigns in each of these countries. These countries, together with the US hold 50 per cent of the quotas in these institutions and control policy and decision-making. The legitimacy of these institutions is slowly waning. Threats to their funding by socially responsible investors and eventually angry tax payers in the rich countries will force these institutions to address the issue of human rights in the manner in which they should be, rather than as they currently are being addressed.



## HEALTHCARE - WHO CARES?

*Executive Summary of A Discussion Document for the People's Health Movement, May 2002.*

Poverty is the deadliest disease, according to the World Health Organisation (WHO). One thousand three hundred million people or over a third of the population in developing countries suffer from this deadliest disease. This is really an epidemic. One would therefore expect the World Health Assembly (WHA) to give a mandate to the WHO to eradicate poverty as a top priority task. The closest the WHA and WHO ever came near poverty eradication and social development was soon after the Alma Ata Declaration in 1978: An Assembly resolution on Health for All by the year 2000 (HFA) identified Primary Health Care (PHC) as the key to HFA. It was underscored that PHC should form an integral part of the overall social and economic development of a country. Unfortunately "experts" advised the WHO that PHC as described in the Alma Ata Declaration was unrealistic; developing countries did not have the necessary resources to implement comprehensive PHC. The WHO forgot PHC, forgot poverty eradication and social development.

The "experts" seemed to have not read the final paragraph in the Alma Ata Declaration, which stated that there were adequate resources in the world to make HFA a reality but a considerable part was spent on armaments and military conflicts. This report provides documented data on the enormous money spent by developing countries on armaments and military conflicts leaving very little resources for health and education.

Health for all, peace and security are very closely interconnected. Health for all the people is fundamental to the attainment of lasting peace and security. Peace and security are essential for the attainment of Health for all.

Poverty eradication has been entrusted to the richest nations of the world. Defining and measuring poverty were taken over by the World Bank (WB). And the world's deadliest disease, poverty, has reached epidemic proportions.

At their summit meetings the G8 governments committed themselves to halving world poverty and reducing child mortality by two thirds by 2015. But the reality is quite different.

In fact, data shows the escalation of poverty and an alarming fall in health standards in spite of an enormous economic growth in the world.

The very poorest and structurally weakest countries are classified as least developed countries (LDCs). The UN Committee for Policy Development (CDP) decides which country should or should not be ranked as an LDC. The first list in 1971 had 21 LDCs. The last revision was done in April 2000. The number of LDCs has risen to 49. The number should have been 51 but two countries identified as meeting the criteria for LDC status refused to have their economic status downgraded. During the last 30 years, therefore, one country has slipped down into deepening poverty each year. And worse - The UN Committee has identified another 16 countries, which meet some but not all of the criteria for LDC status. If the economies of these developing countries continue to deteriorate - a deterioration promoted by rising debt, falling commodity prices and sharp declines in development and foreign investments - the ranks of LDCs will keep on rising. These 16 countries include China, India and Indonesia - the most populous of developing countries.

The report of the CDP gives data on external debt as a per centage of a country's GDP and debt servicing as a per centage of a country's revenue from exports of goods and services. In spite of the Heavily Indebted Poor Country (HIPC) initiative, external debt has a stranglehold on several developing countries. Two-thirds of countries that are now receiving debt relief are spending more on debt servicing than on health. 50 per cent spend more on debt servicing than on primary education and health. It is very clear that these countries can never repay their debts but will be forced to get deeper into debt.

The World Bank's definition and measurement of poverty line are methodologically faulty. Poverty is too complex an issue to be reduced to a single parameter - consumption-based income to define international poverty line. Poverty eradication based on this poverty line will never eradicate poverty. The World Bank planners should understand that the poor are not a different species. Their perceptions of life are the same as ours. They want better choices and opportunities to achieve health, which has been defined by the WHO as a state of complete physical, mental and social well being in addition to absence of disease and infirmity.

Adequate nutrition, safe water at hand, better medical services, more and better schooling for their children, adequate shelters, cheap transport, continuing employment, secure livelihoods and productive remunerative and satisfying jobs are what they want. These are the real indicators of social and economic development as described in the Peoples Charter for Health brought to the World Health Assembly by the People's Health Movement (PHM).

Data on very sensitive health indices including, infant, maternal and under-five mortality rates, life expectancy at birth and prevalence of malnutrition are provided to show the alarming fall of health standards. During a period of 10 years between 1990 and 2000, life expectancy of over a billion people has gone down by 10 years from 50 to 40. This is the greatest indictment against the existing world economic order - globalisation, liberalisation and multilateral trade agreements.

Twenty-three years after Alma Ata and after the enormous resources that have gone into interventions in the name of PHC, the health standards of over a billion people are falling. Over 1.3 billion people live in absolute poverty; over half the population

has no access to basic healthcare; and healthcare systems have either collapsed or not even built in many countries.

It is quite clear that current approaches have failed. People have lost faith in multilateral aid through international agencies or bilateral aid with strings attached. Governments and intergovernmental agencies seem to have forgotten and ignored their commitment made in Alma Ata in 1978.

There is, therefore, an urgent need for a new approach to mobilise the interests, commitments and resources of a broader constituency for the poor.

The People's Health Movement has mobilised all these resources through a participatory process beginning in 1998. There was unprecedented enthusiasm and participation of broad cross sections of people around the world including hundreds of grass-roots level organisations, concerned academicians and health activists from the North and South. Representatives of all these groups, numbering 1453 from 92 countries participated in the Peoples Health Assembly (PHA) convened in Dhaka, Bangladesh, 4-8 December 2000.

The collective wisdom of the thousands of people around the world was distilled into the *Peoples Charter for Health*, which has been placed before the people, governments, and international agencies and brought to their Assembly.

The Charter is a political statement to the world that the agenda for better health lies in the hands of the people and people's organisations.

The People's Health Movement will use the Charter as the main campaigning and lobbying tool to bring PHC back to national and international forums deciding on health policy issues.

The Charter underscores the fact that actions at all levels are needed to combat health crisis. The Charter contains a long list of actions, which provide good entry points to break the vicious cycle of poverty and ill health and promote social and economic development.

This call for action is directed to players at all levels - individuals, community, national, regional and global - and in all sectors. The call for actions is given under the following sections:

1. Health as a human right;
2. Tackling the broader determinants of health:
  - Economic challenges;
  - Social and political challenges;
  - Environmental challenges.
3. Wars, violence, conflicts and natural disasters;
4. A people-centred health sector; and
5. People's participation for a healthy world.

A very wide spectrum of calls for actions is included under the different sections. These provide a wide choice of activities for individuals and organisations, both big and small, to choose from depending on their own interests and resources available. There are, therefore, opportunities for every individual and organisation to take on a health related activity to make HFA a reality.

# MANAGED CARE CONSUMERS' PERSPECTIVES

*Executive summary of a paper presented at a seminar on Managed care, MASEAN Mid - Term Council Meeting, 19-22 November 1998, Penang, Malaysia*

Managed care is a means to an end. It is one of the means of paying for health care delivery. Health care delivery is, again, not an end by itself but a means to an end. The end is quality health for all. Health care delivery is one of several determinants of health; others include food, clean environment, education, security, adequate income, etc.

Managed care, being a means to an end, should not be examined in isolation. For example, it may not be meaningful and realistic to examine how to organise payment for healthcare without first examining the ownership and provision of healthcare. It will, therefore, be necessary to examine all aspects of healthcare reforms and the place of managed care in these reforms, paying particular attention to determine how:

- Managed care compares with alternate ways to pay for healthcare; and
- Managed care influences the ultimate goal of healthcare reforms, namely health for all.

There are four ways by which healthcare is financed. They are:

- General taxation;
- Compulsory social health insurance;
- Managed care; and
- Fee-per-item of service.

USA is the only country in the world where managed care has been used.

Comparing the healthcare services and health outcomes between USA and other developed industrialised countries which have used other ways to pay for healthcare delivery, managed care is certainly not a better way for healthcare delivery.

The total health expenditure in OECD countries in 1990 was about \$1,500 billion. Of this US alone spent \$825 billion or 55 per cent of the total. Though USA has physicians with unsurpassed training and probably among the very best in the world, yet the healthcare delivery system in the country has been described as the most

expensive, least efficient and least equitable in the world. It ranks 24th in infant mortality compared to other OECD countries. It has also the lowest life expectancy among the most highly industrialised countries (G7) and ranks eighth in the world even after Cuba, a developing country.

Health policy reforms and health policy debates in the ASEAN region during the last decade took place in the context of rapid economic growth facilitated by liberalisation of the economy, deregulation and privatisation. The governments in these countries, influenced by the radical market-oriented thinking initiated by Reagan and Thatcher in the early 1980s, began to perceive health as a marketable commodity.

Consumers highlighted the contradiction between the imperative of maintaining solidarity and the social good character of healthcare on the one hand and the fiscal imperative of pursuing market cost-control measures on the other. The adverse impact of the market-based cost-control measures on equity and the health status of the poor and marginalised have been raised in a number of countries.

A heated debate took place between social activists and the market oriented. In the heat of the debate, definitions of key health sector activities became vague and imprecise. The following statement in a 1996 report published by the WHO indicates the terminological confusion and the current level of policy flux and uncertainty. "Most disorienting of all, terms relating to the introduction of coordinated health services like, 'managed care' have become entangled with concepts that stipulate a market related role in financing of health services such as 'managed competition' or 'regulated competition'"

It is also relevant to note that the concept of health services as a marketable commodity, while having been discussed in some policy-making circles, has not been adopted in any single European country. In 1984, 32 countries in Europe adopted Health for All strategy proposed by WHO and UNICEF in 1978. This strategy is based on concepts of social justice and equity.

Countries in Asia, on the other hand, are privatising the health sector, and encouraging the private multibillion-dollar healthcare industry to enter the health market.

Consumers are directly involved in healthcare as taxpayers, as patients and as voters. They need to have clear and objective information. Health care services have inherently normative as well as economic and organisational activities. The normative dimensions are the social aspects including universal access and improved equity with which healthcare services are distributed across social classes.

The application of market-style mechanisms to the health sector is fraught with both conceptual and practical dilemmas. The market mechanism will completely ignore the normative dimensions. There is no place for equity in the market.

A brief glance at the financing of the UK National Health Service gives an example of internal market. This is not a market that any private sector firm will recognise as a free market. It is state controlled and highly regulated.

USA is the only country where managed care organisations (MCOs) have been functioning. There is increasing evidence that such organisation have not been a total success. For example, in a poll in July 1998, 85 per cent of the population said that the healthcare system needed fundamental change and 50 per cent said that managed care would harm the quality of healthcare. One of the most troublesome findings in

a December 1997 survey was that 55 per cent of the public is at least, “somewhat worried that, if they are sick, their ‘health plan’ would be more concerned about saving money than what is the best medical treatment.”

The following are among some of the problems that have alarmed managed care consumers in USA:

- In response to consumers’ concerns about managed care, several states in the US have passed laws that seek to protect consumers from abuses. More than 1000 bills seeking to ban alleged abuses by managed care plans have been tabled in state legislatures in 1997.
- Responding to the legislative battle over managed care regulation, the largest insurers in the US have formed the Coalition for Affordable Quality Healthcare and have launched a multimillion-dollar TV advertising campaign to boost the industry’s sagging image.

# EVOLVING ROLE OF THE CONSUMER

*Executive Summary of the paper presented at a meeting to commemorate the 20th Anniversary of the adoption of the Declaration of Alma Ata, November 27-28, Almaty, Kazakhstan*

Overall survival prospects of the population worldwide have improved but disparities in health levels have, in many cases, increased. This is, in part, due to grossly uneven distribution of resources available for health between the rich and the poor. A major consumer role is to campaign for social justice and equity in the distribution of available health resources. The central thrust of the Alma Ata Declaration on Health for All (HFA) in 1978 is social justice and equity.

The plan of action by Consumers International in its campaign to promote Primary Health Care (PHC) as the key to HFA, is based on the briefing document prepared by WHO to the participants to this conference which, among other things, states:

- The quest for HFA and the problems encountered in its implementation will never end;
- The need for a global dialogue, among all stakeholders, aiming to lead to a better understanding of PHC.
- The importance of clarifying the critical and evolving meaning of PHC and HFA, the processes and relationships necessary for implementation, measures and targets required to affirm real progress, including the needs of the poorest and most vulnerable.

Combining consumers' role with the three very pertinent issues identified by WHO, Consumers International has identified the following plan of action to fulfill its role:

- (i) To continue its campaign and lobby developing countries for the formulation and implementation of national health policies based on WHO's programme of HFA. In 1984, 32 countries in Europe adopted WHO's programme of HFA.
- (ii) Consumers should be associated with all other stakeholders in this campaign that must be an ongoing process. This interaction should not begin and end at international conferences but should be on a regular and continuous basis also at regional and particularly at national levels, where real action of policy formulation and implementation take place.



- (iii) For any campaign to succeed, the target audiences should first be convinced that PHC is the real answer to their problems. To convince them, as WHO has explained, we need to clarify the critical and evolving meanings of PHC and HFA, the processes and relationships for implementation, measures and targets required to affirm real progress. To get meaningful answers, we need to pose several questions.

Some of the relevant questions are simple and their answers are known. They are stated because the underlying issues are of critical importance but are often ignored by policy makers. It may not be possible to get answers to some of the other questions during the conference. They may be included in the agenda for the global dialogue proposed by WHO. The questions relate to health, determinants of health, link between health and healthcare services, planning for health and planning for healthcare services, the achievability of HFA in the context of globalisation, liberalisation and deregulation, health as a marketable commodity, consumer power in the health market, etc. Consumers' roles will include continuing their search for answers to these questions and share them with other stakeholders.

How is health measured? Consumers are concerned that the three guiding targets for HFA by the year 2000 do not measure real progress. They tend to give a false sense of security when they show that in 1997 nearly 3.8 billion people or 64 per cent of the population living in at least 106 countries had achieved all three targets. How illusory these data are, is reflected in the following WHO statements:

- Increased longevity without quality of life is an empty prize. Health expectancy is more important than life expectancy.
- Many countries are experiencing an epidemiological polarisation - a widening gap between the poor and the rich.

Consumers also have doubts as to the validity of these conventional indicators. The under-five mortality and infant mortality rates have doubled in one year (1996-1997) in Iraq. This unprecedented tragedy involving infants and young children can be explained by the UN sanctions imposed on Iraq. However significant decreases in life expectancy at birth and considerable increases in under-five and infant mortality rates within one year (1996-1997) in several other countries cannot be explained. Is it possible that there are methodological faults in computing these indicators in countries where reliable data may not be available? Consumers are convinced that there is an urgent need for appropriate measures and targets to affirm real progress.

In its briefing notes, WHO has referred to the changing global environment now confronting efforts to revitalise PHC. There has been unprecedented economic growth. The global GDP increased by 40 per cent between 1970 and 1985. It was believed that there would be a trickle down effect - some of the wealth will trickle down to the poor and alleviate poverty.

But just the opposite happened as described in a 1997 UN report that stated, "A rising tide of wealth supposed (was) to lift all boats. But some are more seaworthy than others. The yachts and ocean liners are indeed rising; but the rafts and row boats are taking on water and some are sinking fast."

The rafts and rowboats are the least developed countries (LDCs) - countries that are miserably poor. In 1978 when the UN first identified some developing countries as LDCs, there were a total of 28. Today the count is 48. One country per year is joining

the ranks of LDCs - sinking fast indeed! At this rate there will be more rafts and rowboats under water than above! In LDCs, 51 per cent of the population has no access to healthcare.

Has PHC failed? Consumers argue that it has not failed because it was never implemented. PHC, as it is practised now, focuses exclusively on applying technical solutions, top down, to outstanding health problems but completely ignores addressing the social, economic and political causes of the very same health problems. In this context, consumers' role is to show how PHC as conceived in Alma Ata in 1978 can address both the health problems and also the social, economic and political causes of the same health problems.

Economic and social development based on a New International Economic Order is of basic importance to the fullest attainment of HFA and the reduction of the gap between the health status of developed and developing countries. This New International Economic Order, based on the concepts of social justice and equity, provides for special attention to the needs of developing countries. The international community has discarded this New Order in favour of globalisation, liberalisation and deregulation, which call for level playing fields. LDCs have now to compete on equal terms with advanced industrialised countries.

The Alma Ata Declaration underscores the fact that PHC should form an integral part of overall social and economic development of the community. Health is one of several sectors. Other sectors include agriculture, animal husbandry, industry, education, housing, public works and communication, which play a crucial role in achieving the goal of HFA. This conference is quite aptly entitled, "PHC for the 21st Century - Everybody's business" reiterating the fact that PHC extends well beyond the health sector into several other sectors and the crucial role these sectors play in implementing PHC. But very unfortunately, none of these sectors are represented at this conference.

It has been argued that comprehensive PHC described in the Alma Ata Declaration was unrealistic; developing countries did not have adequate resources to implement comprehensive PHC. Unfortunately this argument ignores the final paragraph of the Declaration which states, "An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts..."

There is well-documented empirical data on the enormous resources developing countries and LDCs are spending on armaments and military conflicts. Consumers believe that wars, violence and the arms industry are public health problems; HFA can never be achieved as long as these problems continue. Competitive military spending can never bring peace to any country. The arms race and several military conflicts, particularly in the Third World during the last few decades, is testimony to this fact. As the UN and WHO have reiterated, the health of all people is fundamental to the attainment of peace and security in the world.

Consumers call for international action to initiate changes in the global environment that will lead to a reduction in military spending and the resources transferred to social sectors including health. The UN should consider convening another UN conference on "Disarmament and Development". The first conference was convened in 1987.

*Statement issued by Dr K Balasubramaniam - of CIROAP on the Informal Consultation on Evolving Public-Private Roles for the Pharmaceuticals Sector, 15-18 April 1996, Geneva*

I sincerely thank WHO for inviting Consumers International for this Consultation and giving me an opportunity to make a statement.

I bring greetings from the President, Director-General and Regional Directors of Consumers International and my colleagues from Penang.

Whom do I represent at this Consultation? I represent particularly the interests of about 2.5 billion consumers or about half the world's population. These are the 2.5 billion people, the WHO has estimated, have no regular access to even a few basic essential drugs for the management of common illnesses brought on by poverty and ignorance - common illness which make their lives a misery. Where do these 2.5 billion people live? Table 1 shows the number of people in the Third World countries of Latin America and the Caribbean, Africa and Asia living in absolute poverty expressed as a per centage of the total.

Please note the differences between the rural and urban populations. Vast majorities of the rural population, particularly in Africa, live in absolute poverty. What is the health status of these absolutely poor people? Table 2 shows the infant mortality rates (IMRs) of the rural and urban populations in eleven developing countries. The IMRs in the rural population are almost double of those in the urban population.

