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HAI AP News

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Health Action International Asia-Pacific (HAIAP) is part of an independent global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAIAP is an informal network of non-governmental organisations and individuals in the Asia-Pacific Region committed to strive for health for all now. HAI AP News is the organ of Health Action International – Asia Pacific and presents the happenings in the regional campaigns for more rational and fairer health policies and carries material in support of participants' work.

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Message from the coordinator

Beating drums, burning incense, chanting, bodies swaying and gently stamping feet heralded the start of the People's Health Assembly 3 in Cape Town, South Africa. Traditional healers and shamans from the continent of South America and Africa joined hands with health activists in a healing circle, giving voice to the

many grievances and continued sufferings of Mother Earth and seeking Her forgiveness, healing and blessings for the duration of the Assembly. A blessed beginning indeed!

It was befitting that PHA 3 took place in South Africa, a country grappling with the effects of apartheid and struggling emotionally to come to terms with social, economic and political realities. Over six days we heard moving and heroic stories of people living with life-threatening diseases and fighting for access to medicines, amidst economic and social turmoil. We heard stories of people literally falling dead from sheer hard work on plantations in Latin America and women dying during childbirth due to lack of access to Primary Health Care. We heard stories of bravery in war torn and chronically conflict-ridden places such as Palestine; and the daily anguish and effects on mental health. Food, water, sanitation, housing – social determinants of health - without these, there is **no** Health. As the forces of globalisation and corporatisation continue to wreak havoc with struggling and fragile economies and the social determinants fragment, health remains a dream for the poor and powerless.

PHA 3 was a reminder to all of the peoples' struggles for health equity and justice and the importance of human connection, solidarity and support in these struggles. We are a part of this struggle and the presence of HAI and HAIAP members from at least 10 countries during

this PHA 3 demonstrated our commitment to the struggle for health in a truly people's global movement. Not only in Cape Town, but also in Sydney: HAIAPers demonstrated their commitments with their interventions and presentations during the Asia Pacific Conference on National Medicinal Policies (APCNMP) held there, from 26 – 29 May 2012. Many raised their own travel money to participate at this milestone meeting – clearly dedication, commitment, grit, hard work and resourcefulness have combined to produce the other face of the coin that is HAIAP.

I came away from Cape Town, moved, uplifted, energised and proud – despite the lack of resources, civil society groups and networks such as HAIAP *live* because activism is like a virus; once its RNA is incorporated into the group's DNA, it's a life-long affliction.

Viva HAIAP and viva all movements of peoples for Health!

Shila Kaur, HAIAP Coordinator

The People's Health Assembly

Capetown July 2012

Following the Peoples Health Assembly in Capetown in July 2012, a Call to Action was drafted by the participants to address growing health inequities, the ecological crisis and the food crisis. What follows are extracts from the Call to Action. The full version can be found at <http://www.phmovement.org/>

Cape Town Call to Action

After two years of participatory engagement and planning we, the People's Health Movement have gathered 800 strong from 90 countries representing the voices of tens of thousands more in our movement across every continent in the world.

In Cape Town we have:

- strengthened and deepened our solidarity
- expressed our outrage at the continuing global health crises that are embedded in myriad structural and socio-political inequities
- developed principles for alternative economic, political and social orders and
- re-committed ourselves to work towards the world we have envisioned.

We reaffirm our commitment to the [People's Charter for Health](#) and the [Cuenca Declaration](#) which are the foundational documents to this Call to Action.

This Call to Action will guide our work until the fourth People's Health Assembly is held.

Our Alternative Vision

Our alternative vision is idealistic. We seek a better world. We believe that transformative and radical change is required and can be achieved. Our vision consists of a number of inter-related dimensions:

- A new economics
- New economic systems
- A more just and democratic set of political and economic processes and institutions
- Better global health governance
- Equitable and Public Health Systems.

Specifically, in the arena of global health governance, our vision would see a more coherent and accountable system of governance that would be free from corporate influence and the influence of unaccountable private actors. This would include a radical rationalization of the multiple GHPs and funds that would be replaced with new and more accountable mechanisms for the management and allocation of global public finance would need to be established, working with and through UN institutions. WHO must follow its constitutional mandate to act as the directing and coordinating authority for international and global health must be fully and adequately funded by assessed and untied contributions from sovereign nations accountable to countries and the people of the world.

What is to be done?

This call to action is directed to all delegates of the third Peoples Health Assembly and their fellow health and social activists from across the world.

Power to People; Building the Movement

No change will happen without the mobilization of the people. Power will not be given to the people unless we force it out from the political, corporate and financial elites; and hold our public institutions accountable and make them work in ways that are transparent and truly representative and that serve the public interest and social justice. All this requires the building of social and political power amongst people and communities.

The third PHA has celebrated the successes of the growing People's Health Movement especially in terms of the growth of new PHM country circles in Africa. While we are a movement focused on health and built mainly around health activism, we share many similar goals with other social movements that are also seeking a more just and sustainable world. In order to diminish the power of financial capital; democratise governance; and defeat neoliberal economic policies, we will need to build a more effective and broad-based social movement.

To this end, we will commit ourselves to building alliances with other movements and organisations who seek progressive and transformative change. PHM is in a unique position to build alliances across existing movements. These include the movements of informal and formal sector workers, the landless, indigenous peoples, women and youth. We need to build solidarity with those struggling against big dams, nuclear power plants, illegal mining and movements of people affected by hazardous working conditions. We need to work with the environmental justice movement. We will seek to encourage greater trans-disciplinary engagement with, amongst others, progressive economists, environmental scientists, lawyers, urban planners and political-social scientists.

We will leave Cape Town determined to:

- set up new PHM circles where they do not exist
- energise, broaden and deepen the work of PHM country circles where they do exist
- strengthen and develop the issue-based circles of the PHM

We will leave Cape Town with a renewed and reinvigorated global Steering Council that will facilitate the building of our health movement. Our Steering Council will improve communication within the movement, facilitate effective coordination across the movement, and ensure organic linkages with regional and country circles. This should include facilitating the recruitment and support of PHM outreach workers to assist the development of the PHM in countries and regions.

We will strive to foster and develop community based struggles, campaigns and advocacy initiatives from local to national and global levels on multiple fronts, to develop the health movement in the coming phase.

Creating and communicating alternative visions, analyses, discourses and evidence

We recognise that the neoliberal orthodoxy and the vested interests of the rich and powerful are heavily represented in the mainstream media. We recognise the power of the mainstream media and corporate propaganda in shaping prevailing views and attitudes, and sustaining the belief that there is no alternative to the current political and economic systems.

We recognize that many scientific journals and institutions of education and knowledge generation act to legitimize and sustain the current system. We recognise the lack of investment in research, monitoring and surveillance that would serve the interests of the poor and promote the global social justice and equity agenda.

To this end we will leave Cape Town and commit to:

- communicating alternative visions, analyses and discourses to the people, using a wide variety of media and communication techniques, especially those that engage people creatively.
- using the Global Health Watch as an instrument to communicate an alternative progressive analysis of the state of global health and critiques of the current institutional framework for global health. We will work to improve the dissemination of the contents of the GHW in other languages; other mediums; and to a greater diversity of audiences. We will create and establish local and national health watches.
- expanding and extending the reach of the IPHU as a means of education, empowerment and mobilisation expanding processes such as community based monitoring for ensuring health system accountability and community oriented action research.

Organising and planning to make change happen

To make change happen, movement building and alternative analyses must be translated into concrete campaigns and projects. Local and national actions can only be planned and organised at the local and national level. However, as a global movement, we will seek to actively support and facilitate campaigns, by

- providing information and facilitating the sharing of information on the international context and country experiences
- providing campaigning materials on issues of international priority
- liaising and coordinating between organisations in different countries working on related issues
- providing fora for sharing experiences
- supporting publicity for campaigns at the international level
- facilitating advocacy towards international organisations and Northern governments
- Implementing the right to health campaign.

In addition to supporting local campaigns, we will coordinate campaigns on global issues, seeking to ensure that they reflect the priorities, and are informed by the experiences, of PHM members globally. Such campaigns will include continuing work on: Democratising Global Health; WHO Watch and Supporting the Restitution of the WHO IPHU Global Health Watch.

To enable us to fulfil this role effectively, we will intensify our fundraising efforts, in order to strengthen the secretariat and increase the resources available for information, media and advocacy activities at the international level.

Sydney: APCNMP 2012 Workshop 8: Advertising and Promotion

Convenors: Ken Harvey (HAIAP Australia), Shila Kaur (HAIAP Malaysia); Rapporteurs: Edelina de la Paz (Philippines), Jared Hyams (Australia)

Background

Ethical promotion is a key building block of National Medicines Policy. As far back as 1967 the World Health Assembly expressed concern about improper pharmaceutical advertising. In 1988 the World Health Assembly adopted *Ethical Criteria for Medicinal Drug Promotion* which had been prepared by an expert group representing all stakeholders.¹ Member States were urged to take account of these criteria in developing their own national measures, and to monitor and enforce the measures they developed. In 2007, World Health Assembly Resolution WHA 60.16 (1)5 reiterated the need for governments, 'to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor promotion of medicines, and to develop and implement programmes that will provide independent, non-promotional information about medicines'.²

Workshop objective

- To share and record country experiences on pharmaceutical advertising and promotion directed to both consumers and health professionals. What is the current regulatory /self-regulatory system? Is it in accord with the WHO Ethical Criteria? Did WHA 60.16 have any impact? What monitoring is carried out? Is the system effective in deterring inappropriate promotion? If not, why not and what needs to be done (barriers, enablers and practical steps forward)?

Summary of key issues raised

It was agreed that the WHO Ethical Criteria for Medicinal Drug Promotion were still highly relevant to National Medicines Policy, especially rational drug use. Most countries had introduced legislation to prohibit advertising to the general public of prescription drugs and also medicines for certain serious conditions that should only be treated by qualified health practitioners. Some countries had pre-clearance mechanisms for pharmaceutical advertisements directed to the general public in some media, such as print and television, but not others such as the Internet. Industry self-regulation was commonly used to control promotion to health professionals.

Despite the above situation, workshop participants reported that unethical promotion continued to be serious problem in all countries. Systems to pre-clear advertisements to the general public usually lacked resources to look at the evidence supporting claims and failed to cover new media such as the Internet and cable TV. In addition, the global nature of the Internet meant that offending web sites (some of which promoted prescription drugs for purchase without a prescription) were often outside the jurisdiction of a particular country. Numerous channels available for promotion made monitoring difficult and complaint systems were often under-resourced, overloaded, slow and lacking in effective sanctions.