What happens to these absolutely poor people when government subsidies on health and food are reduced? The most vulnerable group among them, the infants, suffer most.

Table 3 shows the IMR in seven African countries in 1965, 1980 and 1985. Between 1965 and 1980, over a period of 15 years, these countries had improved the health standards of their infants and reduced the mortality rates. The 'debt-war' declared by World Bank and the International Monetary Fund on these African countries in the short period of five years has completely reversed the gains.

TABLE I

People living in absolute poverty expressed as a per centage of the total population (1980-1990)

Country expressed total population	People living in absolute poverty as a per centage of the (1980-1990)		
	Total	Rural	Urban
<b>AFRICA</b>			
Angola	.	65	-
Benin	.	65	-
Botswana	43	55	30
Burkina Faso	-	90	-
Burundi	84	85	55
Central African Republic	-	90	-
Chad	54	56	30
Congo	.	80	-
Djibouti	.	70	-
Egypt	23	25	21
Ethiopia	60	63	-
Equatorial Guinea	67	70	60
Gambia	-	85	-
Ghana	42	54	20
Guinea	-	70	-
Guinea - Bissau	-	75	-
Kenya	52	55	10
Lesotho	54	55	50
Mali	54	60	27
Malawi	82	90	25
Mauritania		80	-
Mozambique	59	65	40
Niger	-	35	-
Nigeria	40	51	21
Rwanda	85	90	30
Senegal	-	70	-
Sierra Leone	.	65	-
Somalia	60	70	-
Sudan	-	85	-
Tanzania	58	60	-
Uganda	-	80	-
Zaire	70	90	-
<b>ASIA</b>			
Afghanistan	53	60	18
Bangladesh	78	86	-
Bhutan	.	90	
China	9	13	
India	40	42	33
Indonesia	25	27	20
Lao PDR	-	85	-
Malaysia	16	22	18
Maldives	.	40	-
Myanmar	35	40	-
Nepal	60	61	51
Pakistan	28	29	26
Papua New Guinea	73	75	10
Philippines	54	64	40
Sri Lanka	39	46	15
Thailand	30	34	17
Vietnam	54	60	-
<b>LATIN AMERICA</b>			
Belize	.	65	-
Bolivia	60	86	30
Brazil	47	73	38
Colombia	42	45	40
Dominica	-	70	
Dominican Republic	55	70	45
El Salvador	51	75	20
Equador	56	65	40
Guatemala	71	74	66
Haiti	76	80	65
Jamaica	.	80	-
Mexico	30	51	23
Panama	42	65	21
Peru	32	75	13
Venezuela	31	58	28

Source: Human Development Report, UNDP, New York, Oxford University Press, 1994 Table 18

**TABLE 2**

Infant mortality rates in the urban and rural areas in 11 developing countries and population as a per centage of the total population

Country	Infant Mortality Rate		Rural Population as a per centage of total
	Urban	Rural	
Bhutan	120.0	300.0	95.0
Congo	107.0	172.0	59.0
Dahomey	46.0	115.0	n.a.
India	65.0	124.0	73.0
Morocco	100.0	170.0	54.0
Mozambique	130.0	183.0	83.0
Papua New Guinea	50.0	80.0	86.0
Peru	73.6	158.2	33.0
Rep. of Tanzania	88.0	215.0	72.0
Senegal	71.4	136.8	63.0
Syrian Arab Rep.	43.0	67.0	49.0

n.a. - Not available

Sources:

1. David Morley (1973): *Paediatric Priorities in the Developing World*, Butterworth, London-Boston, p.6 (Dahomey & Morocco)
2. *Technology Policies in the Pharmaceutical Sector in the United Republic of Tanzania*, UNCTAD/TT/35. p. 1 (Rep. of Tanzania)
3. *Health Care in South East Asia*, WHO, SEARO, New Delhi, 1985, p.58, (Bhutan)
4. *Intersectoral Action for Health*, World Health Organisation, Geneva, 1986, p.24, (all other countries).

**TABLE 3**

Infant mortality rates in seven countries with WB/IMF SAPs

Country	Infant Mortality Rates			Percentage Change	
	1965	1980	1985	1960-1980	1980-1985
Ethiopia	165	146	168	-11.5	+ 15.1
Kenya	112	87	91	-22.3	+4.6
Madaga-scar	n.a.	71	109	-	+53.5
Mali	200	154'	174	-23.0	+26.5
Somalia	165	146	152	-11.5	+4.1
Tanzania	138	103	110	-25.4	+6.8
Uganda	121	97	108	-19.8	+ 11.3

n.a. - not available

Source: Commonwealth Secretariat (1989): *Engendering Adjustment for the 1990s*. Commonwealth Secretariat Publications, London.

## MORE ABOUT THESE 2.5 BILLION PEOPLE

The Food and Agricultural Organisation estimates that 800 million people go hungry every day.

Hunger is the single major cause of ill health, suffering and death. As long as people are poor and go hungry, any discussion on health, healthcare, pharmaceuticals and examination of the roles of the public and private sector are meaningless.

Let us see the State of the Children of the World over a period of ten years between 1982 and 1992 - a period during which the United Nations Children Fund (UNICEF) had spent enormous amounts of resources to improve the health of the children.

The following two excerpts, taken from UNICEF's *The State of the World's Children*, reveal the mortality and morbidity figures for children in 1982 and 1992.

a) Every day of this last year more than 40,000 young children have died from malnutrition and infection. And for every one who has died six now live on in hunger and ill health which will be forever etched upon their lives...

... To allow 40,000 children to die like this every day is unconscionable in a world which has mastered the means of preventing it. (*The State of the World's Children*, 1982-83)

b) A quarter of a million of the world's young children are dying every week, and millions more are surviving in the half-life of malnutrition and almost permanent ill health.

This is not a threatened tragedy or an impending crisis. It happened today. It will happen again tomorrow. (*The State of the World's Children*, 1992)

Infants and young children continue to die in equal numbers in 1992 nine years after UNICEF introduced GOBI-FFF as in 1982. And several millions continue to survive in utter misery in 1992 as they did in 1982.

## **PRIMARY HEALTH CARE - THE ONLY SOLUTION**

Can any one prevent children dying in such large numbers? Primary Health Care as defined in Alma Ata offers the only solution. There is no second-best approach.

Poverty rather than any microbe or parasite is the key vector of ill health. Poverty and hunger are not due to lack of resources but to unfair distribution. Eradication of poverty and the provision of basic needs to all the people are essential pre-requisites for health. The severely indebted countries of the Third World are constrained to initiate programmes to eradicate poverty. They have lost their sovereignty and cannot exercise any control over their own economy. This should not surprise us since we are told that the richest and the most powerful nation in the world has lost some control over its own economy.

Over US\$900 billion worth of currencies cross national borders (traded) every day. But only one out of every 70 dollars that change hands pays for trade in goods or services. The rest of the transactions are purely speculative. Financier George Soros, whose hedge funds control US\$11 billion in assets made nearly US\$1 billion in 1992 by betting against the British pound. In 1990 The Wall Street Journal acknowledged that the Federal Reserve Board, the US central bank, had lost much of its control over US interest rates. Gradually, its power is slipping away to markets in Tokyo and Frankfurt. As the Federal Reserve Board loses leverage, the US loses some of its control over its own economic destiny. ("The Power of Global Finance" in *The Third World Resurgence*, No. 55, March 1995, pp. 18-21.)

In 1978, under the leadership of a visionary Director General, the WHO in collaboration with UNICEF presented a blueprint for survival - the Alma Ata Declaration. Primary Health Care (PHC) would be the key to Health For All. This was not a mere theoretical concept. It was based on many examples of success stories from countries with very limited material resources that had significantly improved the health of their people by formulating and implementing national health policies based on PHC. The world community has unanimously adopted the Alma Ata Declaration.

## **THE IMPERATIVE TO DEFINE PUBLIC HEALTH OBJECTIVES**

The primary purpose of this meeting is to review the public-private roles in the pharmaceutical sector and to identify ways in which WHO can assist countries in guiding this evolution to meet public health objectives.

This statement clearly underscores the fact that pharmaceutical supply system is only one of the means to an end but not the end itself. The end or the final goals are public health objectives.

This meeting has therefore to define and reach a consensus on what the public health objectives are. It is only after reaching this consensus that we can meaningfully examine the pharmaceutical supply system and the roles of the public and private sectors to identify issues, options and relevant experiences.

The discussion paper has very clearly described the public health objective. "Health is a fundamental human right. Access to healthcare, including essential drugs is central to reaching this right." Implied in this statement is the Declaration of Alma-Ata - Health for All.

WHO has, since 1978, repeatedly reiterated that a national health policy based on Primary Health Care offers the only viable option for the majority of developing countries with limited resources to make access to healthcare, including essential drugs, for all the people a reality. There are simply no other options. Access to essential drugs will be facilitated by developing and implementing a drug policy based on the concept of essential drugs. This drug policy will be a component of the national health policy.

The roles of the public and private sectors need to be examined in implementing a national drug policy based on the concept of essential drugs.

To enable the meeting to review evolving public-private roles in the pharmaceutical sector and to identify ways in which WHO can assist countries in guiding this evolution to meet public health objectives, we need empirical data on how the public and private sectors have provided healthcare and pharmaceutical services to the people. It is only after a critical evaluation of the empirical data on their respective performances, that we can review and identify ways to assist the countries. These data are available in reference 87 - WHO/DAP 1996. Pharmaceutical and health expenditures. (Working draft) Geneva: World Health Organisation, which is not yet available to Consumers International. However, a summary of that data is presented in Tables 4 and 5.



**TABLE 4****Public Sector Health and Pharmaceutical Expenditures by Region, 1990**

Region	Public Sector Health Expenditure as a per cent of total	Public Sector Pharmaceutical Expenditure as a per cent of total
Sub-Saharan Africa	43.8	39-55
Asia	40.4	20
Middle-East	57.6	12-18
Latin America and the Caribbean	59.8	24
Established Market Economies	61.1	66

Source: *Draft Discussion Paper*

**TABLE 5****Private Sector Health and Pharmaceutical Expenditures by Region, 1990**

Region	Private Sector Health Expenditure as a per cent of total	Private Sector Pharmaceutical Expenditure as a per cent of total
Sub-Saharan Africa	46.6	45-61
Asia	57.8	80
Middle East	42.8	82-88
Latin America and the Caribbean	38.9	76
Market Economies	38.9	34

Source: *Draft discussion paper*

From these data and from our own work in Penang, it is quite clear that in countries in Asia, Middle East and Latin America and the Caribbean, the public sector provides pharmaceutical services much more cost-effectively than the private sector (Tables 4, 5 and 6).

If we take Asia, for example, the public sector share of the total health expenditure is 40 per cent. It can be safely assumed that 40 per cent of the total healthcare services is provided by the public sector. However the public sector uses only for 20 per cent of the total pharmaceutical expenditure to provide 40 per cent. On the other hand the private sector uses 80 per cent of the total pharmaceutical expenditures to provide 57.8 per cent of the healthcare. The public sectors in the Middle East and Latin America are even more cost effective compared to Asia.

Table 6 gives a comparison of public and private sector health services in Malaysia, 1990-1991.

**TABLE 6****Comparison of Public and Private Sector Health Services in Malaysia 1990-1991**

	Public Sector	Private Sector
Health Expenditure as a per centage of total	43	57
Pharmaceutical expenditure as a per centage of total	25	75
Pharmaceutical expenditure as a per centage of health expenditure	16	38
Average daily outpatient attendance	Equal in both sectors	Equal in both sectors
Hospital beds expressed as a per centage of total	87	13
Number of doctors employed as a per centage of total	43	57

Source: From a paper presented by Dr. K. Balasubramaniam at a Public Education Seminar "Towards Affordable Quality Medication for all Malaysians", 14 February 1993 jointly organised by the Malaysian Medical Association and the Malaysian Pharmaceutical Society.

Health care and pharmaceutical services provided by the public sector in Malaysia are much more cost efficient compared to the services provided by the private sector. The figures are very similar to Asian data in table 4 and 5. The public sector in Malaysia use only 25 per cent of the total pharmaceutical expenditure to provide 43 per cent of the total healthcare; the private sector uses 75 per cent of the total pharmaceutical expenditure to provide 57 per cent of the healthcare.

The Malaysian data confirms an important statement made in the draft discussion paper, "Thus, monetary estimates of public private mix probably under-estimate the volume of drugs provided through the public sector". I wish to add that monetary estimates of public private mix also under-estimate the volume of healthcare services provided by the public sector.

In Malaysia the daily outpatient attendance is equal in both the public and private sectors. But 87 per cent of all hospital beds are in the public sector. This indicates that the volume of healthcare provided by the public sector is several times more than what is provided by the private sector. Thus the monetary estimates of public private mix under-estimate the volume of healthcare services provided by the public sector in Malaysia. And they provide all this using much less resources - 43 per cent of doctors, 43 per cent of the total health expenditure and 25 per cent of the pharmaceutical expenditure. Only 16 cents out of every health dollar is spent on pharmaceuticals in the public sector. In contrast the private sector spends 38 cents out of every health dollar on drugs.

The data presented provide very good evidence that the public sector provides health and pharmaceutical services much more cost-effectively than the private sector in developing countries. I am therefore very confused and cannot understand why we are even discussing certain issues like "Can private sector mechanisms help to ensure access to essential drugs in the public?"

According to the Asian Development Bank (ADB) the largest source of healthcare financing in the Bank's developing member countries (Sri Lanka is one) is from private expenditures; almost all of this is paid out-of-pocket by consumers. Consumers in the rich countries pay out-of-pocket less than 20 per cent of their total health expenditures (HE); public funding either by taxation or social security pays for the rest - 80 per cent. In all the poor developing countries, except Malaysia, which is the richest of the 15 countries listed, consumers pay out of pocket 52-91 per cent of the total HE.

According to the World Health Organisation, there are no private insurance markets at all. When they do exist, they may be guilty of "Cream-skimming". They exclude the riskier customers on the basis of their income or prior health status. Only the high-income earners and healthy ones are insured.

Direct or out-of-pocket payment at point of utilisation is the model that operates in the private sector in Asian Countries. Consumers pay out-of-their pockets for goods and services they purchase from providers without the intervention of a third party. General taxation is the commonest form of public healthcare financing in Asian Countries and also in rich countries such as the UK and Canada. In this model the State collects taxes from all consumers in the form of direct and indirect taxes. Annual allocation is given to the Ministry of Health, which provides the services through public health facilities. In this model a third party, the State intervenes between the consumer and the provider. In some countries, consumers may have to pay a small portion of the costs known as user charges or co-payment.

*Source: World Development Report 2001, World Bank; Asian Development Bank, Key Indicators of Developing Asian and Pacific Countries, 1998, Volume XXIX; Human Development Report 2001, UNDP; Press articles by Dr Bala – Save healthcare from market forces -12 March 2004; Healthcare Financing and health equity – 23 April 2004*

## NATIONAL HEALTH INSURANCE AND FINANCING: THE INTERNATIONAL SCENE AND FOREIGN MODELS

*Executive summary of paper presented at the Seminar on "Future of Health Services in Malaysia", 19-20 October 1996, Kuala Lumpur, Malaysia, organised by the Malaysian Medical Association*

The healthcare systems in the developed or OECD (Organisation for Economic Cooperation and Development) countries can be classified into two groups depending on their financing mechanisms. One group finances its healthcare from general taxation. The UK is an example. The second uses compulsory social insurance. Several European countries including France and Germany are examples of this group. USA is an exception. Free choice and market competition are the features of the American system.

In addition to general taxation and compulsory social insurance, direct payment by patients (user-fees or fee-for-service) and private health insurance are two other mechanisms for financing healthcare. Malaysia and other countries in the British Commonwealth use these two methods together with general taxation.

There are therefore four mechanisms for financing healthcare: general taxation, compulsory social insurance, direct payment and private health insurance.

The healthcare systems in all countries are pluralistic with respect to financing; this means that each country uses more than one mechanism but one particular method predominates.

The major goal of this seminar is to arrive at a consensus on the financing mechanism most appropriate for Malaysia and how the healthcare services should be organised. In this context it will be very important to examine the major objectives of the healthcare services.

There are three major objectives. They are:

- An equitable distribution of healthcare to all Malaysians;
- Clinical and economic freedom for providers of healthcare; and
- Budgetary and cost control on the total healthcare expenditure.

An examination of these will show that they are three competing objectives. A health system can simultaneously attain only two of these objectives in their purity. Consumers will want the first objective - equal access; health professionals want clinical and economic freedom to organise the production of healthcare as they see fit and to charge whatever prices they deem reasonable; the government will want to exert budgetary and cost control so that it can know in advance how much to budget for healthcare in a coming year and to ensure that the total health budget is what the country and people can afford. Therefore a compromise among these three objectives is necessary since any one of them always conflicts with the other two.

Before policy analysts are asked to devise options for healthcare reforms, they should be given clearly articulated guidelines on the relative priorities to be attached to these three objectives and to others lurking behind these.

A critical analysis of empirical data will draw the following conclusions, which need to be considered when formulating policy:

- (i) The public insurance system in the OECD countries has not only improved access to healthcare, it has also played an important part in “nation building” and community solidarity as it emphasises a fundamental equality among citizens. Greater wealth and/or position can buy many things, but they do not buy more or better health: in this respect all citizens are equal.
- (ii) The public insurance system, either through general taxation or compulsory social insurance premiums, is a very efficient mechanism to redistribute income from the healthy or high-income groups to the unhealthy or low-income

groups. The economic burden of the healthcare system is collectively shared according to the ability of the citizens. No one in countries with public insurance system lives in fear of economic ruin following in-patient treatment for a catastrophic illness and more importantly no one needs to depend on charity.

- (iii) Private health insurance is not a viable option for financing healthcare.
- (iv) The most important function of the State is regulation. Formulation and implementation of statutory legislation related to financing methods, organisation and functioning of the financing organisations, payment of providers and a global budget have been the central features of a successful healthcare system.
- (v) Ownership and provision of services is not a critical issue, whether the financing is through general taxation or compulsory health insurance. Canada finances through general taxation but has a mixture of private and public hospitals and its physicians practice as independent entrepreneurs. Most countries with compulsory health insurance have a mixture of public and private providers. The private providers include not-for-profit and for-profit hospitals.
- (vi) Controlling health expenditures while providing universal coverage and equal access to healthcare has not been achieved through market mechanisms in the more affluent countries.

# MODELS OF HEALTHCARE FINANCING

*Executive Summary of paper presented at a consultation on healthcare financing organised by Biro Kesihat, 20th August 2000, BA, Kuala Lumpur, Malaysia*

No country, however affluent it is, can ever afford to have a health system that can provide all its citizens the best treatment modern health technology can offer. There has to be some form of rationing of healthcare in each and every country. There are two ways to ration healthcare and they determine who gets what care. Rationing can be introduced by:

- (i) Prices; or
- (ii) Public policy

## **RATIONING THROUGH PRICES**

Health becomes a marketable commodity when governments privatise health services and hand over the health of its citizens to the private sector. Entrepreneurs, both national and foreign will enter the “health market” to make money out of people’s health. In a market, health is rationed by prices. The poor are denied access to regular healthcare. There is no social justice and equity in the health sector.