In addition, the promotion of vitamins, minerals, nutritional supplements, herbal and traditional medicines was increasing rapidly, often with claims that lacked evidence, yet criticism of these products was regarded as culturally insensitive in some countries and in others denigrated as merely a tactic by the medical establishment to maintain their monopoly on prescription pharmaceuticals. Concern about this issue in Australia has resulted in proposals for regulatory reform.^{3,4}

Self-regulation suffers from inconsistent industry codes, limited or no monitoring, reliance on complaints and relatively weak sanctions. In addition, industry codes often lag behind consumer and health professional views due to the absence of external stakeholders. Furthermore, industry codes did not apply to non-members who are often the worst offenders. To address these problems an Australian government working group recommended that all self-regulatory Codes should encompass specific operational and governance issues; including education, independent monitoring of code compliance (not just relying on complaints) and sanctions that deter non-compliance. In addition, the group recommended that compliance with an industry code should be a condition of marketing approval. That recommendation was rejected by government. It wishes to evaluate the effectiveness of voluntary Code registration.⁵ The limitations of this approach were shown recently when Ranbaxy Australia (who is not a member of an Australia self-regulatory industry association) declined to have a complaint against it heard by the Generic Medicines Industry Association.⁶

¹ <http://apps.who.int/medicinedocs/en/d/Js16520e/16.1.html>

² http://apps.who.int/gb/ebwha/pdf_files/WHASSA_WHA60-Rec1/E/reso-60-en.pdf#page=27

³ <http://www.anao.gov.au/Publications/Audit-Reports/2011-2012/Therapeutic-Goods-Regulation-Complementary-Medicines/Audit-brochure>

⁴ <http://www.tga.gov.au/pdf/media-2011-tga-reforms-111208-a.pdf>

⁵ Australian Government. Working Group on Promotion of Therapeutic Products, 2011.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation:+Position+Paper+on+the+Promotion+of+Therapeutic+Goods>

⁶ <http://theconversation.edu.au/companies-tussle-over-market-share-for-anti-cholesterol-drug-lipitor-and-its-generic-equal-7088>

Other problems noted with self-regulation include arguments over whether certain activities should be permitted. These include product specific media releases, starter packs, product familiarisation programs, disease awareness advertising, patient support programs and company provided 'ghost writers', 'education', gifts and hospitality. While some countries such as Australia had well developed systems of providing independent information for health professions and consumers⁷ others largely left this task to the pharmaceutical industry who were a major funder of health professional activities. In some countries, pharmaceutical representatives were allowed unrestricted access to hospital doctors. There was also concern about undisclosed industry support for 'key opinion leaders' (including their slide preparation) and support for full disclosure by industry of all payments (in cash or kind) to health professionals, their organisations and consumer groups along the lines of the U.S. Physicians Sunshine Act (2010).⁸

Self-regulatory codes in developed countries have been strengthened over time and some unethical promotional practices that were once common are now less so. However, major problems were reported from developing countries. In China, it is common for pharmaceutical and medical equipment companies to pay kickbacks and bribes to doctors and hospital staff to boost product sales.⁹ In India, brand reminders are increasingly being replaced by gifts of greater value. These range from jewellery to electronic items such as air conditioners, washing machines, microwaves, cameras, televisions, and even automobiles. Printed handouts are distributed by companies giving targets for doctors, with incentives like a cell phone handset for prescribing 1,000 tablets, an air cooler for prescribing 5,000 tablets and a motorcycle after 10,000 tablets were prescribed.¹⁰

Key barriers to improvement

- Tension between 'creative' promotion to increase sales and provision of ethical information, eg pharmaceutical representatives are usually paid bonuses related to sales volume, not for achieving rational (quality) use of medicines.
- Monitoring advertising and promotion is large task, difficult and time consuming, especially evaluating the evidence for claims made.

⁷ <http://www.nps.org.au/>

⁸ <http://sunshineact.blogspot.com.au/>

⁹ Yang Z, Fan D. How to solve the crisis behind Bribe-gate for Chinese doctors. The Lancet Vol 379 January 21, 2012, e13.

DOI:10.1016/S0140-6736(11)60137-2.

¹⁰ <http://indiacurrentaffairs.org/industry-doctor-nexus-under-the-scanner-amit-sen-gupta/>

- Difficulty in enforcing regulations; requires easily applied civil penalties.
- Availability of drug advertising in more and more channels, cable TV, online, etc.
- Industry opposition, industry pretending to comply.

Key enablers

- WHA resolutions seen as a call to action
- Funding research on advertising legislation / regulations / Codes and industry compliance
- Developing ethical frameworks in conjunction with industry and health professionals (takes two to tango). For example, the U.K. ABPI collaborative guidance document¹¹
- Underpinning Codes by regulation / legislation (marketing approval requires agreement to comply with a code; non-compliance results in product removal from the market)
- Using regulations rather than legislation
- Working with regulators in other countries and Interpol (Internet)
- Informing the public about complaint mechanisms, violations and sanctions applied
- Making CME independent of drug companies (speaker(s) and topic chosen independently)
- Advising / educating consumers not to buy medicines from the internet.

Steps to address barriers and enablers

- Strengthening pre-approval process and /or monitoring systems of drug advertising
- Increasing powers for enforcing laws and regulations with sanctions that bite
- Providing independent, objective information to health professionals and public

HAI, in collaboration with the WHO, has drafted a manual for the critical appraisal of promotion and also a methodology to assess individual country regulatory controls.¹²

How to monitor progress in implementation

- Monitor industry sponsored CME; advocate for independent arrangements
- Use HAI indicators of successful regulation, advertising laws (country survey)
- Monitor regulators and industry activities
- Track complaints and sanctions applied.

¹¹ <http://www.abpi.org.uk/our-work/library/guidelines/Pages/collaboration-guidance.aspx>

¹² http://www.haiweb.org/03_other.htm

Feature: Solomon Islands - Upscaling the use of Zinc Sulphate in management of diarrhoea

Michael Nunan, Jayms Faneagalo, Michelle Pirpineas¹

Background

Despite a strong body of evidence supporting its use in children with diarrhoea, the availability of Zinc Sulphate remains low across the Pacific region.

The Solomon Islands introduced Zinc Sulphate 20 mg dispersible tablets onto the national Essential Medicines List in 2009 but anecdotal evidence suggested it was not widely available at the Primary Health Care Level and was not being used. The National Pharmacy Services Division sought to examine this and undertake interventions to improve both the availability and knowledge of Zinc Sulphate amongst Primary Health Care workers.

It was determined to start this with a pilot project in the Western Province of Solomon Islands.

Methodology

A survey was written by the Pharmacy Services Division, the Child Health Program and the Nutrition Department of the SI Ministry of Health to examine indicators for health worker's comprehension of Zinc Sulphate and ORS use in children with diarrhoea; and to examine actual availability of the agents.

Twenty of Western Province's 45 facilities were randomly selected for a baseline data survey in September 2011. One nurse from each clinic was interviewed and one clinic was not open (N = 19)

Following the initial survey, the Pharmacy Services Division undertook a series of low-cost interventions (see Box page 7) to improve availability and knowledge of the agent across Western Province over a period of six months to March 2012.

Twenty further clinics were then randomly selected from the remaining 25 for follow-up in April 2012. Three of these clinics were not open during the survey (N= 17).

Comprehension was measured by a series of questions about Zinc Sulphate; the correctness of answers was determined by the touring Pharmacist and all answers were recorded for verification. Availability was measured by a physical stock-check in clinics. Zinc Sulphate was recorded as being 'available' if stock was physically available in the clinic at the time of survey.

A qualitative survey was carried out in five additional facilities in December 2011 to assess comprehension of the training materials being disseminated. Using the results of this survey, the training and promotional materials were adjusted and continued to be rolled out.

Results

Comprehension

Knowledge of what Zinc Sulphate is used for increased from 16% to 88%. All other indicators of comprehension also increased.

Availability

The availability of Zinc Sulphate in clinics increased from 0% to 65%. All stock was recorded as being in date. The availability of ORS increased from 84% to 88% but there was an increase in the number of clinics holding expired stock at the time of follow-up; this suggests problems in the Supply Chain.

Implications

We have demonstrated it is possible to increase the availability and comprehension of Zinc Sulphate for use in children with diarrhoea, with a series of low-cost, contextually appropriate interventions. This pilot study will now be rolled out across all provinces; further work may also focus on all 30 WHO Priority Medicines for Mothers & Children. This work is likely to be reproducible in similar settings across the Pacific but more methodological rigour is needed in larger studies.

We believe that these low-cost interventions, which incorporate patient education simultaneously with staff education and supply chain mechanism improvements are more effective and considerably less expensive than staff workshops, which are often used by vertical programs and external agencies. More research is needed in this area.

¹ Solomon Islands Ministry of Health and Medical Services

Comprehension Indicator	Baseline N = 19	Post-intervention N = 17	Change
What is the main indication for Zinc in children?	16%	88%	+72%
What is the benefit of giving a child Zinc for diarrhoea?	5%	65%	+60%
What is the benefit of giving a child ORS for diarrhoea?	89%	94%	+5%
Can Zinc be taken at the same time as ORS?	11%	82%	+71%
Should the child be given less ORS if they are being given Zinc?	11%	18%	+7%
What is the recommended dose of Zinc in diarrhoea?	5%	35%	+30%
What is the duration of Zinc therapy in diarrhoea?	0%	65%	+65%
Where can you check the dose and duration of treatment for Zinc?	84%	88%	+4%

Feature: Sri Lanka - Promoting pharmaceutical health: A novel method

Manuj Weerasinghe

The western medical system is the mainstay of healthcare in Sri Lanka at present. Hence, medicinal drugs take a centre stage. Medicines are given free of charge at the point of delivery in state institutions. In addition, there are over 8,000 private retail pharmacies catering to the public. However, Sri Lanka has a severe shortage of pharmacists, particularly in the private sector. Unqualified personnel are dispensing medicines in many of those pharmacies. Adding to the problem, we still do not have a national medicinal drug information centre.

These circumstances invariably lead to potential misuse of medicinal drugs. Hence, public education of rational use of medicines is seen as an urgent need.

The objective of this study was to try out a new method to disseminate information on rational use of medicines through school programs.

Rational use of medicines as part of the school science program

As a pilot project the author utilized Science Day programs organized by the Sri Lanka Association for Advancement of Science between the years 2009 and

2011 to include an interactive session on Rational Use of Medicines as an intervention. The audience was school children between the ages of 14 and 16 years and their teachers. Brief messages on proper use of medicines were delivered in an interactive way by the author. After the session students were asked to talk on different topics given on rational use of medicinal drugs. Successful candidates were rewarded with educational material. At the end of the program brief discussions were held with participants to elicit their perceptions on rational use of medicines.

Brief interviews held after the session with students and teachers revealed interesting facts.

A PILL for every ILL was the norm among them before the session; afterwards they became aware that this was not the case. The concept of generic vs brand medicines was totally new to them. They requested more information on commonly used medicines and their generic names. Students learnt about price differences between generic and branded products and how to effectively reduce cost when buying medicines. They understood the importance of asking questions about medicines from the prescriber during a

consultation and the need to break the hierarchical barrier in order to receive better care. They suggested the need for inclusion of basic knowledge on Rational Use of Medicines in the school curriculum.

Conclusion

It was found that inclusion of Rational Use of Medicines in school programs was seen by participants as a positive step. They showed enthusiasm to learn more. Hence, this approach could be a strategy for pharmaceutical health promotion in the community.

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News from the region

Pacific Island Countries: Implementing National Medicines Policies

Melenaite Mahe: Kingdom of Tonga

At the Asia Pacific Conference on National Medicines Policies in Sydney, May 2012, Melenaite Mahe from Tonga presented a summary of the pharmaceutical situation in the independent Pacific Island Countries. The countries include Cook Islands, Federated States of Micronesia (FSM), Fiji, Kiribati, Marshall Islands, Nauru, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu.