## **RATIONING THROUGH PUBLIC POLICY**

Health is a fundamental human right. The State has a responsibility to ensure equal access to healthcare for all its citizens depending on their need. Health demands are enormous but resources are limited. A critical analysis of empirical health data in Malaysia shows that health policy makers have to formulate and implement national health policies which will determine who will live and who will die. This is a very hard choice; it is a political and not a technological choice. Health is politics.

## **OBJECTIVES OF A HEALTH SYSTEM**

Policy makers need to know that the objective of a health system is not only to obtain good vital statistics for the whole country such as low infant, neonatal and maternal mortality rates, but also to ensure that there is no inequality in health outcomes among

different groups of people. Health systems, therefore, have two objectives: Goodness and Fairness.

*Goodness.* Best attainable average levels of health outcomes such as low infant mortality rate.

*Fairness.* This will include:

- Smallest differences in health outcomes between groups.
- Reduction of inequalities to improve the situation of the worst off.
- Regular availability of affordable healthcare for all the people.

Very sensitive indicators of the health of a community include infant and neonatal mortality rates. These refer to the number of babies who die within one year of birth for every 1000 live births or number of babies who die within one month of birth for every 1000 live births respectively. These rates are estimated for each calendar year.

The report presents empirical data on infant and neonatal mortality rates, number of people per doctor, number of hospital beds per 100,000 people, and the incidence of poverty in the different states of Malaysia. The income distribution is also given.

While the averages for IMR, neonatal mortality rates, number of people per doctor, number of hospital beds per 100,000 people and the incidence of poverty in Malaysia are good in comparison with other developing countries, there are gross inequalities among states and among population sub-groups.

The following two tables illustrate the inequalities among states in Malaysia and the maldistribution of the per capita income (GNP) among seven population sub-groups. National average is RM11,700 (1997). The ratio of the incomes of the poorest and the richest in Malaysia is 1:20. This is the widest in the Asia-Pacific region.

	National Average	Lowest (State)	Highest (State)	Federal Territory KL
Infant mortality rate	9.1	5.7 (Sarawak)	14.1 (Sabah)	12.2 (Second highest)
Neonatal mortality rate	6.0	3.4 (Sarawak)	10.7 (Sabah)	8.3 (Third highest)
Incidence of poverty	6.8	0.1 (Fed. Territory)	22.1 (Sabah)	-

Population sub-group in millions	2	2	4	4	4	2	2
Per capita income in millions - RM (GNP)	2,223	3,300	4,855	7,605	12,110	18,485	444.343

These data indicate that while there is goodness in the Malaysian health system, the second objective of a health system - namely fairness - is lacking.

Achieving goodness and fairness in healthcare

To achieve its twin objectives of goodness and fairness, a health system should give equal attention to four key functions. These are:

1. Providing services;
2. Generating the human and physical resources that make service delivery possible;
3. Financing healthcare; and
4. Stewardship or leadership - setting and enforcing rules of the game and providing strategic direction for all the different actors involved in healthcare services.



Available data indicate that policy makers in the Ministry of Health have focused only on the first two functions but neglected financing healthcare and stewardship. And this has led to the lack of fairness resulting in gross inequalities.

The neglect started in the early 1990s when the government proposed certain radical healthcare reforms based on privatisation of healthcare and shifting the cost of healthcare from the state to the people. The government's proposal for privatisation was based on the assumption by policy makers that increased costs of healthcare after privatisation would be affordable by an affluent society. Unfortunately, the assumption is being proved wrong, and the majority of Malaysians will be denied access to regular healthcare under the proposed reforms which encourage changes in the ownership of the means of financing and producing healthcare through managed care organisations, private health insurance and private hospitals.

The government's policy of privatising healthcare was based on a second assumption that market approaches to healthcare financing will increase efficiency and contain costs. This is also proving to be a myth. In fact, the advanced industrialised countries, which have relied very heavily on market mechanisms to achieve high incomes they now enjoy today, are the very same countries that rely on public financing for healthcare and have rejected market approaches to healthcare financing.

There are two models of healthcare financing in these advanced industrialised countries and one of them -mandated social health insurance - could be a suitable model for Malaysia. This model will rectify two major problems facing the Malaysian healthcare system:

- i. Healthcare costs are escalating. Majority of Malaysians cannot afford regular access to healthcare under the present system of healthcare financing
- ii. There is an exodus of doctors, particularly the senior specialists, from the public to the private sector.

Social Health Insurance will integrate the public and private health sectors through this model of healthcare financing and provide a stable funding base to extend the benefits of free point-of-delivery health services to the whole country with emphasis on individual health protection.

## **SOCIAL HEALTH INSURANCE**

Social health insurance is an efficient mechanism to pool the total health risks in the country and to re-distribute income from the healthy and/or high income groups to the unhealthy and/or low income groups and thereby to collectively share the economic burden of the healthcare system in the country. This system will not only ensure universal health coverage but also play an important part in nation building and community solidarity as it emphasises a fundamental equality among citizens.

Studies carried out by the government and several conferences on the future of Malaysian health services organised by the Malaysian Medical Association, some of them in collaboration with the Ministry of Health and consumer organisations, have focused on health financing systems particularly on social health insurance. A blueprint for a social health insurance is already available in Malaysia.

According to this blueprint, a social health insurance fund will be established outside the Ministry of Health. The fund will be responsible for collecting, managing and paying providers both in the public and private sectors.

## **STEWARDSHIP OF THE HEALTH SYSTEM**

When health financing is taken away from it, the Ministry of Health will be able to concentrate on the fourth key function namely stewardship or leadership. One of the immediate tasks will be to prevent fragmentation of the health delivery system and to regulate and control the private sector.

Fragmentation occurs firstly between the public and private sectors and secondly within each of these sectors. When health delivery systems become fragmented, allocative efficiency suffers and healthcare costs escalate.

In 1993 the President of the Association of Private Hospitals described the growth of private hospitals as the commercialisation of health. The trend was marked by increasing foreign ownership of the private hospitals and changes occurring in charity hospitals. Private hospitals are built close to each other in the cities and each of them is equipped with all modern expensive high technology diagnostic and curative appliances to attract patients and increase profits. As a result patients undergo unnecessary expensive procedures. The Ministry of Health has to urgently intervene and stop this perverse practice.



*Resource persons addressing the participants at the National Workshop on FTA between Thailand and the US: impact to drug and health system, Bangkok, Thailand in Feb 2004. HALAP was one of the organizers of the national workshop*



*Dr Bala, Coordinator/Advisor addressing the participants at the Second International Consultation on Undergraduate Medical and Pharmacy Education convened by HALAP, SEARO/WHO and EMRO/WHO in September 2005 at Negombo, Sri Lanka*



*Niyada Kiatying-Angsulee, HAIAP Governing Council Member and a member of the Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, at a presentation at the sub regional workshop on pharmaceuticals and health for health officials and NGOs from Cambodia, Laos PDR, Myanmar and Vietnam held in October 2004 in Bangkok, Thailand organized in collaboration with HAIAP*



*Participants of the 2005 Asia Health Forum organized by HAIAP in Penang, Malaysia pose for a group photograph*





*Participants, during the 25th Anniversary celebrations of HAI at the Regional Seminar on “The future of health services: who will live and who will die” pose for a group photograph in Gonoshasthaya Kendra, Savar, Dhaka, Bangladesh, 10 - 12 April, 2006*



*Dr Balasubramaniam – Advisor/Coordinator HAIAP, Prof Abul Qasem Chowdhury – Vice Chancellor, Gono Bishwabidyalay, Dr Khondaker Mosbaraff Hossain – Minister of Health and Family Welfare, Bangladesh who was also the Chief Guest, Dr George Kombo-kono representing the WHO office in Bangladesh and Dr Prem Chandran John – Chairperson, Governing Council, HAIAP at the inaugural session of the Regional Seminar “The future of health services: who will live and who will die” in April 2006*



*Charles Medawar, Dr Mira Shiva, Dr Andrew Herxheimer, Catherine Hodgkin and Eva Ombaka at the John Knox, Geneva, Switzerland*



*HAI Regional Coordinators Margaret Ewen and Dr K Balasubramaniam with colleagues during the launch of the WHO/HAI Medicines Prices manual in Geneva, May 2003*

# CHARTER OF PATIENTS' RIGHTS AND RESPONSIBILITIES: A DRAFT FOR CONSULTATION

*A Draft for Consultation, Peoples' Movement for Rights of Patients, September 2005, Sri Lanka.*

## INTRODUCTION

Formalised in 1948 and accepted by the world community, the Universal Declaration of Human Rights recognises the “inherent dignity” and the “equal and unalienable rights of all members of the human family”. And it is on the basis of this concept of the person and the fundamental dignity and equality of all human beings that the notion of patients’ rights was developed.

Patients’ rights refer to what is owed to the patient as a human being by the healthcare providers and the State.

Patients’ rights and responsibilities vary in different countries and in different jurisdictions. The prevailing cultural and social norms will determine the set of patients’ rights and responsibilities in a particular country.

Assuring that the rights of patients are protected requires much more than educating policy makers and healthcare providers. It requires educating citizens about what they should expect from their governments and their healthcare providers.

The Sri Lankan national health system should put in place the rights of patients, consumers, users, family members, weak populations and ordinary people at risk.

The public does not accept that patients’ rights can be affirmed in theory, but then denied in practice, because of financial limits. Financial constraints, however justified, cannot legitimise denying or compromising patients’ rights. In view of the financial constraints, the Sri Lankan Peoples’ Health Charter realised that the right to health of all Sri Lankans can only be achieved by formulating and implementing national health policies based on the concepts of Primary Health Care as outlined in the Alma Ata Declaration.



## **PATIENTS' RIGHTS**

### **RIGHT OF ACCESS AND HUMANE TREATMENT**

- The right to receive medical advice and treatment which fully meets the currently accepted standards of care and quality regardless of age, sex, ethnic origin, religion, political affiliation or social class. The currently accepted standards are those adopted by a responsible body of the profession in the light of accepted medical practice.
- Healthcare services shall be available on the basis of clinical need regardless of the ability to pay. It shall be the responsibility of the government to ensure that every person has access to essential health services whenever the need arises.
- Right to a second opinion at any time.
- No patient care is abandoned by a healthcare professional worker or a health facility, which initially took responsibility for one's care.
- Healthcare providers shall display a positive disposition that demonstrates courtesy, human dignity, patience, empathy, tolerance, respect and without discrimination of any kind.
- All drugs prescribed and dispensed shall be of acceptable standards of quality, safety and efficacy as determined by the Drug Regulatory Authority of Sri Lanka.
- The right to prompt and timely emergency care in the nearest government or private sector health facility regardless of one's ability to pay.
- There shall be provision for special needs in case of new born infants, young children, pregnant women, the aged, disabled, and patients in pain, persons living with HIV/AIDS.
- The right to ready access to palliative care that is effective and affordable in cases of incurable or terminal illness.

### **RIGHT TO INFORMATION AND CONSENT**

- The right to information about what healthcare services are available and how to obtain them.
- The right to be given a clear description of a patient's medical condition with diagnosis, prognosis (i.e. an opinion as to the likely future course of that illness) and of the treatment proposed including common risks and appropriate alternatives.
- The right to know the names of medications prescribed; the prices of the brand names and the prices of the generic equivalents of the medications prescribed.
- The right of the patient to choose between the brand name and its generic equivalent.
- All medications shall be labelled and shall include the generic or International Non-Proprietary Name (INN). The labelling should also provide the following information.
  - The dosage and how often to be taken
  - The purpose of the medicine
  - Potential side effects
  - The avoidance of any food, beverages or other drugs
  - Duration of a course of treatment

- The right to an itemised account for the fees paid for consultation and treatment and to have this explained.
- Where it is appropriate to a patient's continued care and management, the patient shall be given advice about self-care, continued drug treatment, special precautions, life styles which may be necessary or desirable and the existence of special associations, facilities, aids or appliances which may be of assistance.
- The right to be given full and accurate information about the nature of one's illness, diagnostic procedures, the proposed treatment and the costs involved, for one to make an informed decision that affects any one of these elements.
- The right to choose whether or not to take part in medical research programmes.

## **RIGHT TO PRIVACY AND CONFIDENTIALITY**

- The right to have one's privacy, dignity and religious and cultural beliefs respected.
- The right to ensure the details of the patient's condition, treatment, prognosis, and all communications and other details relating to the patient's care to be treated as confidential, unless
  - Authorised in writing by the patient, parent or guardian in case of children
  - The information is required by due legal process.

## **RIGHT TO COMPLAIN**

The right to complain about healthcare services whenever a patient has suffered a harm; to have such complaints investigated and the right to receive a response or other feed back.

- The health services ought to guarantee the exercise of this right, providing (with the help of third parties) patients with information about their rights, enabling them to recognise violations and to formalise their complaint. A complaint must be followed up by an exhaustive written response by the health service authorities within a fixed period of time.
- The complaints must be made through standard procedures, facilitated by independent bodies and/or citizens' organisations and cannot prejudice the patients' right to take legal action or pursue alternative dispute resolution.

## **RIGHT TO COMPENSATION**

- Each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical, moral or psychological harm caused by a health service treatment.
- The health services must guarantee compensation, whatever the gravity of the harm and its cause (from an excessive wait to a case of malpractice), even when the ultimate responsibility cannot be absolutely determined.

## **RIGHT TO PREVENTIVE MEASURES**

The right to a proper service in order to prevent illness. The health services have the duty to pursue this end by raising peoples' awareness, guaranteeing health procedures at regular intervals free of charge for various groups of population at risk, and making the results of scientific research and technological innovation available to all.

## **PATIENT'S RESPONSIBILITIES**

The patient shall:

- Ensure that she/he knows and understands what patients' rights are and shall use these rights reasonably and responsibly.
- Keep appointments, be on time and shall inform the health professional in advance if unable to do so.
- Give her/his health provider as much information as she/he can about the present health, whether consulting with or under the care of another healthcare provider or traditional healer in connection with the same complaint or any other complaint.
- Use the healthcare system properly and not abuse it.
- Not waste medical resources unnecessarily.
- Take good care of all health records in her/his possession.
- Comply with prescribed treatment or rehabilitative processes.
- Show consideration and respect for the rights of other patients and healthcare providers by following the hospital rules concerning patient conduct.
- Have a regular family Doctor, Dentist and Pharmacist to ensure that there is continuing healthcare for the patient and patient's family.
- Seek a Consultant's advice only when referred to by the family Doctor or General Practitioner.

## **GUIDELINES FOR IMPLEMENTING THIS CHARTER**

The dissemination and application of the contents of this Charter will have to be carried at national, regional and local levels.

## **INFORMATION AND EDUCATION**

As a means of informing and educating the public and healthcare workers this Charter may be promoted in all health institutions, mass media, in universities, schools and other appropriate public places.

## **SUPPORT**

Support for and subscription to the Charter need to be gathered from healthcare stakeholders and civil society organisations. The special commitments of those health services and professionals that subscribe to the Charter should be defined.

## **DIALOGUE**

It will be important to initiate a dialogue among the various stakeholders on (the basis of the contents of the Charter in order to work out policies, programmes and action plans for the protection of patients' rights. Such a dialogue will take place among governmental authorities, public and private sector institutions involved in healthcare, professional associations of doctors, dentists, nurses & pharmacists, trade unions of healthcare workers and civil society organisations.

## **LEGISLATION**

The Charter rights and responsibilities may be incorporated into national laws and regulations in full or in part to make the goal of protecting patients' rights an ordinary part of public policies.

# SRI LANKAN PEOPLES HEALTH CHARTER

## PREAMBLE

- One of the most fundamental human rights is the assumption that each person matters and everyone deserves to be treated with dignity. This is the tenet from which all other human rights follow. Another is that those who are most vulnerable deserve special protection.
- The recognition of the inherent dignity and equal and inalienable rights of every citizen is the foundation of freedom, justice and peace in Sri Lanka.
- Emergence of Sri Lanka as a country in which all its citizens shall enjoy freedom of speech and freedom from fear and want is the highest aspiration of the common people.
- Sri Lankans reaffirm their faith in fundamental human rights, in the dignity and worth of the human person and in equal rights for men and women. They are determined to promote social progress and better standards of life in larger freedom.
- Health, a fundamental right, is a social, political and economic issue.
- While Health is a fundamental human right indispensable for the exercise of all other rights, health and ill-health are themselves the outcome of social, economic and political influences. Without sustained improvements in socio-economic conditions and consequent improvements in standards of living, optimum health for all is unlikely to be achieved and maintained.
- Inequality, poverty, exploitation, violence and injustice are at the root of ill health.
- Every one has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices.
- Every one has the right to a standard of living adequate for the well being of himself/herself and of his/her family, including food, clothing, housing, medical care, necessary social services and the right to social security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his/her control.
- The right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life and extends to the underlying determinants of health including food and nutrition housing, access to safe and

potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.

- Poverty is the deadliest disease
- Hunger is the commonest cause of death
- These clearly demonstrate that the Ministry of Health and the Department of Health Services alone cannot ensure the right to health, but points to the non-exhaustive examples of the obligations of other government Ministries and Departments.
- The right to health in all its forms and at all levels described above contains the following interrelated and essential elements.

## **A. AVAILABILITY**

Well functioning public health and healthcare facilities, goods and services as well as programmes have to be available in sufficient quantities within the government institutions.

## **B. ACCESSIBILITY**

Health facilities, goods and services have to be accessible to every one without discrimination. Accessibility has four overlapping dimensions.

### **i. Non-discrimination**

Health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalised sections of the population.

### **ii. Physical accessibility**

Health facilities, goods and services must be within safe physical reach of all sections of the population, especially the vulnerable or marginalised groups.

### **iii. Acceptability**

All health facilities, goods and services must be respectful of medical ethics and culturally appropriate.

### **iv. Quality**

Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

- People have the right and duty to participate individually and collectively in planning and implementation of healthcare.

## **THE ROLL OF THE STATE**

- The state has the responsibility for the health of its entire people. This can be fulfilled only by provision of appropriate and adequate health and social measures.
- Health for all Sri Lankans can be achieved only when the right to health is protected by the laws of the country and enshrined in the constitution.
- The realisation of the right to health can be achieved by formulation and implementation of national health policies based on the concepts of Primary Health Care as outlined in the Alma Ata Declaration on Primary Health Care as the key to Health for All. Sri Lanka, along with other Member States of the World Health Organisation, adopted the Alma Ata Declaration at the International Conference on Primary Health Care in September 1978. This conference

reaffirmed that health was a fundamental human right. The WHO member states, including Sri Lanka, gave a solemn promise to the world community that they would introduce national health policies based on Primary Health Care in their respective countries.