Characteristics of Pacific Island countries (PICs)

- Countries are geographically far from the suppliers
- Transport problems between suppliers and the states are significant between and within countries due to isolation and widely dispersed islands/population
- Human resource capacity is limited

- There are no local medicines manufacturers (import only)
- Purchase is through open/negotiation/restricted tenders
- Some countries are in the process of developing medicine registration (Fiji, PNG, Tonga)
- Quality of medicines is guaranteed through purchase from prequalified suppliers
- Private pharmaceutical sector is almost non-existent
- Health services including medicines are free of charge to populations (a flat rate of 3-5 USD per prescription in some countries)
- Annual income is low
- There is heavy reliance on remittances

The story of NMP in the Pacific

- PIC Health Ministers Meetings (1995,1997,1999, 2009) stressed the need for strengthening PIC pharmaceutical sector
- First NMP in the region was by Tonga (2000)
- Currently 14 PICs have developed and/or drafted or reviewed NMP

NMP objectives: Access and availability of good quality essential medicines/universal access

History and features of Tonga NMP

- First list compiled in 1982 for Pharmaceuticals – Standard Drug List
- Health Reform in 2000 - new initiative of the new Minister of Health at the time
- Inclusion of Pharmacy Services as a priority area
- NMP - 2000
- Pharmacy Legislation
- Assessment of the pharmaceutical sector and household survey
- Standard Treatment Guidelines.

Progress in the Pacific Island Countries

- National procurement and supply systems are reviewed and necessary actions taken
- A computerized inventory management system has been introduced and strengthened
- Supply management guidelines/ SoPs/ training manuals have been developed
- Supervisory visits to outer islands and health facilities have been undertaken
- Capacity building on drug supply management etc. has been undertaken.

- Review of inventory system in Palau achieved
- Review of supply management guidelines in Kiribati
- Medical Store Extension, Solomon Islands.

Availability?

- Percentage of essential medicines stock-out dramatically decreased in Palau (0% in 2010)
- All 15 key indicator essential medicines were available in CMS, Tonga. Availability of the 15 key EM was 92% in the surveyed health facilities (Tongan Level II assessment, 2008)
- PSM improved in many PICs (Tuvalu, Kiribati, Cook Islands, Nauru, FSM.)

Affordability?

- Participation in the Regional Information Sharing Network enabled the Price Information Exchange
- Review of pharmaceutical expenditure including NCD medicines was completed.

All medicines are obtained free-of-charge in the public sector. User pay, co-payment, insurance, and other forms of payment are under consideration. Medicines insurance coverage for acute and chronic conditions is practically nonexistent given the widespread availability of public services.

Other indicators of progress in the Pacific

- Medicines are procured from prequalified suppliers
- Medicines legislation development and review has been achieved in several countries
- Pacific network - DIEFPIC (Drug Information Exchange for Pacific Island Countries) enables easy communication between PICs
- STG and EML have been developed and updated in most of PICs
- Drugs and Therapeutic Committees have been established or reactivated
- Public education on rational use of medicines has occurred in a number of countries
- Antimicrobial and medicines use studies have been undertaken.

The EC/WHO Collaborative Project 'EC/ACP/WHO Partnership on Pharmaceutical Policies' has made a great impact on the pharmaceutical sector development in Pacific island countries

Challenges

- Other MoH priorities supersede need for NMP to be spearheaded
- Legislation needs review and update

- Funding support is needed for implementation
- There is lack of manpower with necessary skills while staff changeover is frequent.

Conclusions

- PICs have made significant improvements in the pharmaceutical sector
- Tailor-made assistance is required to meet each country's needs
- Human resource capacity building in specific areas of NMP implementation is needed
- NMP and its implementation plan should be aligned and linked to Health Strategies and National development plans
- Additional vertical and donor programs must be integrated with national plans and programs
- There is need to strengthen Monitoring and Evaluation of NMP implementation.

India: Big Pharma in legal battles for monopoly prices

Source: Hans Lofgren, School of Humanities and Social Sciences at Deakin University, Australia.

The Conversation. 5 June 2012

<https://theconversation.edu.au/big-pharma-in-legal-battles-for-monopoly-prices-in-india-4472>

[Copied as fair use]

Two large multinational pharmaceutical companies are fighting for patents and monopoly pricing in Indian courts. The outcomes of the cases – involving Novartis and Bayer – are likely to determine the country's future as a major global supplier of low-cost essential medicines.

India is the third largest manufacturer (by volume) of drugs, and produces about 10% of drugs consumed across the world. The rise of domestic firms was made possible by India's abolition of product patents for pharmaceuticals in the Patents Act of 1970 (which came into effect in 1972). Only patents for processes were recognised for a maximum of seven years. This was to encourage the development of a domestic drug industry and the supply of more affordable medicines. The result was a spectacular rise of Indian firms over subsequent decades.

Family-owned companies such as Cipla, Ranbaxy and Dr Reddy's (often in collaboration with public sector research organisations) developed alternative processes for manufacturing a wide range of pharmaceutical raw materials and generic drugs (alternatives to the originator brands).

Large multinationals' monopoly on supply of critical HIV antiretroviral drugs, for instance, was first broken by Cipla in 2001, when it commenced supply to developing countries for \$350 per annum per patient. The multinational drug companies had charged more than \$10,000 per patient per year.

Today, the same drugs are available for about \$150 for a year's supply. Indian manufacturers supply more than 80% of the HIV medicines used to treat millions of people in developing countries, as well as generics to treat many other diseases.

Most people in India cannot afford expensive drugs.