- The constraints faced by the government due to the limits of available resources is acknowledged. However, there are minimum core obligations of the government. These include at least the following:
  - a. Ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups;
  - b. Ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;
  - c. Ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
  - d. Provide essential drugs as, from time to time, defined under the WHO Action Programme on Essential Drugs;
  - e. Ensure equitable distribution of all health facilities, goods and services;
  - f. Adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored and evaluated; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalised groups.
  - g. Ensure reproductive, maternal and child healthcare.
  - h. Provide immunisations against the major infectious diseases occurring in the community.
  - i. Take measures to prevent, treat and control epidemic and endemic diseases.
  - j. Provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them.
  - k. Provide appropriate training for health personnel including education on health and human rights.

Finally, the obligation of the State to fulfill the various requirements for the Right to Health of all obliges the State to enshrine the Right to Health in the constitution and adopt appropriate legislative, administrative, budgetary and judicial measures towards the full realisation of the right to health.

## **GUIDELINES FOR IMPLEMENTING THE SRI LANKAN PEOPLES' HEALTH CHARTER**

The dissemination and application of the contents of this Charter will have to be carried at national, regional and local levels.

## **INFORMATION AND EDUCATION**

As a means of informing and educating the public and healthcare workers this charter may be promoted in all health institutions, mass media, in universities, schools and other appropriate public places.

## **SUPPORT**

Support for and subscription to the Charter need to be gathered from the Ministry of Health, healthcare workers and civil society organisations. The special commitments of those health services and professionals that subscribe to the Charter should be defined.

## **DIALOGUE**

It will be important to initiate a dialogue among the various stake-holders on the basis of the contents of the Charter in order to work out policies, programmes and action plans for the protection of and promotion of people's health. Such a dialogue will take place among governmental authorities, public and private sector institutions involved in healthcare, professional associations of doctors, dentists, nurses, pharmacists, trade unions of healthcare workers and civil society organisations.

## **LEGISLATION**

The Charter may be incorporated into national laws and regulations in full or in part to make the goal of protecting promoting peoples' health an ordinary part of public policies.



# TRADITIONAL MEDICINES

*Executive summary of a paper presented at the Regional Seminar on Traditional Medicine, Universiti Sains Malaysia, Penang, Malaysia, 18<sup>th</sup> April 2004*

In low and middle income countries up to 80 per cent of the population rely on TM for their Primary Health Care needs. (Source: WHO/EDM/TRM/2002). For these millions, traditional medicines are the only affordable source of Primary Health Care. Studies indicate that there are many more traditional medicine providers available than providers of allopathic care, especially in the rural areas. Traditional medicines are highly popular in many developing countries because of their firm embedment within the wider belief systems. (HAIAP Traditional Medicines position paper).

In Asia, there are formalised traditions/systems of traditional medicine, which have

- A theoretical framework.
- An established tradition of training, formalised educational process.
- A recorded materia medica with many preparations.
- A clinical practice with a range of preventative and therapeutic modalities.

Some of the existing traditional medicine systems in the region include Traditional Chinese Medicine, Ayurvedic Medicine, Unani, Siddha and Mixed systems: Tibetan medicine, Thai, Korean and Malaysian.

*Traditional Chinese medicine* is fully integrated into China's health system, being under the administration of State Administration of TCM and Pharmacology. 95 per cent of Chinese hospitals have units for traditional medicine. It takes seven years of university education to acquire a Doctoral degree in TCM, which accounts for

- Annual production over 400,000 tons in more than 5,000 varieties.
- 30-50 per cent of total consumption.
- 800 manufacturers of herbal products.
- A total annual output of US\$ 1.8 billion.
- 13,000 farms which grow the required plants.

*In Vietnam*, traditional and oriental medicines are fully integrated into the country's health system. 30 per cent of patients receive treatment with traditional medicine. Vietnam National Association of Acupuncture has 18,000 members, 4,500 of whom work in public hospitals.

*In Thailand*, the National Institute of Traditional Medicine was established in 1993. Thai traditional medicine was integrated into the facilities of 1120 health centres in 1999.

*In India*, the Department of Indian Systems of Medicine was established in 1995. There are more than 200,000 registered traditional medical practitioners in India. 2860 Indian hospitals provide traditional Indian medicine. Over a hundred colleges provide Ayurvedic education. Ayurveda, Siddha and Unani systems of medicine have coexisted with yoga, naturopathy and homeopathy for centuries.

*In Malaysia*, a coordinated approach to integration based on self regulation by complementary professions, establishment of a Council comprising five umbrella organisations (2000) representing Malay, Chinese, and Indian traditional health systems, complementary therapies, and homoeopathy.

*In Indonesia*, 40 per cent of Indonesia's population uses traditional medicine; 70 per cent in rural areas 750 manufacturers of traditional medicines, 92 of which are large scale industries.

# HERBAL MEDICINES

*Paper presented at Second International Workshop on Herbal Medicines in the Caribbean, 14-16 June 1999, St. Croix US, Virgin Island. The paper was presented in two parts: (i) Holistic Approach, and (ii) People's Guide to Herbal/Traditional Medicines and Medicinal Plants*

## (I) HOLISTIC APPROACH

Herbal medicine is as old as humankind and as contemporary as the latest discovery in biomedical science. A wide spectrum of sectors, issues and activities are encompassed within herbal medicine together with a number of stakeholders including several intergovernmental and international agencies.

A holistic approach to herbal medicine needs to take into consideration and examine the various sectors, issues and activities and the needs and concerns of the different stakeholders. Quite often each stakeholder group examines its particular sector in isolation ignoring the ultimate objectives. Consumers, on the other hand, are concerned with each and every sector, issue and activity in this long and complex chain.

The ultimate objectives of the consumer include the following:

- Ensuring the availability, accessibility and affordability of safe and effective herbal medicines of good quality to all those who need them now and in the long term future;
- Regulating the manufacture, promotion, sales and use of herbal medicines to ensure the safety of consumers;
- Defining the place of herbal medicine in Primary Health Care;
- Searching for new medicines among the many medicinal plants that are yet untapped;
- Looking for, protecting and preserving endangered plant species;
- Conserving biological diversity; and
- Searching, protecting and preserving indigenous cultures, which are the repositories of the knowledge of medicinal plants.

It is indeed a paradox that in an era of molecular biology, genetic engineering, biotechnology, computerised drug design and an annual global pharmaceutical market of over \$300 billion, herbal medicines serve the healthcare needs of 80 per cent of the world's population, or over four billion people.

There is evidence that consumers in developed countries are becoming disillusioned with modern healthcare and are seeking alternatives. Consumer demand for herbal medicines is, therefore, increasing in these developed countries.

The multinational drug industry in the North is showing renewed and heightened interest in the South's medicinal plants. Over 200 firms are screening plants for medicinal properties.

However, in both developing and developed countries, there are no integrated national policies on herbal medicines to facilitate drug administrators to regulate the manufacture, trade, promotion, sales and use of herbal medicines.

There is an urgent need for national policies on herbal medicines with regulatory control to regulate the herbal medicine market.

The lethal combination of increased consumer demand, the renewed industry interest in bioprospecting and the lack of national legislation or effective international agreements on conservation of biodiversity has resulted in 'slaughter harvesting' of medicinal plants and massive depletion of biodiversity.

Tropical rain forests are the home to 70 per cent of the million or so species of higher plants that are believed to inhabit the earth. Less than one per cent of the tropical rain forest species has been examined. Of the total plant material utilised in the preparation of traditional medicine, about 90 per cent are collected from the tropical forest.

Indigenous cultures living close to these plants use thousands of them in their medical practice. Many of these have not even been named, let alone studied. Indigenous people know much more about the properties of these plants than modern scientists. This knowledge is community-owned intellectual property but there is evidence that this knowledge is pirated by the multinational drug industry and patented as private intellectual property.

High degrees of forest cover are extremely important for the preservation of diverse species of medicinal plants. Tropical rain forests are declining at an alarming rate of 16.8 hectares per year. Since 1970 tropical forests have declined from 4.4 sq. mile per 1000 people to 2.8. In the US 2400 acres of native habitat is lost everyday.

The destruction of tropical rain forest threatens not only countless species of valuable medicinal plants but also the indigenous cultures and individuals who know and depend upon these plants every day of their lives. What we are witnessing today makes the burning of the library in Alexandria look insignificant by comparison. It is as if the greatest medical library in the world is burning faster than we can read its contents, which we have just begun to catalogue.

Several intergovernmental and international agencies have been sounding alarm bells over the last two decades to raise global awareness on the enormous extent of loss of biological diversity and threatened extinction of tens of thousands of valuable medicinal plants. Health professionals have raised serious concerns on the lack of regulatory control of herbal medicines, nutraceuticals and dietary supplements that are promoted as drugs, and abuse of herbal remedies.

The alarms, concerns and fears were based on critical analysis of enormous empirical data. Remedial measures were carefully considered and rationally presented in the form of comprehensive conclusions and recommendations.

The commitments made at international summits have proved to be mere lip service. There is no evidence that any of the recommendations have been implemented. The dramatic pleas and recommendations were made to appreciative but docile audiences - scientists, research workers and international civil servants. These people are no match for the vested interests who are depleting genetic resources, threatening several plant species and heavily promoting thousands of ineffective phyto-pharmaceuticals, nutraceuticals and dietary supplements directly to the consumer. Sales of these “natural products” are skyrocketing.

The inability of the international initiatives to bring about appropriate changes in public policies and national legislation is due to their failure to inform and educate the voting public and thereby mobilising their support for campaigning and lobbying for changes in public policies. The history of humankind clearly illustrates that changes in public policy are possible only through mass movements when the entire general (voting) public is sincerely convinced of the urgent need to bring about appropriate changes.

## **(II) PEOPLES' GUIDE TO HERBAL/TRADITIONAL MEDICINES AND MEDICINAL PLANTS**

### **SITUATION ANALYSIS**

- Health is a basic and fundamental human right. It is not a commodity in the market place.
- In spite of the spectacular advances in modern medicine including genetic engineering, biotechnology, organ transplant, designer drugs, etc, the World Health Organisation, since 1978 has repeatedly stated that 80 per cent of the world's population or over four billion people depend on traditional systems of healthcare.
- Medicinal plant lore or herbal medicine is a major component of traditional systems of healthcare. Medicinal plants are of vital importance in healthcare.
- Medicinal plants are essential in Primary Health Care both in self-medication and in the National Health Service.
- There is increasing consumer demand for herbal medicines in developing and developed countries.
- Medicinal plants are a valuable global resource increasingly threatened by loss of habitat and over-exploitation. Increasing consumer demand aggravates the threat.
- Indigenous knowledge about plants and their properties is intellectual property. There is evidence that this community-owned knowledge is being pirated by multinational pharmaceutical industry and patented as privately owned intellectual property.
- There is a sprawling, unmonitored, unregulated and expanding trade in medicinal plants.
- There is a loss of biological diversity around the world. Many of the plants that provide traditional and modern drugs are threatened with extinction. This will have a major negative impact on the health of over four billion people.

- The conflagration of the tropical rain forest threaten not only the countless species of valuable medicinal plants, but also the cultures and individuals who know their properties and use them in their daily lives.
- Conservation of medicinal plants currently lacks priority in public policies and national legislation.
- There are three aspects that are of critical importance to ensure the success of herbal medicines now and in the future:
  - Safety, efficacy and quality of herbal medicines
  - Knowledge of medicinal plants;
  - Continued availability of medicinal plants

#### **GUIDELINES TO POLICY AND ACTION**

- National governments should encourage discussions among traditional healers, health professionals and the general public to formulate and develop public policies including regulations, which address the utilisation of traditional medicine in Primary Health Care.
- International organisations, governments, NGOs, manufacturers and traditional healers need to develop ethical criteria for the promotion of traditional medicine and herbal remedies.
- International organisations, governments, traditional healers should examine the concept of a selection of a limited list of useful medicinal plants and a formulary of over the counter phyto-pharmaceuticals for Primary Health Care.
- Appropriate methods for the clinical evaluation of traditional and herbal remedies should be developed. These methods and criteria should not be limited to methods and concepts of modern biomedical science.
- Academic and research institutions, traditional healers, NGOs and community organisations should be supported by national governments to raise public awareness of the benefits and risks of traditional medicine and herbal remedies.
- Academic and research institutes, traditional healers, NGOs and community organisations should develop criteria for the establishment of a priority list of existing herbal medicines for research and development.
- Academic and research institutes and traditional healers should consider the development of national pharmacopeial monographs on selected medicinal plants.
- There is an urgent need for international co-operation and coordination to provide assistance to developing countries to establish programmes for the conservation of biodiversity so that adequate quantities of medicinal plants are available for future generations.
- Collection of non-cultivated medicinal plants from the wild should be encouraged only if the supply can be maintained and ecosystem damage does not result.
- International organisations, national governments, traditional healers, manufacturers and traders should develop international norms and agreements to monitor, regulate and control international trade in medicinal plants.
- Countries importing medicinal plants should have adequate facilities to ensure that supplies originate from sources that are biologically and socially sustainable.

- Knowledge of medicinal plants resides in communities rather than individuals. This knowledge is intellectual property. There is no provision in the TRIPS Agreement to confer rights and ownership of intellectual property to communities by awarding patents. An alternative suggested is that in these instances intellectual property rights could be awarded as Traditional Resource Rights and recognised as such in national laws and international agreements. This will help developing countries to prevent the indigenous and community knowledge of medicinal plants from being pirated by the uncontrolled profit making interests of multinational drug companies.
- International agencies, national governments, academic/research institutes, NGOs, manufacturers and traders need to give priority in implementing the proposed codes of ethics in international trade and conservation guidelines for medicinal plants contained in various international agreements such as the Convention on Biological Diversity, Convention on International Trade of Endangered Species, the Declaration of Chiang Mai, Declaration of Belem, etc.
- The International agreements provide the mandate for national governments to enact appropriate policies and regulations for conservation, cultivation, processing and marketing of medicinal plants and to monitor the implementation of international agreements.
- These national instruments should be designed as a possible bridge linking together sustainable economic development, affordable healthcare and conservation of vital biological diversity.

*Source: "Herbal Medicines: An Evidence Based Look", Therapeutics letter, Issue 25, June-July\998. [Http://www.ti.ubc.ca/pages/letter25. btm](http://www.ti.ubc.ca/pages/letter25.htm)*



## HERBAL REMEDIES: CONSUMER PROTECTION CONCERNS

*Paper presented at the International Symposium on Herbal Medicines,  
1-4 June 1997, Honolulu, Hawaii.*

“**M**aintains Healthy Cholesterol: Reduces Total Cholesterol, Reduces LDL ‘Bad’ Cholesterol, Reduces Triglycerides and Increases HDL ‘Good’ Cholesterol.”

“Suitable for migraine, weak heart, hernia, menstrual pain, kidney stones, rheumatism, sexual stress, impotence, frost-bite, internal and external cancer and infection.”

The first claim appears on the label of Cholestin, a recently launched cholesterol lowering natural ‘dietary supplement’ in USA. The second is an advertisement for ‘Tea of Longevity’, a herbal tea, which appeared in a daily newspaper in Malaysia in 1995. A 150 mg pack of this herbal tea costs between 160-240 Malaysian Ringgits. This is equivalent to about 10 days wages of an unskilled worker in Malaysia.

These health claims have not been approved by the drug regulatory agencies in either country. They are addressed directly to the consumer and reflect the major concerns consumers have on the way herbal remedies are marketed. The extent of consumer concern is also evident from the fact that since 1990 the US Congress has received more mail on the regulation of herbal remedies than any other issues including Bosnia, the Gulf War, Somalia, gun control, tax reform and healthcare reform!

This paper describes the legal control, patterns of utilisation, and consumers’ perceptions of herbal remedies in selected countries. Based on the analysis of the empirical data obtained, some recommendations for assuring the safety, efficacy and quality of herbal remedies are suggested.

There is now documented evidence that people in both developed and developing countries are purchasing and consuming herbal remedies in increasing amounts. There is also evidence that some of the herbal remedies in the market are not safe, effective and of good quality.

To examine, study and analyse the utilisation of herbal remedies in developed and developing countries, it will be useful to classify herbal remedies into the following three categories:

- i. Phytomedicines sold as over-the-counter (OTC) products in modern dosage forms;
- ii. Dietary supplements, containing herbal products, in modern dosage forms;

- iii. Traditional medicine, consisting of crude, semi-processed or processed medicinal plants and herbs.

Consumers in developed countries and those in the urban areas of developing countries use phytomedicines and dietary supplements.

Traditional medicine, according to the World Health Organisation (WHO) is believed to serve the health needs of about 80 per cent of the world's population. It is relevant to note that in the US, because of the difficulty of approving herbs as OTC drugs and the limitations placed on health claims for dietary supplements, particularly for herbs, there is a suggestion to create a third category - traditional medicines.

In both developed and developing countries, there are no comprehensive integrated national policies on herbal remedies which will facilitate drug regulators and health administrators to regulate the market and ensure that all herbal remedies in the market are safe, effective, of good quality, of reasonable cost and are used rationally. A major recommendation follows from this conclusion - the need to recommend guidelines for developing national policies on herbal remedies. These guidelines can serve as a model to enable individual countries to develop their own national policies on traditional medicines and herbal remedies including appropriate legislation to provide legal support for the national policy to regulate the market.

The proposed guidelines should take into consideration the various consumer protection concerns identified in this paper so that appropriate components can be formulated to take care of these concerns.

1. A model legislation on traditional medicines needs to be developed. At present there seems to be as many approaches to regulating herbal remedies, as there are countries. Some countries such as Australia and Germany have useful components in their legislations that may be incorporated into the proposed recommendations. In Japan, Chinese-Medicine Manufacturers have developed voluntarily "Regulations for Manufacturing Control & Quality Control of Ethical Extract Products in Kampomedicine (Oriental Medicine) Formulations", a useful model for developing Good Manufacturing Practices (GMP) for traditional medicines.
2. It will be useful to have universally acceptable definitions for the various terms used such as herbs, botanicals, medicinal plants, herbal remedies, phytomedicines, dietary supplements, traditional medicines. In this context it is relevant to note the definition of a 'therapeutic good' in the Australian law which states "Any product that is likely to be thought to be a therapeutic good for any reason, most often because of advertising, dosage form or appearance."
3. Consumers are confused over tens of thousands of herbal remedies in the market. It will not be possible to formulate a national policy to regulate all of them. Consumers want this symposium to debate the concept of a limited number of useful herbal remedies and traditional medicines. This could be at two levels:
  - Limited number of useful medicinal plants and herbs for use at the household level.
  - Limited number of phytomedicines and traditional medicines and
  - Development of a formulary of phytomedicines.
4. Herbs, which are in fact drugs, are regulated and sold as foods in several countries. Consumers are concerned that herbal products regulated as dietary supplements

will not provide an adequate level of safety. Consumers ask for a pre-market safety review for plant derived products marketed as food supplements and compulsory post-marketing surveillance.