India's approach to TRIPS

The 1995 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) created a new era of globalised intellectual property rights. TRIPS gave developing countries, such as India, a ten-year transition period before patents had to be introduced in all product categories. (The least developed countries must be fully TRIPS compliant by 2016).

Indian firms are allowed to continue production of drugs marketed before 2005, but can no longer produce generic versions of medicines patented in India after 2005 (unless voluntarily licensed by the originator company). This will result in high monopoly prices for many more years for new products, including second- and third-line AIDS medicines, unless countermeasures are taken in the interest of public health.

TRIPS triggered a global struggle between public health advocates and some developing countries, and the big pharmaceutical companies backed by the United States and the European Union. Much of this conflict revolves around the public health safeguards contained in the TRIPS Agreement. These were confirmed and extended in the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

Legally, World Trade Organisation (WTO) member countries have significant leeway in their interpretation of TRIPS. But most countries do not effectively use these options to lessen the impact of patents on affordable access to essential medicines.

India has used them more extensively than probably any other country with its Patents (Amendment) Act, 2005. Two of the safeguards in Indian legislation relate to definition of patentability and compulsory licensing.

Novartis' challenge

Now, Swiss drug multinational Novartis is spearheading a global industry campaign against India's utilisation of its right to public health safeguards. Indian legislation contains a section intended to prevent the awarding of patents for slightly modified versions of known molecules, unless a 'significant enhancement of efficacy'

can be demonstrated. This measure is intended to prevent 'evergreening', the extension of monopoly pricing through patenting of trivial modifications.

Novartis' challenge centres on the anti-leukaemia (blood cancer) drug imatinib mesylate, marketed by Novartis as Glivec (or Gleevec), which has global sales in excess of \$4bn. In 2006, the Indian patent office rejected Novartis' application for a patent on Glivec on the grounds that it's a slightly modified version of a known molecule.

The original patent on imatinib mesylate dates from 1993, and the product has long been produced and marketed in India by local companies. Novartis charges Rs120,000 (about US\$2,400) for a month's supply, which makes this drug unaffordable to more than 99% of the population. Several Indian manufacturers sell the same drug for Rs 8,000 (US\$160), 1/15th of Novartis' price.

Novartis has pursued its case through India's legal system since 2006. It has now reached the Supreme Court where final arguments were set to commence on 10 July. [The Gleevec case was postponed (from 10th July) and shall come up again in September]. If Novartis is successful, no other brands of imatinib mesylate can be supplied in India or exported from India.

What's more, a victory for Novartis will open the floodgates for patent extensions on many well-established medicines, to the detriment of patients in India and throughout the developing world. Novartis' stance has garnered a strong reaction from public health activists and NGOs in India and around the world.

Bayer and compulsory licensing

The second recent development of great importance is the granting of India's first compulsory licence for production of a drug. A compulsory licence authorises a third party to manufacture and sell a product without the consent of the patent holder, in return for adequate compensation.

Multinational drug companies put strong pressure on developing countries for compulsory licenses to only be considered in circumstances of national emergency.

It is, however, clear in Article 31 of TRIPS and in the 2001 Doha Declaration that countries are free to determine 'any and all grounds upon which CLs may be issued'. In fact, there is a long history of compulsory licenses for pharmaceuticals in Canada, the United Kingdom, Italy, and more recently in developing countries, such as Brazil, Thailand and Malaysia.

The United States and the European Union, on behalf of their pharmaceutical companies, have brought extreme pressure to bear on developing countries, through so-called free trade agreements and in other ways, to dissuade them from issuing compulsory licences.

A compulsory licence was issued on the grounds that Bayer's price for an anti-cancer drug was exorbitant.

On 12 March, 2012, the Indian generic drug company Natco Pharma was successful in gaining a licence for the production and supply of the patented anti-cancer drug sorafenib, marketed by Bayer as Nexavar. Bayer's version of this drug costs Rs 280,000 (A\$5,600) a month, an astronomical figure for almost all Indian households. Natco will sell the same drug at 3% of this price, while paying a license fee – and it will still make a profit.

The compulsory licence was issued essentially on the grounds that Bayer's price is exorbitant. It also does not manufacture the drug in India and imports in such small volumes that only a tiny fraction of potential patients could benefit.

The Indian Controller General of Patents, Designs and Trademarks concluded that the drug 'was not bought by the public due to only one reason, that is, its price was not reasonably affordable to them'. This decision in favour of Natco sets a very important precedent for possible compulsory licences on other patented products sold at unaffordable prices.

Bayer filed an appeal against the compulsory licensing decision on May 4 to the Intellectual Property Appellate Board but observers believe it's likely the decision will ultimately stand.

India is in a very special category within the global pharmaceutical sector because its domestic drug companies have unique technological capabilities. Although they are just as profit-oriented as firms in any other sector, Indian drug manufacturers have made it possible for millions of poor people to access essential medicines. For these gains not to be reversed, it's essential that Novartis loses its Supreme Court appeal, and that India's first compulsory licence is followed by many more.

India: Drug regulation in India-the time is ripe for change

[The Lancet editorial below points at a worrying state of affairs in India's drug regulatory authority (CDSCO). The parliamentary standing committee on Health and Welfare has issued a 118 page report which is available at:

<http://164.100.47.5/newcommittee/reports/englishcommittees/committee%20on%20health%20and%20family%20welfare/59.pdf>

One of the remarkable observations: '2.2 The Committee is of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO. For decades together it has been according primacy to the propagation and facilitation

of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder, ie the consumer, has never been ensured. Taking strong exception to this continued neglect of the poor and hapless patient, the Committee recommends that the Mission Statement of CDSCO be formulated forthwith to convey in very unambiguous terms that the organization is solely meant for public health.' Below the editorial comments from the Lancet - copied as fair use.]