5. At present FDA can intervene only if there is evidence of injury to consumers by dietary supplements. Consumers demand legislation that can proactively regulate for safety but will never accept a legislation that provides for reactive safety regulation after evidence of injury has been proved.
6. There is no monitoring and control over advertising and promotion of herbal remedies in almost all countries. In some countries, the regulation applies to media advertising and health claims on packages but no control over the promotional practices of medical representatives when they visit health professionals. Consumers ask for the development of an Ethical Criteria for Promotion of Herbal Remedies, which must include promotional practices of medical detail men and direct selling of health products to consumers.
7. Modern pharmacies stock herbal remedies and pharmacists are expected to help consumers make appropriate product selection. However, at present there are no authoritative sources from where pharmacists can obtain relevant information on herbal remedies to advise consumers and other health professionals. Consumers request this symposium to examine how best to provide this information to pharmacists.
8. There is uncontrolled cross-practice. This means that practitioners not trained in a particular system prescribe and dispense drugs belonging to that system indiscriminately. This should be prevented by appropriate legislation.
9. Consumers propose that there should be self-regulation by appropriate professional bodies as well as state legislative control on the training, certification and registration of traditional healers and practitioners.
10. There is insufficient data on the per capita consumption of traditional medicines in developing countries. Estimates are available for Malaysia and the Republic of Korea. In Malaysia the per capita consumption of traditional medicines is more than double that of modern pharmaceuticals although traditional healers are not recognised in Malaysia and there is no formal system of traditional healthcare. In the Republic of Korea, the per capita consumption of traditional medicines is about 36 per cent more than that of modern drugs.  
Consumers consider that it will be important to carry out a cost/benefit analysis of herbal remedies and traditional medicine in a selected number of countries and make it available to consumers and health administrators.
11. Consumers in both developed and developing countries use both modern and traditional medicines simultaneously. But they do not provide this information to the prescriber or dispenser. There is a potential risk of adverse drug interactions. Increasing public awareness of the benefits and risks associated with the use of traditional medicines should be built into the components of a national policy on traditional medicines and herbal remedies.
12. There should be a structure and mechanism in place for an international alert system for rapid sharing of information on toxicity and adverse reactions to herbal products among drug regulators.

# G8, GLOBALISATION AND GLOBAL POVERTY

*A discussion document prepared for the People's Health Movement,  
May 2003*

## INTRODUCTION

In the beginning globalisation made the African continent borderless to promote international trade in humans. The perpetrators were G3, the predecessors of G8. England, Portugal and Spain, using their military might and diplomacy, employed Africans to capture fellow Africans and transported them across the Atlantic Ocean to the New World. Slavery and slave trade, blessed by the church was institutionalised by the governments of these three countries. The slaves in the colonies lived in abject poverty, which was handed down from generation to generation; two centuries later pockets of poverty yet exist in the richest country in the world. Statistics reveal that a black male born in Washington DC has a shorter life expectancy than a male born in Ghana, Bangladesh or Bolivia. Nearly one in five Americans or 56 million people is considered clinically obese, meanwhile 31 million Americans, including one in six children face chronic hunger in any given year.

As the world became more "civilised", and slavery became a dirty word, it had to be officially abolished. The industrial revolution in Western Europe set in motion the next phase of globalisation. Colonisation replaced slavery. France and the Netherlands joined the original G3, sending their armies and navies with guns to capture countries in Africa and Asia. The colonialists took control of land, raw material, cheap labour and markets. They controlled international trade, with Britain accounting for 40 per cent of the world trade in the late 19th and early 20th century. Britain was then the super-power.

There was a sea change in international relations soon after the end of the Second World War in 1945. Colonisation and imperialism became dirty words. Beginning with India in 1947, the imperialists were chased away from the colonies in Asia and Africa.

## NEOCOLONIALISM

The United Nations, the World Bank, the International Monetary Fund and the General Agreement on Tariffs and Trade were some of the intergovernmental institutions set

up in the late 1940s to bring about peace and prosperity to the whole world, particularly the previous colonies in Asia-Pacific, Africa and Latin America, which were designated developing countries.

But today there is neither world order, nor peace nor prosperity because neocolonialism has replaced colonialism. The very institutions set up to bring about peace and prosperity are being used by the rich nations, led by G8, to implement neocolonialism.

What is common among slavery, colonialism and neocolonialism? The commonality is that a minority using its military, its economic strength and its power, control access to resources. The wealth and income generated by these resources are, therefore, very unevenly distributed. About 20 per cent of the world's population living in OECD countries today controls approximately 80 per cent of the resources and wealth of the world.

The strategies used by the neocolonialists, headed by G8, are globalisation and multilateral trade agreements. Intergovernmental policy making in today's globalised economy is in the hands of the G8 - the seven richest industrial countries (G7) and Russia - and the three institutions they control - WB, IMF and WTO (GATT's new name since 1995). The rules and regulations of these institutions create a very secure environment for selective open markets but an adverse environment for social and human development in the developing countries. The central banks in these rich countries still guide the supervision of the global banking system.

## **G8 AND POVERTY**

Throughout the history of humankind, there has been only one basic cause of poverty, the lack of access to and control of resources. The wealth and income generated by these resources are, therefore, unequally distributed.

Globalisation is not new. It has been there for two centuries; since the 1950s it has gathered speed and went into an accelerated spin in the 1980s when Thatcher - Reagan axis took over the lead role in the international agencies. An analysis of long-term trends in the disparities that separate the rich from the poor demonstrates this. The ratio of the incomes of the rich and poor countries was about 3:1 in 1820, 11:1 in 1913, 35:1 in 1950, 44:1 in 1973 and 72:1 in 1992. Wealth today is concentrated in fewer and fewer hands. According to the *Human Development Report 2002*, the world's richest one per cent receive as much income as the poorest 57 per cent. The income of the world's richest five per cent is 114 times that of the poorest five per cent.

Globalisation and multilateral trade agreements have therefore enabled the G8 to keep the wealth in the developed countries, leaving 1.3 billion people in developing countries to live on less than one dollar a day. Another 1.7 billion live on less than two dollars a day. Across the world about 56 per cent of the population lives below two dollars a day. In some rural areas of Sub-Saharan Africa and South Asia the proportion reaches 75 per cent and 84 per cent respectively.

It is indeed ironical that G8, which is the cause of global poverty, has taken upon itself the task of eradicating poverty. This is similar to landlords being given the task of implementing land reforms and distributing their lands to the landless! It is therefore, not surprising that poverty eradication has gone on reverse gear!

The United Nations has classified the very poorest and structurally weakest countries, as “Least Developed Countries” (LDCs). Their numbers have risen from 21 in 1971 to 49 in April 2000; this means a total population of 620 million lives in LDCs. One country a year has been joining the ranks of LDCs. Poverty eradication gone on reverse gear!

At their summit in Cologne in 1999, the G8 committed to halve world poverty and reduce child mortality by two-thirds by 2015. Since then, at their annual summits, G8 leaders constantly stress their commitment to poverty reduction. But in reality, they use their trade policy to rob the world’s poor. Poverty escalates.

International trade is not inherently opposed to the needs and interests of the poor nations. But the rules that govern international trade as designed by G8, inflict enormous suffering on the world’s poor. Rich countries reserve their most restrictive trade barriers for the world’s poor.

When desperately poor farmers and exploited female garment workers enter the world market, they face import barriers four times as high as those faced by producers in rich countries. These barriers imposed by the rich countries cost developing countries \$100 billion a year. This is twice as much as the poor countries receive as aid from the rich. When rich countries lock poor countries out of their markets, they close one of the entry points to break the vicious cycle of poverty.

If Africa, East Asia, South Asia and Latin America were each to increase their share of world export by just one per cent, the resulting income could lift 128 million people out of poverty. The low and unstable commodity prices that consign millions into poverty are never an issue at the summit meetings of G8. The terms of trade and prices of primary commodities are decided by multinational corporations.

Exporters of primary commodities have seen their share of international trade shrink with Sub-Saharan Africa worst hit with very low prices. Deteriorating terms of trade in Sub-Saharan Africa since the late 1970’s have cost the region the equivalent of 50 cents for every dollar that it receives in aid. While the rich country markets are closed to the poor, the WB and IMF pressurise poor nations to open their markets at break-neck speed with very damaging consequences. Powerful multinational corporations are free to engage in investment and employment practices that contribute to poverty and insecurity.

## **POVERTY, DEBT AND DEVELOPMENT**

In the 1970s the UN agencies, particularly UNCTAD started discussions on a New Economic World in order to promote economic, commercial and technological development of Third World countries. Initiatives included the preparation of a Code of Conduct for Multinational Corporations, a Report on Restrictive Business Practices and Revision of the Paris Convention on Intellectual Property Rights.

All these were put on hold and reversed with the emergence of Thatcher-Reagan axis taking over the international agencies. New development experiments in the 1980s with ill-conceived economic policies pursued by the WB and the IMF in relation to developing countries not only failed to bring about economic growth and improvements in living standards for the majority of people in developing countries, but these policies have also been responsible for the Third World debt crises.

In 1997 the total debt stock owed by the developing world to the developed world was USD 2.17 trillion, up from USD 1.4 trillion in 1990.

Each day developing countries pay rich nations USD 717 million in debt service. Every baby born in the developing world carries an external debt of USD 482 at birth. Jubilee 2000, a coalition of NGOs campaigning for Third World debt cancellation, estimated that every five seconds a child dies in the Third world because of external debt. In 1993, the rich nations took back £ 3 in debt repayments for every £1 they gave in economic aid to poor nations.

## **PROTESTS AT G8 MEETING**

Millions of children are dying every year in developing countries because of debt, and many more are growing up unable to read and write as government budgets for health and education are cut to enable these countries repay debt. Niger, one of the poorest countries in the world, spends three times more on debt repayment than on health and education. The economic policies of WB and IMF, and the WTO rules on intellectual property rights, investment and services, protect the interests of the G8 and powerful multinational corporations while imposing enormous costs to developing countries and pushing more into poverty and life long suffering as shown by the empirical data given in this paper.

And yet the G8 nations naively ask why there are protests at their summit meetings. The same way the British imperialists asked why the Indians were protesting against the Raj. The civil disobedience movement was initiated by Mahatma Gandhi at the national level to gain independence for India. The protests at G8 meetings are very similar to the Indian civil disobedience movement at the global level.

The objective of the peaceful protest include the following:

1. Hold a mirror to G8 leaders to let them and the world know the enormous injustice inflicted on poor developing countries in the name of globalisation and free trade.
2. Campaign for a New World Economic Order which will guarantee distributive justice so that:
  - (a) Economic growth will ensure social and human development.
  - (b) There will be equity in access to and control of resources leading to equitable distribution of wealth and income generated by the resources
3. Let the people of the world know that the existing institutions are inadequate to meet the aspirations of all the people of the world.

An essential aspect of global governance is transparency, accountability and responsibility to people - to equity and social justice. These are missing in the existing systems of institutions, rules and practices.

Social protection to be built into the New World Economic Order will need altogether new global governance that will ensure global responsibility. The *Human Development Report 1999*, had identified some of the key institutions of global governance to put human development and social protection at the centre of international policy and action, which included a stronger and more coherent UN with representation from civil society, a global central bank which would be a last-resort lending agency also, a WTO more inclined towards fair trade than towards free trade, a world environment agency, a world investment trust to ensure more equity in distribution, and an international criminal court with a special focus on human rights.



It goes without saying that these rights should include health rights and food rights of the people of the world.

These are the messages that PHM protesters at the G8 meeting in June in Evian, France will convey to the World Community.

Further readings include:

1. Human Development Reports 1997, 1999, 2000, 2001 and 2002
2. World Development Forum - On line discussion article - "Third World Debt Crisis)  
([http://www.derby.ac.uk/seas/geog/jollyfranc/third\\_world\\_debt.htm](http://www.derby.ac.uk/seas/geog/jollyfranc/third_world_debt.htm))
3. Passanna Gunasekera and Dr. K. Balasubramaniam "Why do the poor stay poor?"  
*HAI News* No 124, Jan-March 2003.

# STRUCTURAL ADJUSTMENT PROGRAMMES, GLOBALISATION, ECONOMIC GROWTH AND HUMAN DEVELOPMENT

*Executive summary of paper presented at the Workshop on Media and Public Health, 17-21 June 1998, Panchgani, Mahavastra*

The genesis of the debt crisis can be attributed to the irresponsible lending by multinational banks in the North to developing countries for grandiose industrial and agricultural schemes. These failed, and debtor countries were unable to honour their repayment schedules. The creditor banks were in danger. The World Bank (WB) and the International Monetary Fund (IMF) went to rescue the banks by offering loans to the debtor countries. But there was a condition. These countries had to introduce extreme austerity measures by agreeing to implement Structural Adjustment Programmes (SAPs). SAPs had extremely adverse impacts on the health and economies of the debtor countries, as evidence from African and Latin American countries shows. Economic growth stagnated or declined.

Over a period of 15 years in a few years, SAPs wiped out the gains painstakingly achieved in the health sector by several African countries. Infants and young children paid the heaviest price. Millions of children died. Communicable diseases that had been controlled, reappeared in outbreaks as immunisation programmes were cancelled.

In spite of the obvious failure of globalisation, liberalisation and deregulation, the WB and IMF are forcing all developing countries to adopt SAPs.



*Dr Olle Hansson (middle) with a radio interviewer, Gothenburg 1984*



*During the Medical Education workshop organised by ARDA and the Council for Primary Health Care in the HAIN office Philippines Gerry Andamo, Dr Edelina P de la Paz, Dr Mira Shiva and Emily Guerrero*



*Participants who attended the Regional Seminars on Healthcare Financing and Traditional Medicine organized by HAIAP pose for a photograph at the University Sains Malaysia, Penang, Malaysia in 2003*



*Dr Prem Chandran Jobn, Chairperson of the Governing Council of HAI Asia-Pacific speaking at the inaugural session at the Regional Seminar on "The future of health services: who will live and who will die" in April 2006 in Savar, Bangladesh*



*Andrew Chetley, Catherine Hodgkin and Dr Mira Shiva engage in a Role Play during a HAI workshop, John Knox, Geneva, Switzerland, 1991*



*Dr Olle Hansson making lunch for Mira Shiva, Gothenburg 1984*





*Dr Mira Shiva, Foo Gaik Sim, Josie Fernandez, Dr Ivan Wolffers and others in Pennag, Malaysia*



*Dr Zafrullah Chowdbury, Dr Mira Shiva, Dr Ken Harvey and others inside Dr Senaka Bibile's room at the University of Colombo, Sri Lanka during the National Drug Policy Consultation in 1991*

# **A DRAFT PROPOSAL FOR AN INTERNATIONAL CODE ON PHARMACEUTICALS - HEALTH ACTION INTERNATIONAL (HAI)**

**Discussion Document (1982)**

**T**his draft International Code, intended for further discussion and amendment in the light of comments from experts worldwide, was presented in 1982 by Dato Anwar Fazal on behalf of HAI to the UNCTAD Committee on the Transfer of Technology.. The scope of the proposed code is such that its adoption will require the expertise of various UN agencies, most importantly WHO and UNCTAD.

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- Article 7 Information
- Article 8 Labelling, package inserts and promotional material
- Article 9 Sales promotion of pharmaceutical products
- Article 10 Pricing, sales and distribution
- Article 11 Pharmaceutical technology
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- Article 13 Implementation and monitoring
- Article 14 Review procedure

## **PREAMBLE**

The participating countries:

1. Reaffirming that good health is a fundamental human right;



2. Recognising that governments have a responsibility for ensuring the health of their people;
3. Recalling that a main social target of governments, international organisations and the whole world community in the coming decades should be the attainment by all the peoples of the world by the year 2000, of a level of health that will permit them to lead a socially and economically productive life;
4. Convinced that the promotion and protection of the health of the people is essential to sustained economic and social development;
5. Drawing attention to the fact that provision of an adequate supply at reasonable cost of essential drugs, among other things, is a prerequisite for the promotion and protection of the health of the people;
6. Aware that a majority of the world population, particularly those in the rural areas and urban slums of developing countries, does not have regular access to even a few essential drugs necessary for Primary Health Care whilst the drug bills in these countries may account for up to 40-50 per cent of the total health expenditure;
7. Affirming the right of every sick person to have access to essential pharmaceuticals;
8. Considering that a limited number of Transnational Corporations based in developed countries manufacture almost 90 per cent of the world output of pharmaceuticals and control drug technology and world trade and that the existing system of marketing practices of these corporations is inappropriate to meeting the health needs of the people, particularly in developing countries;
9. Bearing in mind that in a number of instances the prices of pharmaceuticals do not relate to the actual cost of manufacture but are determined by what the market can bear;
10. Drawing attention to the fact that there are wide discrepancies in the prices of drugs on the world market which cannot be explained by market forces;
11. Recognising that the pharmaceutical industry is characterised by an unusual degree of market power;
12. Recalling that the Non-Aligned and other developing countries have expressed an urgent desire to reform the existing system for the procurement and provision of pharmaceuticals;
13. Taking into consideration that a large number of developing countries have already established local manufacture of pharmaceuticals and are purchasing pharmaceutical technology on the world market and that some of them are forced to pay exorbitant amounts of foreign exchange for their technology imports;
14. Convinced that the development and strengthening of indigenous technological capacity in the pharmaceutical sector is critically dependent on ongoing research and development activities and that a research base in developing countries is necessary to insure against underdevelopment;
15. Believing that certain fundamental principles associated with trade and technology in the pharmaceutical sector transcend national and regional boundaries and are universally applicable;
16. Recognising that the indispensable role of pharmaceuticals in the control of disease and the prevention of human suffering distinguishes them from other consumer goods which are subject to the laws of supply and demand;

17. Believing that, in the light of the foregoing considerations, an International Code of Pharmaceutical Marketing Practices, including norms on promotion, pricing, sales, distribution, trade, technology, research and development, in the pharmaceutical sector would, under mutually agreed and advantageous terms to all parties, enable all participating countries, particularly developing countries to provide to all their people, safe and effective essential drugs at prices they can afford;
18. Agree on the adoption of the following International Code of Pharmaceuticals Marketing Practices.

#### **ARTICLE 1: AIM OF THE CODE**

The aim of this code is to enable consumers, particularly those from the developing countries, to procure safe and effective pharmaceuticals essential to their real health needs, at costs they can afford.

#### **ARTICLE. 2: SCOPE OF THE CODE**

- 2.1 This Code shall apply to all international activities connected with the procurement of pharmaceuticals and pharmaceutical technology.
- 2.2 The Code applies to the following activities associated with the pharmaceutical sector:
  - drug registration
  - registration of new drugs
  - pre-registration clinical trials of new drugs
  - provision of information
  - labelling, package inserts and promotional material
  - sales promotion of pharmaceutical products
  - pricing, sales and distribution - pharmaceutical technology - research and development.

#### **ARTICLE 3: DEFINITIONS**

- 3.1 'Active substance': that portion of a drug product intended to produce a therapeutic effect.
- 3.2 'Adverse reaction': a reaction to a drug which is noxious or unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.
- 3.3 'Advertisement': any representation conveyed by any means whatever for the purpose of promoting directly, or indirectly, the distribution or sale of any drug.
- 3.4 'Auxiliary pharmaceutical substance': a substance added to the active substance to give the latter suitable consistency, so that a convenient dosage form can be formulated.
- 3.5 'Benefit/risk ratio': the ratio of benefit to risk in the use of a drug: a means of expressing a judgement concerning the role of the drug in the practice of medicine, based on *efficacy* and safety data along with consideration of misuse potential, severity and prognosis of the disease etc. The concept may be applied to a single drug or in comparing two or more drugs used for the same indication.

- 3.6 'Clinical trial': a procedure for comparing the relative advantages and disadvantages of one drug with another by administering them according to a planned protocol to a group of patients under controlled conditions.
- 3.7 'Contra-indications': conditions which make the administration of a drug positively harmful. These conditions include diseases, physiological states (e.g. pregnancy, lactation, specific groups (neonates, infants) etc.
- 3.8 'Drug' (synonymous with 'pharmaceutical product'): any substance or mixture of substances that is manufactured, sold, offered for sale or represented for use in (i) the treatment or diagnosis of disease, an abnormal physical state or the symptoms thereof in humans, or (ii) the restoration, correction or modification of organic functions in humans.
- 3.9 'Drug registration': the term used for the procedure of release, compliance or approval for marketing after a drug evaluation (by a competent health authority).
- 3.10 'Efficacy': the ability of a drug to produce the purported effect as determined by scientific methods.
- 3.11 'Ethical drug': a drug that can be purchased only after obtaining a valid prescription for it from a medical doctor or other authorised health personnel. This is also referred to as 'prescription drug'.
- 3.12 'Interactions': a noxious or unintended reaction which occurs when two or more drugs are administered simultaneously at normal doses. This term also refers to similar reactions between a drug and food taken together.
- 3.13 'International Non-proprietary Name' (INN): this is the official name assigned to the drug by the World Health Organisation and is internationally recognised. It is also known by its generic name.
- 3.14 'Label': a display of written, printed or graphic matter upon the immediate container or the outside of a drug package.
- 3.15 'Marketing': a product promotion, distribution, sales, advertising, product public relations and information services.
- 3.16 'New drugs': a drug which has not been previously registered or marketed for medical purposes and esters of an already registered active substance, new fixed combinations of substances previously marketed, or of any drug previously marketed if its indications, mode of administration, or other formulation are changed.
- 3.17 'Over the counter drug': a drug that can be purchased without a prescription from a medical doctor or other authorised health personnel. This is also referred to as a proprietary drug.
- 3.18 'Package insert': a leaflet containing specified relevant information on a drug included in every package containing that particular drug.
- 3.19 'Pharmaceutical manufacturers': all persons involved in the production of a drug, including processing, compounding, formulating, filling, packing, repacking, altering, finishing and labelling with a view to its storage, sale and distribution.
- 3.20 'Pharmaceutical traders': all persons involved in the process of import, storage, sale and distribution of drugs whether as wholesalers or retailers.
- 3.21 'Purity': the degree to which other chemical or biological entities are present in any substance.
- 3.22 'Sample': single or small quantities of a product supplied without cost.

- 3.23 'Side-effects': expected but noxious or unpleasant effects produced by a drug at normal doses.
- 3.24 'Trade name' (also called brand name): this is a name given to a drug by the manufacturer which if registered and protected under national legislation, can be used exclusively by the manufacturer to distinguish his product from other products containing the identical active chemical substance or substances

#### **ARTICLE 4: DRUG REGISTRATION**

- 4.1 All pharmaceutical products, both ethical drugs and over-the-counter (OTC) preparations offered for sale in a country, should be duly registered by a competent authority in that country.
- 4.2 Pharmaceutical manufacturers and traders will abstain from making available in a country pharmaceutical products which are not registered in that country.
- 4.3 Pharmaceutical manufacturers and traders must provide the national registration authorities with all the information available to them on a pharmaceutical product, including all information they have given to countries with an efficient drug registration system, even if all this information has not been requested by the registration authority.
- 4.4 Pharmaceutical manufacturers and traders must provide the registration authority with a list of all countries in which the specific product has not been accepted for registration.
- 4.5 Pharmaceutical manufacturers and traders should inform the registration authority if
- 4.6 Pharmaceutical manufacturers and traders, when applying for registration of a product, must undertake that subsequent to the product's registration they will provide the registration authority and consumers with all new information they receive on its effects, adverse reactions and interactions.

#### **ARTICLE 5: REGISTRATION OF NEW DRUGS**

- 5.1 Pharmaceutical manufacturers and traders shall apply for registration of a new drug only if the new drug:
- (a) in comparison with existing drug/ drugs used for the same conditions
    - has an equal or superior benefit/risk ratio or
    - has equal or better pharmaceutical properties or
    - can be marketed at a lower price;
  - (b) is recommended for a condition for which no suitable drug treatment is available.

#### **ARTICLE 6: PRE-REGISTRATION CLINICAL "TRIALS OF NEW DRUGS"**

- 6.1 No new drug comprising of a single or more than one pharmaceutically active substance may be tested on human beings without formal and written permission from national, regional or international public health authorities.
- 6.2 Clinical trials of new drugs on human beings will only be permitted for products which have been accurately tested on experimental animals. Animal tests will be carried out in accordance with national or international legislation and must provide, in the case of each new drug, complete information on the main general

and organ system directed pharmacological effects; whether such effects may be therapeutically useful or not; on the absorption, distribution, metabolism and excretion of the active substance/substances contained in a drug; on inter-actions with other drugs in use, environmental chemicals or food; on acute and short-term toxicity for all drugs and on long-term toxicity for such drugs as may be used for extended periods in human beings and on the environmental toxicity of drugs or drug metabolites liable to be excreted by users of the drugs.

- 6.3 Requirements for animal testing of new drugs before human trials should be unified and internationally standardised.
- 6.4 Laboratories both within the premises of pharmaceutical manufacturers or those consulted by manufacturers must be open to inspection by the public health authorities of all countries in which a new drug may be submitted for trial on human subjects.
- 6.5 Clinical trials of new drugs on human subjects may only be carried out by suitably qualified and experienced researchers who must be qualified physicians, and according to procedures which must be authorised by the public health authorities. The conduct and protocols for the conduct of clinical trials must be open to inspection by public health authorities at any time. Protocols and information on these trials must also be made available to the registration authorities of countries in which a drug, which has been primarily tested in another country, is proposed for marketing.
- 6.6 Whenever a new drug is tested on healthy human subjects or on patients, the clinical trial must be authorised and monitored by a local 'ethical committee' and must be carried out only with the full informed consent of the people and patients concerned. Governments may require written consent in countries in which the majority of the population is literate; and in countries where the majority of the population is not literate, orally, in the presence of a witness. Consent to volunteer to participate in the trial of a new drug can only be given by the subject, not by his/her legal representative. In the case of children and the insane, consent given by a legal representative to the use of a new drug will be accepted only in situations in which there is a serious and nearly certain danger to the life or to the health of the subject which cannot be averted by existing available pharmaceutical products.
- 6.7 If permission for the clinical trial of new drugs on human subjects has been refused by the competent authorities of one country, any attempts to obtain such permission in other countries may only be undertaken with the disclosure of full information.
- 6.8 Drugs which have been banned from sale after being marketed in one country may not be submitted for clinical trials or marketing in another country, unless the competent authorities of the second country are provided with complete information on the reasons for the drug's withdrawal from the market.
- 6.9 Physicians in charge of clinical trials of a new drug must rapidly be brought up to date with all new findings on the properties of the drug obtained during the time of the study on human subjects.
- 6.10 Unnecessary duplication of trials of new pharmaceutical products should be avoided. Procedures for pre-registration trials of new drugs should be internationally agreed.

## ARTICLE 7: INFORMATION

- 7.1 Governments should be responsible for ensuring that objective and consistent information is provided on all pharmaceutical products marketed in the country. This responsibility should cover either the design, provision and dissemination of information or their control.
- 7.2 All information on pharmaceutical products must be accurate, balanced, objective and complete. It must be presented in such a way as to conform to legal requirements, to defined ethical standards and to standards of good taste. It should not mislead either directly or by implication. Information must be provided in a language readily understandable to the person who will use it.
- 7.3 All information provided must be based on up-to-date evaluations of all available scientific evidence and must reflect this evidence accurately and clearly. Sources of evidence must be identified.
- 7.4 Information submitted to registration authorities and other public health authorities should include both all information required by these authorities and all other information which the pharmaceutical manufacturer possesses which may be relevant to their deliberations.
- 7.5 The minimum information which must be made available by pharmaceutical manufacturers for all products to be marketed will include:
  - (i) *Package inserts* - a package insert must be added to every package to be sold to a consumer. For drugs sold to public health authorities for distribution, a sufficient number of package inserts for distribution to each potential user must be provided.

For over-the-counter (non-prescription) drugs the package insert must state the name of the drug, the names of all its pharmaceutically active ingredients which must be given as approved International Non-proprietary Names if such names exist, and the names of all auxiliary pharmaceutical substances.

Furthermore, the package insert must state the indication or indications (use or uses) of a drug and precise instructions for dosage and the spacing of doses in adults, as well as in children of the main age groups. If a drug is not to be used in a certain age group, this must be stated in the package insert.

Furthermore, the package insert must enumerate all major side-effects of the active drug(s) and possible known side-effects of the auxiliary pharmaceutical substances and must instruct the user on what to do if such side-effects occur. Furthermore, warnings of known inter-actions (instructions as to which drugs or food should not be combined with that particular pharmaceutical product) and precautions (e.g. drugs not to be used in pregnancy etc.) must be enumerated. Package inserts for drugs sold over-the-counter, as well as for prescription drugs or drugs to be distributed by health officials, must convey information that is readily intelligible to all prospective consumers and not in a language restricted to the prescriber or distributor. Such medical or scientific terms as are used must be explained in lay language.

For drugs sold without a prescription, the package insert must explain for how long a drug may be taken without consulting a health professional and the period of time after which a health professional must be consulted in the case

of lack of effect of the pharmaceutical product or after the occurrence of side-effects.

(ii) Scientific data sheet for the use of physicians and other health professionals

This data sheet may be written in a language intelligible to its prospective readers, i.e. physicians or health professionals. It must contain a full description of the pharmaceutical product, listing all active substances by their International Non-proprietary Name, if such a name exists, and their doses, and must enumerate all auxiliary pharmaceutical substances used. In the case of organic chemicals for which there is no accepted non-proprietary name, chemical names should be given and illustrated by structural formulas. The scientific data sheet should briefly summarise experimental pharmacological and toxicological data on the pharmaceutically active substances used. It must contain a full description of suggested and accepted therapeutic uses of the pharmaceutical product. Suggested uses may only be included if they are substantiated by reliable scientific evidence which must be quoted. Furthermore, there must be a short but complete description of contraindications to use of the pharmaceutical product; pre-cautions over its use; mechanisms of action (if known); known interactions with other pharmaceutical products, chemicals or food; and of dosage regimens in adults, as recommended for the different indications. Doses for children of different age groups must also be stated unless the pharmaceutical product is marked: 'Not for use in children under the age of .... Doses for the elderly must be stated if they are different from doses in other adults.

The scientific data sheet must include the address/es of the manufacturers and their representatives or the address of other persons from whom additional information on a pharmaceutical product may be obtained. Furthermore the data sheet must state the address of the manufacturers' representative or of the competent national authority to be informed in the event of unforeseen side-effects or interactions.

- 7.6 All materials containing drug information must be cleared by the national registration authorities which must also be consulted before any changes can be made to subsequent editions of the materials.
- 7.7 Information must be presented in scientifically acceptable, precise terms. None of the following words - 'safe', 'effective', 'potent', or 'cure' should be used without qualification.
- 7.8 Longer information booklets on a specific pharmaceutical product must include the standard information contained in the scientific information sheet and as much additional information as the manufacturer can provide. The information reproduced should be reliable and its validity must be capable of scientific substantiation by independent experts. Longer information booklets should not be distributed to all potential prescribers or distributors, but only to those who specifically request them after learning of their existence from publicity or promotional material. The contents of information booklets must be modified if registration authorities require amendments.



## **ARTICLE 8: LABELLING, PACKAGE INSERTS AND PROMOTIONAL MATERIAL**

- 8.1 Pharmaceutical products are either sold to the public for self-medication (over-the-counter drugs) or sold to the public on prescription from a physician or other health officials, or used by physicians or other health officials on human beings. The intended mode of sale will be clearly indicated on all containers and packaging materials for pharmaceutical products.
- 8.2 The International Non-proprietary Name of each pharmaceutically active substance for which such a name exists must be stated prominently on each package insert and on all promotional material. For pharmaceutically active substances for which no accepted non-proprietary name exists, a suggested non-proprietary name should be indicated.
- 8.3 In countries in which drugs may be sold and prescribed only under their International Non-proprietary Names, the packages must not bear any trade name for pharmaceutically active substances. However, the information from the manufacturers may refer to trade names used in other countries, specifying the country in which a given trade name is used.  
On the packaging material, the names of manufacturers may be mentioned in brackets after the non-proprietary name and in lettering of the same size as that used for the non-proprietary name.
- 8.4 In countries where drugs may be sold or distributed under protected trade names, Non-proprietary names of the pharmaceutically active ingredients must be stated on all packages in a size of lettering not smaller than one half the size used for the protected trade name.
- 8.5 Each pharmaceutical product belongs to a class and/or a category or a sub-category of therapeutic or diagnostic products. The class and, if relevant, the category or sub-category must be stated on the packaging material.
- 8.6 Indications for the therapeutic or the diagnostic use of a pharmaceutical product will not be stated on the packaging material but will be enumerated in package inserts and information for health professionals. Only indications approved by the public health authorities, or generally recognised and endorsed by reputable and independent scientific publications will be included.
- 8.7 Contra-indications against the use of a pharmaceutical product will be mentioned on the packaging material if the use of a pharmaceutical product in certain categories of human beings may endanger their life or severely endanger their health. All other known contra-indications will be explicitly stated in the package inserts and in the information for health professionals.
- 8.8 The amounts of the active substance(s) and of auxiliary pharmaceutical substances contained in a pharmaceutical product will be stated in package inserts, as well as in information sheets. Only the active substance(s) and their doses must be stated on the packaging material. Active substance(s) will be designated by their International Non-proprietary Names if and when such names exist. Auxiliary pharmaceutical substances will be designated by names which can be readily identified by physicians, pharmacists or public health officials. The grade of purity of active substances and of auxiliary pharmaceutical substances found in a pharmaceutical product will be identified by reference to a standard list of inter-nationally recognised pharmacopoeia.

## **ARTICLE 9: SALES PROMOTION OF PHARMACEUTICAL PRODUCTS**

- 9.1 Pharmaceutical products that may legally be sold to the public without a prescription ('over-the-counter drugs') may be promoted to the public through advertisements in the press or displayed publicly or by the media, but not by direct mailings. All promotional texts must state the non-proprietary names of the pharmaceutically active substances contained in a pharmaceutical product, the approved uses, contra-indications and precautions. All statements used in the promotion must represent strict scientific truth. The texts must be designed in such a manner as to avoid promoting the use of a drug by persons who do not need to take the drug and may be quite as well off without using it. Promotion may suggest the use of one drug rather than of another but must then state scientifically backed reasons. All promotional material must be cleared by the drug registration authority.
- 9.2 Drugs that may legally be sold only on prescription by physicians or other profession-ally trained prescribers cannot be advertised publicly and must not be promoted through either advertisements or articles inserted in the lay press or by radio, television or interviews. Promotion must be limited to professional journals and to personally addressed mailings to prescribers; promotion is also permitted in radio or television programmes addressing exclusively a professionally trained audience. Promotion material for advertising to health professionals must include the information required for the scientific data sheet. In promotional material, this data may be summarised or abbreviated. In this case attention should be drawn to the scientific data sheet. All promotional material must be cleared by the drug registration authority.
- 9.3 Pharmaceutical products to be distributed by public health officials may be promoted to them under conditions similar to those outlined above for medical prescribers. All promotional material must be cleared by the drug registration authority.
- 9.4 All promotional material must be modified if registration authorities request an amendment. Any given promotional item may be banned by a ruling from the competent public health authorities.
- 9.5 Pharmaceutical products which may legally be sold only under prescription may be promoted by medical representatives in all countries where medical representatives are allowed to work. Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present complete, accurate and valid information on their company's products. The manufacturer and his representatives are responsible for all statements made by their representatives and may be held liable. Governments may prescribe particular training courses for medical representatives and impose examinations or other evaluations of their knowledge and their skills. Oral statements made by medical representatives must contain the minimum information required for printed promotional material. The number of medical representatives working for one company in a given country must not exceed one representative per promoted pharmaceutical product per 500 registered physicians or other prescribers.
- 9.6 Pharmaceutical products to be sold under prescription may be promoted through the organisation of scientific meetings, symposia and sessions within congresses.

If more than 50 per cent of the total cost of such meetings is financially supported by a pharmaceutical manufacturer, this fact must be clearly and visibly stated on all programmes, invitations or abstracts. The information displayed must always draw attention to the minimum information required for the scientific data sheets and must be scientifically accurate and presented objectively and in good taste. Entertainment and hospitality offered during promotional meetings must be limited and must be secondary to the main purpose of the meeting. The level of hospitality must not exceed the provision of goods or services which the participants could not afford to buy or might not normally pay for in everyday life.

- 9.7 Samples of pharmaceutical products may be provided free of charge to prescribers only at their request. All samples must be clearly labelled as samples in such a manner that they can under no conditions be sold.
- 9.8 Drug samples for clinical trials may be supplied by manufacturers free of charge to physicians only, and only in the framework of a correctly designed therapeutic trial. The conduct of such a trial must be approved by an 'ethical committee' responsible for the control of medical experiments on humans in a given institution or region, or else by public health authorities.