The Lancet, Volume 379, Issue 9829, P. 1862, 19 May 2012

Drug regulation in India-the time is ripe for change

To say that India's drug regulatory authority, the Central Drugs Standard Control Organisation (CDSCO) - whose remit includes new drug approval, licensing of manufacturing facilities, and regulation of drug trials - is not fit for purpose seems a gross understatement.

A damning 118-page report from the Indian Parliamentary Standing Committee on Health and Family Welfare documents its successive failings. It describes a vast, geographically disseminated organisation that is dangerously understaffed: nine officers at headquarters deal with 20,000 applications, more than 200 meetings, 700 parliamentary questions, and 150 court cases per year.

There is also a dearth of medically qualified staff, poor support infrastructure, a seeming lack of coordination between departments, and a scarcity of decent computer systems.

It is therefore not surprising that, of 42 approved drugs randomly chosen for investigation by the Committee, some had not passed through the correct regulatory channels. But the fact that 11 had no phase 3 studies done, 13 'did not have permission for sale in any of the major developed countries', and there was 'no scientific evidence to show that 33 drugs are really effective and safe in Indian patients' points to problems at the very foundations of CDSCO. Its mission of meeting 'the aspirations, demands and requirements of the pharmaceutical industry', rather than the protection of patients, is a very shaky foundation indeed.

The Committee's report has several suggestions for improvement. However, rather than trying to overhaul an organisation that is failing so catastrophically, India should seize this opportunity to wipe the slate clean and form a new drug regulatory body. A smoothly running, professional drug regulatory body is essential to ensure, first, that high-quality, adequately assessed drugs are available to India's population and, second, that India's drug industry is regulated well enough to contribute successfully to India's domestic and export sectors. It should go without saying that whatever action India takes, the philosophy of the drug regulatory body should be the protection of patients, wherever they are.

Bangladesh: A Long History of National Medicines Policy: where are we now?

Dr Zafrullah Chowdhury, at the Asia Pacific Conference on National Medicines Policies, Sydney, May 2012.

Lessons from Bangladesh National Drug Policy 1982

We need to continuously educate physicians at Undergraduate and Postgraduate level to understand and remember the economics of cost-effective, affordable quality medicines for the people and the clever game of the pharmaceutical industry.

In April 1982 President H. M Ershad constituted an Expert Committee with Dr. Nurul Islam, Professor of Medicine and Director of Institute of Postgraduate Medicine and Research (IPGMR) and seven other members including the author to evaluate all drugs locally manufactured and imported into Bangladesh.

Key features of the 1982 decisions

The Expert Committee developed 16 simple criteria: 12 are medico-pharmacological and four are politico-economic. Important criteria are:

- Only single ingredient products to be recommended for easy quality assurance and evaluations of side-effects, adverse reactions and contraindications.
- Combinations not to be allowed except for few exceptional products such as ORS, B-complex, Iron- folic, cotrimoxazole etc.
- No cough mixtures, throat lozenges, gripe water, alkalies, tonics, enzyme digestive mixtures etc . These have little or no therapeutic value and create wrong impressions in the minds of the people.
- Big bottles of liquid vitamins and minerals not to be allowed. Only paediatric drops allowed in 15 ml bottles.
- Chemicals and galenical preparations not included in the latest edition of British Pharmacopeia and British Pharmaceutical Codex will be prohibited.
- Multinational companies (MNCs) allowed to manufacture all registered drugs except antacid and vitamins provided they have their own factories in Bangladesh. However, MNCs will be allowed to produce injectable vitamins because of higher technology required.
- No foreign brands will be allowed to be manufactured in Bangladesh under third party license.
- Imports will not be allowed if similar products are manufactured locally.
- Production of basic raw materials will be encouraged and be given protection.

- The Indian Drugs Act of 1940 will be amended to incorporate the control of manufacture and sale of Ayurvedic, Unani and Homeopathic drugs.
- It was recommended that a heavy penalty be imposed for possessing or selling stolen drugs from the government hospitals.
- Physicians should not own retail pharmacy. Registered pharmacists should own and manage retail chemist pharmacy shops.

Also established were:

- National Drug Control Committee for registration of drugs
- Price Control Committee for price fixing of formulation products and raw materials.

It was recommended that a Review Committee for hearing appeals be reconstituted with qualified professional representatives of manufacturers (**not owner**), medical faculties and consumer protection societies.

The Directorate of Drug Administration must be adequately strengthened with qualified human resources (Pharmacologists, independent financial analyst, health economists etc) to inspect periodically all manufacturing units and collection of samples for quality check up and detection of fake, spurious and substandard drugs.

Over 1700 drugs were banned and withdrawn

The total number of registered products both locally produced and imported from 122 foreign companies of 22 countries were 4340 of which 1742 were found to be harmful, inappropriately formulated or therapeutically ineffective. Out of 1742 harmful and / or ineffective drugs, 176 were imported and 949 were manufactured by 156 local manufacturers.

Capitalist countries had exported more ineffective, useless or harmful drugs than that of socialist countries. West German and Swiss Companies ranked very high in mischiefs.

Price Fixation Strategy

A drug is a special commodity, whose usefulness, safety and quality cannot be judged by the consumer even though they pay for it. To protect the consumer, the government will check and fix the price of all drugs manufactured locally and imported, giving a good return on the investment of the pharmaceutical industries

For Price fixation purpose, all available drugs locally produced and imported are placed in five categories:

- A. Simple repackaging without any processing or formulations.
- B. All oral medicines and topical preparations other than antibiotics.

- C. All oral forms of antibiotics
- D. Hormone and steroid preparations
- E. All sterile preparations.