#### **ARTICLE 10: PRICING, SALES AND DISTRIBUTION**

- 10.1 With a view to regulating the equitable distribution of drugs throughout the country, the Government of that country may fix the maximum price at which a drug shall be sold.
- 10.2 In order to encourage indigenous technological development, the Government shall carefully examine and compare the cost of production of every locally manufactured drug with the landed cost of a similar but imported drug. If the cost of local production is higher than the landed cost of the imported drug, the Government may, in order to reduce or eliminate the wide discrepancies in the retail price of these two categories of the same drug, impose a suitable excise tax on the landed cost of the imported drug to bring it closer to or on par with the cost of local production.
- 10.3 Every importer of a drug shall within fourteen days of the import of a drug make an application to the Government in Form I (see below at end of Article 10). The Government may, after taking into consideration the information furnished in Form I and examining the cost of production of a similar locally manufactured drug, impose, if necessary, a suitable excise tax on that drug as mentioned in Article 10.2.
- 10.4 While fixing the cost of production of a locally manufactured drug as mentioned in Article 10.2, the Government may take into account the average cost of production of such a drug by an efficient manufacturer and also take into consideration material cost, labour charges, overhead costs, etc. For the purpose of this article, an efficient manufacturer means a manufacturer:
  - (i) whose production of a drug in relation to the total consumption of that drug in that country is comparatively large, or (ii) who employs efficient technology in the production of such a drug.

- 10.5 The Government shall fix a maximum retail price for a drug by specifying the maximum mark-up on the cost of production or the landed cost (if applicable landed cost plus an excise duty as described in Article 10.3). The mark-up will include the manufacturers'/ importers' margin, transport and distribution costs, promotional expenses and retailers' commission.
- 10.6 Every manufacturer, importer or distributor of a drug intended for sale shall display an indelible print mark on the label of the container of the drug or the minimum pack thereof offered for retail sale, the maximum retail price of that drug with words "retail price not to exceed" preceding it.
- 10.7 No dealer shall sell any drug to any person at a price exceeding the maximum retail price indicated on the label of the container or pack thereof.
- 10.8 No dealer shall sell loose quantities of any drug drawn from a container of such a drug at a price which exceeds the *pro rata* price of the drug plus five per cent thereof.
- 10.9 In order to make a limited number of essential drugs easily accessible to the poorer sections of the population, the Government may fix a lower mark-up for these compared to the other drugs. For the purpose of this article, the limited number of essential drugs refer to those which are so defined and listed by a competent health authority (e.g. Formulary Committee).
- 10.10 The Government may oblige an importer or manufacturer to allocate a minimum percentage of his total annual turnover to import or locally manufacture (whichever is applicable) essential drugs described in Article 10.9.
- 10.11 The Government may oblige a retail distributor to carry always a sufficient inventory of essential drugs referred to in Article 10.9.
- 10.12 A retail dealer shall maintain a list of all drugs available with him and their prices; this list should be easily accessible to any person wishing to consult the same.
- 10.13 No importer, wholesaler or manufacturer shall withhold from sale or refuse to sell to a retail dealer any drug available to him without good and sufficient reasons.
- 10.14 No retail dealer shall withhold from sale or refuse to sell any drug available to him/her to a customer wanting to purchase such a drug for which he/she has a valid prescription or which is sold over the counter.
- 10.15 An officer authorised by the Government may, with a view to securing compliance with this Article or to satisfy himself/herself that the provisions of this Article have been complied with: (a) enter and search any place; (b) seize any drug, along with containers, packages or coverings in which the drug is found, in respect of which he/she suspects that any provision of Article 10 has been, is being, or is about to be, contravened.
- 10.16 When the Government (but not a private trader) imports drugs and the landed cost of an imported drug is lower than the cost of production of a similar drug locally manufactured, the Government may purchase the total output from the local manufacturer after fixing the cost of production as described in Article 10.4 and allowing him a reasonable return on his investment and then fix a common pooled wholesale price for both the imported and the locally produced drug.

# Form I

(To be submitted in duplicate by an importer, within fourteen days of the import, for each imported consignment)

1. Name of the company
2. Address of Registered/Head Office/Factory if any
3. Reference to permission given by the drug registration authority for import of the drug
4. Name of the drug
5. Specifications of the drug
6. Country from which the drug is imported
7. Quantity imported (kg/litres/tonnes, etc.)
8. C.i.f. value in foreign currency

	<b>Total</b>	<b>Per unit</b>
	local currency	local currency
a. Total c.i.f. paid in local currency	...	...
b. Customs duty paid	...	....
c. Clearing charges with full details	...	...
d. Landed cost (a + b + c)	...	....

(Note: The figures given here should be certified by a practising Cost Accountant/Chartered Accountant)

## ARTICLE. II: PHARMACEUTICAL TECHNOLOGY

The general provisions contained in the draft International Code of Conduct on the Transfer of Technology being negotiated in UNCTAD shall apply to all technology transfer trans-actions in the pharmaceutical sector.

Alternatively this Code could include the following provisions which are in the UNCTAD draft Code.

- 11.1 The pharmaceutical technology transferred to a developing country should be appropriate to the economic and social development objectives of that country.
- 11.2 Upon request of the technology acquiring party, the technology supplying party shall make arrangements, as far as possible, to unpackage the technology in terms of information concerning the various elements of the technology to be transferred, such as that required for technical, institutional and financial evaluation of the offer.
- 11.3 In a technology transfer agreement specific provisions should be made for the maximum use of locally available resources.
- 11.4 Technology transfer agreements should not contain restrictive practices which adversely affect the economic and technological development of the acquiring country. These restrictive practices include, among others:
  - grant back provisions
  - restrictions on research
  - restrictions on use of personnel
  - price fixing
  - restrictions on adaptations
  - tying agreements
  - export restrictions

- payments and other obligations after expiration of industrial property rights
  - restriction after expiration of agreement
  - restrictions on the scope, volume and capacity of production and field of activity
  - obligation to use trademarks
  - requirement of the acquiring party to provide equity capital or to allow supplying party to participate in management
  - unlimited or unduly long duration of transfer agreements
  - limitations upon the use of the imported technology
- 11.5 When negotiating, concluding and performing a technology transfer agreement, the parties should observe fair and honest business practices which include, among others:
- fair and reasonable terms and conditions
  - provision of all relevant information
  - access by the acquiring party during the period of the agreement to any improvements to the technology transferred under the agreement
  - the right to cease negotiations if, during the negotiations, either party determines that a satisfactory agreement cannot be reached
  - the supplying party shall, to the extent feasible, provide the acquiring party, during the period of the agreement, with spare parts, accessories and raw materials produced by the supplying party for using the technology transferred particularly where alternative sources are unavailable
  - the technology suppliers' guarantee that the technology meets the description contained in the transfer agreement the technology suppliers' guarantee that the technology, if used in accordance with the description in the transfer agreement, is suitable for the manufacture of goods as agreed upon by the parties and stipulated in the agreement
  - the supplying party shall provide adequate training to the personnel of the acquiring party or to the personnel designated by it, in the knowledge and operation of the technology transferred, on the terms stipulated in the agreement
  - the prices, charges or other considerations made for all elements involved in the transfer of technology transactions shall be distinctly specified for each item
  - where the acquiring party has no other alternative than to purchase goods and/ or services from the supplying party, or from any enterprise designated by it, the prices for such inputs shall be fair and not higher than current world prices for goods or services of the same quality offered on comparable commercial terms and conditions.
  - the supplying party shall be liable for the loss of, damage or injury to property or persons arising from the technology transferred or the goods produced by it, provided that the technology is used as specified in the agreement, or in the absence of such specification, in a technically correct manner.
- 11.6 Patent protection should not be given to pharmaceutical products or processes... If, however, some form of protection has to be given, only process patents should be granted and adequate safe-guards aimed at ensuring satisfactory

working of the patented invention should be provided. These safeguards would be to:

- (a) specify that importation does not constitute working of the patent;
- (b) provide for an expeditious system of compulsory licensing;
- (c) use forfeiture or revocation of the patent on specific grounds;
- (d) shorten the duration of the patent and use it to ensure satisfactory working of the patented invention.

## **ARTICLE 12: RESEARCH AND DEVELOPMENT**

- 12.1 Since the national pharmaceutical industry in most developing countries is still in its formative stages, Governments shall enter the area of research and development by setting up special research and development institutions and linking their activities to production and innovation.
- 12.2 Pharmaceutical manufacturers, if they are not engaged in research and development activities themselves, and pharmaceutical importers, shall set aside an agreed percentage of their total turnover for research and development. This money may be credited to the state sponsored research institutions.
- 12.3 Pharmaceutical manufacturers and traders may be allowed tax relief on their contributions to research and development.
- 12.4 The Governments shall, in view of the requisite manpower and facilities, the small volume of total research effort, and the low research capability in most developing countries, set up appropriate organisations to define the priorities and problems needing research and coordinate the entire research activities between the specialised institutions set up by the Government, universities, and institutes of technology.

## **ARTICLE 13: IMPLEMENTATION AND MONITORING**

- 13.1 Countries which have accepted the Code should take appropriate steps at the national level to meet their commitment to the Code, including the adoption of national legislation, regulations or other suitable measures. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aims of the Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of pharmaceutical products.
- 13.2 WHO and UNCTAD shall, on request, provide technical support to countries preparing national legislation or regulation or taking other appropriate measures in implementation and furtherance of the principles and aims of this Code.
- 13.3 Monitoring the application of this Code lies with the governments of the countries acting individually and together with WHO and UNCTAD. Pharmaceutical manufacturers and traders, appropriate non-governmental organisations, professional groups and consumer organisations should collaborate with governments to this end.
- 13.4 Independently of any other measures taken for implementation of this Code, pharmaceutical manufacturers and traders should regard themselves as responsible for monitoring their marketing practices, according to the principles



and aims of this Code and for taking steps to ensure that their conduct at every level conforms to them.

- 13.5 Non-governmental organisations, professional groups, consumer organisations and individuals concerned should also undertake to draw to the attention of pharmaceutical manufacturers and traders activities which are incompatible with the principles and aims of this Code, so that they can take appropriate action. The appropriate government authority should also be informed.
- 13.6 Pharmaceutical manufacturers and traders should appraise each member of their marketing personnel of the principles and aims of this Code and of their responsibilities under it.
- 13.7 WHO and UNCTAD should provide fora for consultations, discussions and exchange of views between countries on matters related to this Code, in particular to its application and greater harmonisation and the experience gained in its operations.

#### **ARTICLE 14: REVIEW PROCEDURE**

WHO and UNCTAD shall submit a report in four years to the World Health Assembly and the United Nations Conference on Trade and Development, respectively, reviewing all the aspects of the Code with proposals for the improvement and further development of the Code.

# PEOPLES CHARTER FOR HEALTH

## *The People's Health Assembly and the Charter*

The idea of a People's Health Assembly (PHA) has been discussed for more than a decade. In 1998 a number of organisations launched the PHA process and started to plan a large international Assembly meeting, held in Bangladesh at the end of 2000. A range of pre- and post-Assembly activities were initiated including regional workshops, the collection of people's health-related stories and the drafting of a *People's Charter for Health*.

The present Charter builds upon the views of citizens and people's organisations from around the world, and was first approved and opened for endorsement at the Assembly meeting in Savar, Bangladesh, in December 2000.

The Charter is an expression of our common concerns, our vision of a better and healthier world, and of our calls for radical action. It is a tool for advocacy and a rallying point around which a global health moment can gather and other networks and coalitions can be formed.

## **PREAMBLE**

Health is a social, economic and political issue and above all a fundamental human right. Inequality, poverty, exploitation, violence and injustice are at the root of ill-health and the deaths of poor and marginalised people. Health for all means that powerful interests have to be challenged, that globalisation has to be opposed, and that political and economic priorities have to be drastically changed. This Charter builds on perspectives of people whose voices have rarely been heard before, if at all. It encourages people to develop their own solutions and to hold accountable local authorities, national governments, international organisations and corporations.

## **VISION**

Equity, ecologically-sustainable development and peace are at the heart of our vision of a better world - a world in which a healthy life for all is a reality; a world that respects, appreciates and celebrates all life and diversity; a world that enables the flowering of people's talents and abilities to enrich each other; a world in which

people's voices guide the decisions that shape our lives. There are more than enough resources to achieve this vision.

## **THE HEALTH CRISIS**

***“Illness and death every day anger us. Not because there are people who get sick or because there are people who die. We are angry because many illnesses and deaths have their roots in the economic and social policies that are imposed on us.”***

***(A voice from Central America)***

In recent decades, economic changes world-wide have profoundly affected people's health and their access to health care and other social services.

Despite unprecedented levels of wealth in the world, poverty and hunger are increasing. The gap between rich and poor nations has widened, as have inequalities within countries, between social classes, between men and women and between young and old.

A large proportion of the world's population still lacks access to food, education, safe drinking water, sanitation, shelter, land and its resources, employment and health care services. Discrimination continues to prevail. It affects both the occurrence of disease and access to health care.

The planet's natural resources are being depleted at an alarming rate. The resulting degradation of the environment threatens everyone's health, especially the health of the poor. There has been an upsurge of new conflicts while weapons of mass destruction still pose a grave threat.

The world's resources are increasingly concentrated in the hands of a few who strive to maximise their private profit. Neoliberal political and economic policies are made by a small group of powerful governments, and by international institutions such as the World Bank, the International Monetary Fund and the World Trade Organisation. These policies, together with the unregulated activities of transnational corporations, have had severe effects on the lives and livelihoods, health and well-being of people in both North and South.

Public services are not fulfilling people's needs, not least because they have deteriorated as a result of cuts in governments' social budgets. Health services have become less accessible, more unevenly distributed and more inappropriate.

Privatisation threatens to undermine access to health care still further and to compromise the essential principle of equity. The persistence of preventable ill health, the resurgence of diseases such as tuberculosis and malaria, and the emergence and spread of new diseases such as HIV/AIDS are a stark reminder of our world's lack of commitment to principles of equity and justice.

## **PRINCIPLES OF THE PEOPLE'S CHARTER FOR HEALTH**

- 1 The attainment of the highest possible level of health and well-being is a fundamental human right, regardless of a person's colour, ethnic background, religion, gender, age, abilities, sexual orientation or class.
- 2 The principles of universal, comprehensive Primary Health Care (PHC), envisioned in the 1978 Alma Ata Declaration, should be the basis for formulating

policies related to health. Now more than ever an equitable, participatory and intersectoral approach to health and health care is needed.

- 3 Governments have a fundamental responsibility to ensure universal access to quality health care, education and other social services according to people's needs, not according to their ability to pay.
- 4 The participation of people and people's organisations is essential to the formulation, implementation and evaluation of all health and social policies and programmes.
- 5 Health is primarily determined by the political, economic, social and physical environment and should, along with equity and sustainable development, be a top priority in local, national and international policy-making.

## **A CALL FOR ACTION**

To combat the global health crisis, we need to take action at all levels - individual, community, national, regional and global - and in all sectors. The demands presented below provide a basis for action.

## **HEALTH AS A HUMAN RIGHT**

***Health is a reflection of a society's commitment to equity and justice. Health and human rights should prevail over economic and political concerns.***

*This Charter calls on people of the world to:*

- 1 Support all attempts to implement the right to health.
- 2 Demand that governments and international organisations reformulate, implement and enforce policies and practices which respect the right to health.
- 3 Build broad-based popular movements to pressure governments to incorporate health and human rights into national constitutions and legislation.
- 4 Fight the exploitation of people's health needs for purposes of profit.

## **TACKLING THE BROADER DETERMINANTS OF HEALTH**

### **Economic challenges**

***The economy has a profound influence on people's health. Economic policies that prioritise equity, health and social well-being can improve the health of the people as well as the economy.***

***Political, financial, agricultural and industrial policies which respond primarily to capitalist needs, imposed by national governments and international organisations, alienate people from their lives and livelihoods. The processes of economic globalisation and liberalisation have increased inequalities between and within nations.***

***Many countries of the world and especially the most powerful ones are using their resources, including economic sanctions and military interventions, to consolidate and expand their positions, with devastating effects on people's lives.***

*This Charter calls on people of the world to:*

- 1 Demand transformation of the World Trade Organisation and the global trading system so that it ceases to violate social, environmental, economic and health rights of people and begins to discriminate positively in favour of countries of

the South. In order to protect public health, such transformation must include intellectual property regimes such as patents and the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement.

- 2 Demand the cancellation of Third World debt.
- 3 Demand radical transformation of the World Bank and International Monetary Fund so that these institutions reflect and actively promote the rights and interests of developing countries.
- 4 Demand effective regulation to ensure that TNCs do not have negative effects on people's health, exploit their workforce, degrade the environment or impinge on national sovereignty.
- 5 Ensure that governments implement agricultural policies attuned to people's needs and not to the demands of the market, thereby guaranteeing food security and equitable access to food.
- 6 Demand that national governments act to protect public health rights in intellectual property laws.
- 7 Demand the control and taxation of speculative international capital flows.
- 8 Insist that all economic policies be subject to health, equity, gender and environmental impact assessments and include enforceable regulatory measures to ensure compliance.
- 9 Challenge growth-centred economic theories and replace them with alternatives that create humane and sustainable societies. Economic theories should recognise environmental constraints, the fundamental importance of equity and health, and the contribution of unpaid labour, especially the unrecognised work of women.

## **SOCIAL AND POLITICAL CHALLENGES**

***Comprehensive social policies have positive effects on people's lives and livelihoods. Economic globalisation and privatisation have profoundly disrupted communities, families and cultures. Women are essential to sustaining the social fabric of societies everywhere, yet their basic needs are often ignored or denied, and their rights and persons violated.***

***Public institutions have been undermined and weakened. Many of their responsibilities have been transferred to the private sector, particularly corporations, or to other national and international institutions, which are rarely accountable to the people. Furthermore, the power of political parties and trade unions has been severely curtailed, while conservative and fundamentalist forces are on the rise. Participatory democracy in political organisations and civic structures should thrive. There is an urgent need to foster and ensure transparency and accountability.***

*This Charter calls on people of the world to:*

- 1 Demand and support the development and implementation of comprehensive social policies with full participation of people.
- 2 Ensure that all women and all men have equal rights to work, livelihoods, to freedom of expression, to political participation, to exercise religious choice, to education and to freedom from violence.

- 3 Pressure governments to introduce and enforce legislation to protect and promote the physical, mental and spiritual health and human rights of marginalised groups.
- 4 Demand that education and health are placed at the top of the political agenda. This calls for free and compulsory quality education for all children and adults, particularly girl children and women, and for quality early childhood education and care.
- 5 Demand that the activities of public institutions, such as child care services, food distribution systems, and housing provisions, benefit the health of individuals and communities.
- 6 Condemn and seek the reversal of any policies, which result in the forced displacement of people from their lands, homes or jobs.
- 7 Oppose fundamentalist forces that threaten the rights and liberties of individuals, particularly the lives of women, children and minorities.
- 8 Oppose sex tourism and the global traffic of women and children.

## ENVIRONMENTAL CHALLENGES

***Water and air pollution, rapid climate change, ozone layer depletion, nuclear energy and waste, toxic chemicals and pesticides, loss of biodiversity, deforestation and soil erosion have far-reaching effects on people's health. The root causes of this destruction include the unsustainable exploitation of natural resources, the absence of a long-term holistic vision, the spread of individualistic and profit-maximising behaviours, and over-consumption by the rich. This destruction must be confronted and reversed immediately and effectively.***

*This Charter calls on people of the world to:*

- 1 Hold transnational and national corporations, public institutions and the military accountable for their destructive and hazardous activities that impact on the environment and people's health.
- 2 Demand that all development projects be evaluated against health and environmental criteria and that caution and restraint be applied whenever technologies or policies pose
  - 1 potential threats to health and the environment (the precautionary principle).
- 2 Demand that governments rapidly commit themselves to reductions of greenhouse gases from their own territories far stricter than those set out in the international climate change agreement, without resorting to hazardous or inappropriate technologies and practices.
- 3 Oppose the shifting of hazardous industries and toxic and radioactive waste to poorer countries and marginalised communities and encourage solutions that minimise waste production.
- 4 Reduce over-consumption and non-sustainable lifestyles - both in the North and the South. Pressure wealthy industrialised countries to reduce their consumption and pollution by 90 per cent.
- 5 Demand measures to ensure occupational health and safety, including worker-centred monitoring of working conditions.

- 6 Demand measures to prevent accidents and injuries in the workplace, the community and in homes.
- 7 Reject patents on life and oppose bio-piracy of traditional and indigenous knowledge and resources.
- 8 Develop people-centred, community-based indicators of environmental and social progress, and to press for the development and adoption of regular audits that measure environmental degradation and the health status of the population.

## **WAR, VIOLENCE, CONFLICT AND NATURAL DISASTERS**

***War, violence, conflict and natural disasters devastate communities and destroy human dignity. They have a severe impact on the physical and mental health of their members, especially women and children. Increased arms procurement and an aggressive and corrupt international arms trade undermine social, political and economic stability and the allocation of resources to the social sector.***

*This Charter calls on people of the world to:*

- 1 Support campaigns and movements for peace and disarmament.
- 2 Support campaigns against aggression, and the research, production, testing and use of weapons of mass destruction and other arms, including all types of landmines.
- 3 Support people's initiatives to achieve a just and lasting peace, especially in countries with experiences of civil war and genocide.
- 4 Condemn the use of child soldiers, and the abuse and rape, torture and killing of women and children.
- 5 Demand the end of occupation as one of the most destructive tools to human dignity.
- 6 Oppose the militarisation of humanitarian relief interventions.
- 7 Demand the radical transformation of the UN Security Council so that it functions democratically.
- 8 Demand that the United Nations and individual states end all kinds of sanctions used as an instrument of aggression which can damage the health of civilian populations.
- 9 Encourage independent, people-based initiatives to declare neighbourhoods, communities and cities areas of peace and zones free of weapons.
- 10 Support actions and campaigns for the prevention and reduction of aggressive and violent behaviour, especially in men, and the fostering of peaceful coexistence.
- 11 Support actions and campaigns for the prevention of natural disasters and the reduction of subsequent human suffering.

## **A PEOPLE-CENTERED HEALTH SECTOR**

***This Charter calls for the provision of universal and comprehensive primary health care, irrespective of people's ability to pay. Health services must be democratic and accountable with sufficient resources to achieve this.***

*This Charter calls on people of the world to:*

1. Oppose international and national policies that privatise health care and turn it into a commodity.



2. Demand that governments promote, finance and provide comprehensive Primary Health Care as the most effective way of addressing health problems and organising public health services so as to ensure free and universal access.
3. Pressure governments to adopt, implement and enforce national health and drugs policies.
4. Demand that governments oppose the privatisation of public health services and ensure effective regulation of the private medical sector, including charitable and NGO medical services.
5. Demand a radical transformation of the World Health Organisation (WHO) so that it responds to health challenges in a manner which benefits the poor, avoids vertical approaches, ensures intersectoral work, involves people's organisations in the World Health Assembly, and ensures independence from corporate interests.
6. Promote, support and engage in actions that encourage people's power and control in decision-making in health at all levels, including patient and consumer rights.
7. Support, recognise and promote traditional and holistic healing systems and practitioners and their integration into Primary Health Care.
8. Demand changes in the training of health personnel so that they become more problem-oriented and practice-based, understand better the impact of global issues in their communities, and are encouraged to work with and respect the community and its diversities.
9. Demystify medical and health technologies (including medicines) and demand that they be subordinated to the health needs of the people.
10. Demand that research in health, including genetic research and the development of medicines and reproductive technologies, is carried out in a participatory, needs-based manner by accountable institutions. It should be people- and public health-oriented, respecting universal ethical principles.
11. Support people's rights to reproductive and sexual self-determination and oppose all coercive measures in population and family planning policies. This support includes the right to the full range of safe and effective methods of fertility regulation.

## **PEOPLE'S PARTICIPATION FOR A HEALTHY WORLD**

***Strong people's organisations and movements are fundamental to more democratic, transparent and accountable decision-making processes. It is essential that people's civil, political, economic, social and cultural rights are ensured. While governments have the primary responsibility for promoting a more equitable approach to health and human rights, a wide range of civil society groups and movements, and the media have an important role to play in ensuring people's power and control in policy development and in the monitoring of its implementation.***

*This Charter calls on people of the world to:*

- 1 Build and strengthen people's organisations to create a basis for analysis and action.

- 2 Promote, support and engage in actions that encourage people's involvement in decision-making in public services at all levels.
- 3 Demand that people's organisations be represented in local, national and international fora that are relevant to health.
- 4 Support local initiatives towards participatory democracy through the establishment of people-centred solidarity networks across the world.

#### **AMENDMENT**

- After the endorsement of the PCH on December 8, 2000, it was called to the attention of the drafting group that action points number 1 and 2 under Economic challenges could be interpreted as supporting the social clause proposed by WTO, which actually serves to strengthen the WTO and its neoliberal agenda. Given that this countervails the PHA demands for change of the WTO and the global trading system, the two paragraphs were merged and amended.
- The section of War, Violence and Conflict has been amended to include natural disasters. A new action point, number 5 in this version, was added to demand the end of occupation. Furthermore, action point number 7, now number 8, was amended to read *to end all kinds of sanctions*. An additional action point number 11 was added concerning natural disasters.

#### **JOIN US - ENDORSE THE CHARTER**

We call upon all individuals and organisations to join this global movement and invite you to endorse and help implement the *People's Charter for Health*.

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## KEY PUBLICATIONS

The following include publications by the International Organisation of Consumers Unions (IOCU) which hosted Health Action International Asia - Pacific (HAIAP) from its inception in 1981 up to 2001 and was a key partner throughout its history.

### 1981

Howorka, Wolfgang, comp. ***Forty-four Problem Drugs***. Penang, 1981

Compiled in close collaboration with the Chairman of IOCU's Health Working Group, Dr Andrew Herxheimer, it consists of fact sheets on 44 pharmaceutical products which could have serious side effects.

### 1983

Beardshaw, Virginia. ***Prescription for Change***. The Hague, 1983.

A guide on organising to raise awareness and change the political will to achieve more equitable health policies.

Blum, Richard, Andrew Herxheimer, Catherine Stenzl and Jasper Woodcock. ***Pharmaceuticals and Health Policy: International Perspectives on Provision and Control of Medicines***. Penang, 1983.

Originally published by Croom Helm, London in 1981, this edition was published by IOCU and Social Audit to support the work of HAI.

Foo, Gaik Sim. ***Anabolic Steroids: Availability and Marketing***. Penang, 1983.

This is a report of a survey of the availability and marketing in 12 countries of this drug which can cause sexual mal-development in children.

***Health, Safety and the Consumer***. Penang, 1983.

Proceedings of the IOCU seminar on health and safety issues, held in Ranzan, Japan, April 6-9, 1983.

***Pharmaceutical and Health Policies***. Penang, 1983.

Report of a South-east Asian seminar organised by IOCU and the Quaker International Affairs Program Office for South-east Asia held in Penang, Malaysia, on 22-25 November 1983.

### 1984

Ellwood, Wayne. ***Generating Power: a Guide to Consumer Organising***. Penang, 1984.

A guide to organising effective consumer campaign. It includes profiles of the main global campaign networks, with which IOCU is involved. It also details HAI campaigns. (Other editions, Spanish by Instituto Nacional Consumo, Spain, 1986; Portuguese by Associaçao Portuguesa para a Defesa do Consumidor, Portugal, 1987; Indonesian by Yayasan Lembaga Konsumen, 1988; Arabic by the Arab Office for Youth and Environment, Egypt, 1990.)

Lachovics, Eva and Lakshmi Menon, comp. ***The Health Portfolio***. Penang, 1984.

An annotated bibliography of publications, journals and audio visual materials on health issues compiled from CIDOC collection. (CIDOC - Consumer Information and Documentation Centre of IOCU, Penang).

Medawar, Charles. ***One Drug at a Time***. The Hague, 1984.

Jointly published by IOCU and Social Audit (UK), it argues the case against rampant and uncritical use of combination drugs.

## 1986

Chetley, Andrew and David Gilbert. ***Problem Drugs***. The Hague, 1986.

A pack containing up-to-date fact sheets on many drugs. Published jointly by IOCU and HAI. Other editions include French and Spanish.

McDonnell, Kathleen, ed. ***Adverse Effects: Women and the Pharmaceutical Industry***. Penang, 1986.

Women are targets worldwide of the multi-billion dollar pharmaceutical industry. This anthology looks into such concerns as mood modifiers, hormone manipulation and population control drugs. A Canadian edition was published by the Women's Press in the same year.

Tiranti, Dexter. ***The Bangladesh Example – Four Years on 1982-86***. Oxford, 1986.

This report examines the situation in the Third World countries which attempted to rationalise their drug policies in order to reduce the price of essential drugs, increase their local production, and reduce the unnecessary drugs. The aim of this booklet was to encourage other Third World nations to seriously examine the Bangladesh example. Jointly published with New Internationalist Publications and War on Want, both of UK.

## 1988

Balasubramaniam, K. ***Global Marketing of Pharmaceuticals: Prescription for Disaster***. Penang, 1988

This paper outlines the strategy to challenge the multinationals and to rationalise the pharmaceutical supply system in both developed and developing countries.

Balasubramaniam, K. ***Policies and Strategies on Drug Pricing Regulations: International Experiences***. Penang, 1988.

This paper argues for a drug pricing policy, as part of an integrated national drug policy, in each country to limit the profitability of drug production. It draws on the experiences of countries which have successfully implemented such policies.

Balasubramaniam, K. ***Policy Options in Pharmaceutical Patents for Developing Asian Countries***. Penang, 1988.

It examines key issues in drug patenting and focuses on the adverse effects patent protection can have on the economic, commercial and technological development of the pharmaceutical sector in developing Asian countries.

Balasubramaniam, K. ***The Rational Use of Drugs: a Universal Concept***. Penang, 1988.

This monograph identifies the factors which influence the rational use of drugs in a country and suggests steps to improve drug availability.

***Problems with Drugs: Action for Essential Drugs***. Montevideo, 1988.

Proceedings of the First Regional Meeting of AIS (Accion Internacional para la Salud)-HAI Latin America and the Caribbean held in Montevideo, December 1987. Also published in Spanish.

## 1989

Hansson, Olle. ***Inside Ciba-Geigy***. Penang, 1989.

Exposes some of the operations of the pharmaceutical company, Ciba-Geigy. The book is in three parts; Part I is a story of clioquinol, a drug which damaged thousands of people's lives, Part II examines examples of drug marketing by Ciba-Geigy and other transnational companies; and Part III describes the events that followed Hansonn's long struggle with Ciba-Geigy.

## 1990

Balasubramaniam, K., ed. ***Towards Rational Drug Use***. Penang 1990.

Proceedings of the International Consultation on Rational Drug Use in Undergraduate Medical/Pharmacy Education. Over 50 teachers of Medicine and pharmacy from five continents worked out strategies and action plans to spearhead changes within the teaching institutions – changes designed to introduce the concepts of essential drugs and their rational use into undergraduate teaching. They set up an informal network – Educators for Rational Drug Use (ERDU) to follow up on the recommendations of the consultation.

## 1992

Andrew Chetley. ***From Policy to Practice: The Future of Bangladesh Drug Policy***. Penang, 1992.

Bangladesh received international acclaim in 1982 when it was the first country to introduce a National Drug Policy based on the public health concepts such as Primary Health Care and need for essential drugs. Ten years later, this report provides an independent assessment of the achievements of the National Drug Policy and prospects for future improvements in the supply and use of medicines in Bangladesh.

## 1996

Kaur, Shila Rani, Padmaja Padman and Dr K. Balasubramaniam (Editors). ***Proceedings of the Asia – Pacific Seminar on Implementing National Drug Policies***. Penang, 1996.

The seminar underscored that National Drug Policies based on the concepts of essential drugs and their rational use provide the framework within which essential



drugs of acceptable quality, safety and efficacy will be made available to all those who need them at prices they can afford. A priority issue for the seminar was to examine options available for countries to enact legislation, formulate rules and regulations that would make a National Drug Policies applicable to both public and private sectors.

Balasubramaniam, K. ***Health and Pharmaceuticals in Developing Countries: Towards Social Justice and Equity***. Penang, 1996.

This is a collection of papers presented by Dr Balasubramaniam at national, regional and international forums between 1988-1995. The central thrust in this collection of papers is that "Health for All – Now" is a possibility in all developing countries, irrespective of their stages of development. What are needed are the formulation and implementation of national health policies based on the concepts of primary health care and national drug policies based on the concepts of essential drugs and their rational use.

## **1997**

Balasubramaniam, K. ***National Health Insurance and Financing: the International Scene and Foreign Models***. Penang, 1997.

The paper examines the various options for health care financing. Based on a critical analysis of empirical data presented the paper concludes that a public insurance system, either through general taxation or compulsory social insurance premiums, is a very efficient mechanism to redistribute income from the healthy or high income groups to the unhealthy or low income groups. The economic burden of the health care system is collectively shared according to the ability of the citizens.

Balasubramaniam, K. ***Herbal Remedies : Consumer Protection Concerns***. Penang, 1997.

This paper was presented at the International Symposium on Herbal Medicines 14-17 June 1997, Honolulu, Hawaii, co-sponsored by United Nations Industrial Development Organisation (UNIDO) and the University of San Diego, California. The paper presents some data on the use of herbal remedies in developed and developing countries and calls for the development of national drug policies on traditional medicine and herbal remedies to inform and educate the public of the benefits as well as risk associated with uncontrolled unregulated use of herbal remedies.

Snell, Beverly, Jonathan Dartnell, Shila Kaur (Editors). ***Pharmaceuticals in the Pacific: Problems and Prospects***, Penang 1997.

This is the report of the seminar on pharmaceuticals in the Pacific region held in Fiji, 8-11 September 1997. Health Ministry Officials from 14 Pacific Island Nations participated in the seminar. One of the recommendations was the development of regional networking procedures to share information on pharmaceuticals.

## **1998**

Balasubramaniam, K. ***Heads – TNCs win, Tails – South Loses***. Penang, 1998.

This report warns that pharmaceutical and biotechnology industries have taken away the power of economic decision making from national governments, which in turn will have a significant impact on peoples' health. Several strategies are suggested for the developing countries to mitigate the negative impact of TRIPS including the

provisions related to the principle of exhaustion of rights, compulsory licensing and the transitional period.

## **2001**

Aja, Godwin Nwadibia. ***ABC of Rational Use of Medicines***. Ibadan, 2001.

A handbook of basic information for students, NGOs and people working in health at the community level.

## **2004**

Weissman, Robert, ed. ***WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses***. Penang, 2004.

This is the report of the Regional Consultation, 17-19<sup>th</sup> April 2003, Colombo, Sri Lanka jointly published by HAIAP and Third World Network. The participants analysed the terms of WTO/TRIPS Agreement to assess how it impacts public health and access to essential medicines and to examine the most pro-public health policy options that are available to countries. ***A Manual on Good Practices in Public Health Sensitive Policy Measures and Patent Law*** prepared by the Third World Network was presented and adopted.

## **2001**

## **2006**

Amailuk, Elizabeth, ed. ***Information Resource List***. Nairobi.

An index of online resources which provides links to some key work on various issues that relate to access to medicines. While this resource list is not exhaustive, it is a helpful reference point. Most of the materials are freely available online. It is continually updated.

Amailuk, Elizabeth. ***HEPS Uganda: Civil Society Making a Difference***. Nairobi, 2006.

A case study of a Ugandan health civil society organisation which is advocating for patients' rights and access to medicines.

## **PERIODICALS.**

***HAI News***. Quarterly. No 1, October 1981 to present.

***HAI Africa, Regional Newsletter*** - bimonthly periodical from November 2005 to present.

## HEALTH ACTION INTERNATIONAL ASIA-PACIFIC

Health Action International Asia-Pacific (HAIAP), an independent, regional, informal and dynamic network of public interest and health advocates, consumer groups and individuals, was established in 1986 out of necessity to uphold health as a fundamental human right and aspire for a just and equitable society in which there will be regular access to essential medicines to all who need them. HAIAP works with governments, academic institutions and NGOs at community, national and regional levels on issues such as promoting equitable and affordable access to essential medicines, the essential medicines concept, rational use of medicines, traditional medicine, ethical drug promotion, fair drug prices, the impact of multilateral agreements particularly TRIPS and GATS on access to affordable healthcare and essential medicines, poverty eradication as well as other priority themes relevant to countries in the Asia Pacific region.

Working towards its goals through a variety of means HAIAP spans across 18 countries in Asia and the Pacific and consists of approximately 60 Individual and Organisation Members and Associate Members. They vary from powerful international/regional NGOs to grass root level organisations and concerned individuals working in the fields of medicine, pharmaceuticals, health, development and human rights. These organisations and individuals participate and volunteer their expertise and time, pooling and sharing expertise, skills and experience to achieve the common goal of Health for All.

Swimming against the tide is never easy, and in today's climate that encourages cutthroat competition and values of unbridled consumerism through the medium of the market, HAI stands for basic human values and compassion.

*Amit Sen Gupta, India*

When we were born, we promised "a sustained, vigorous and multi-faceted international campaign". 25 years later, we can proudly say we delivered and will continue this spirit of vigilance and action towards "real health for real people."

*Anwar Fazal, Penang, Malaysia*

HAIAP has been on the cutting edge of the struggle against the hegemony of trans-national pharmaceutical corporations and has been primarily responsible for keeping this issue alive in the public eye.

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