Price Fixation Strategy

The cost of Raw Materials (RM) (both active ingredients and excipients) and Packaging Materials (PM) are based on landed cost, conversion of US Dollar to Taka, transport cost from port to factory, Advance Income Tax (AIT) and custom duties and other taxes. Value Added Taxes (VAT) is added after the fixation of Maximum Retail Price (MRP). Cost of RM and PM should usually be reviewed once a year. The suggested strategy entitled them double figure profit.

Changes followed 1984-94

- Drug Prices in Taka had fallen between 50% and 75% despite increase in Taka-Dollar conversion rate.
- Quality of manufactured drugs improved remarkably due to vigilance of Drug Authority.
- Drug market had enhanced from Taka 1000 million to over Taka 25000 million. Ten powerful national companies emerged.

National pharmaceutical companies had taken over 60% business from less than 20% business in 1981 - producing about 90% of Bangladesh's needs.

BAPI (Bangladesh Association of Pharmaceutical Industries) which condemned the NDP in 1982 congratulated Government in 1986 for helping the unexpected growth of pharmaceutical companies and improved quality control.

Situation in 2010:

Drug Price started rising

Success in domestic market and little export

- The pharmaceutical sector recorded sales of Taka 87 880 million (US\$ 1098 million) meeting almost 97% of local demand, growing 23.6% in term of sales in 2011 according to IMS report ¹
- 36 local companies and three MNCs had exported Taka 4212 million (US\$ 52.6 million) worth of medicines to 84 countries.
- Sales of herbal medicine had jumped to Taka 10000 million (US\$ 125 million) in 2010 against Taka 10 million in 1980²
- Allopathic doctors were found to be prescribing herbal medicines whose quality and appropriateness raised big questions.
- Drug prices started shooting up since early 2010 along with higher number of irrational and unethical prescriptions. Deaths in government hospitals and private clinic were reported in daily newspapers ^{3,4,5}

Unethical Promotions and Irrational Prescriptions

Unethical promotions by Pharma representatives led a sudden influx of unethical and irrational prescriptions.

Azithromycin is frequently used for diarrhoea by General Practitioners among poor patients without their informed consent by ICDDR,B ⁶ as promoted with unethical research.*

Pharma reps were bribing doctors directly⁷ and violated every norm to check doctors' prescriptions in medical college hospitals⁸

- Doctors write more prescriptions for nitazoxanide instead of metronidazole for amoebiasis and diarrhoeas; azithromycin for diarrhoea, typhoid and pelvic inflammatory disease (PID)
- Other misused drugs are caffeine with paracetamol, diclofenacs, statins, irrational vitamin preparations with all sorts of minerals which cannot be detected in Government Drug Laboratory; benzodiazepines, sex hormones, steroids, terbinafine, butenafine, crotamiton, etc
- Direct to Consumers promotion occurs through daily newspapers with a separate advertising sheet on Dukoral (a Swedish company, Crucell product) for prevention of diarrhoea and cholera, tactfully using names of WHO and ICDDR,B.

Counterfeit

Aggressive and unethical promotion increases irrational prescriptions leading to multiplication of profit of the companies. Counterfeit versions of costly drugs are progressively surfacing. More spurious and substandard drugs are freely moving into the market.

Why such reversal?

By 1994, some national pharmaceuticals achieved tremendous growth and invested their profit in other business for faster return. They became greedy and quietly bribed health ministry top personnel. A six member committee was constituted. The majority of members were well known for their opposition to NDP '82. A departmental order was passed on their recommendation in gross violation of the spirit of the NDP '82.

1. A list of 117 drugs (referred to as **Listed Drugs** should remain under existing price control regulation, 26 of 117 Listed Drugs were contraceptives, intravenous solution and vaccines.
2. Fast selling drugs such as cimetidine, ranitidine, diclofenac, cephalosporins, vitamins with minerals and newer drugs were **excluded** from the Listed Drugs.

*International Centre for Diarrhoeal Disease Research, Bangladesh.

3. Every manufacturer should ensure 60 % of drugs it produces are Listed Drugs.

4. To ensure sufficient production of Listed Drugs duties on unlisted drugs may be raised to 15%.

Clause 3 & 4 had never been enforced

5. Prices of drugs *not in Listed Drugs* will be fixed by pharmaceutical manufacturing companies themselves. This is called **Indicative Price** on which Drug Authority will add 15% VAT.

Profit for Indicative Price Drugs is enormous, while profit on listed drugs is reasonable but they are less than 10 percent of the indicative group. All committees were reconstituted with greater numbers of drug industry owner representatives.

On the other hand, the Medical Association is poorly represented - by only one junior teacher.

Drug Administration is allowing more and more combination drugs, all of which are in *indicative* Category.

Easy excessive profits made pharma companies reckless - making misleading statements that implicated the Dollar Taka conversion rate as a reason for increased price.

A continuous claim was that pharma exports will soon overtake garment exports. Present pharma export is not even one percent of total national exports. They also cleverly changed the mark-up system of 117 listed drugs.

The existing five categories were expanded to nine, to harness further profit from the **Listed group**

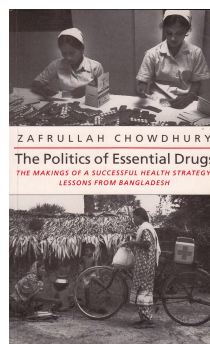
Some price comparisons of listed drugs and indicative priced drugs

Listed Drugs	Unit price	Indicative Price drugs	
Tab metronidazole 400 mg	Tk 1.20	Nitazoxanide 500 mg	Tk 10.00
Erythromycin 500 mg	Tk 8.00	Tab azithromycin 500 mg Inj azithromycin 500 mg	Tk 30.00 Tk 250.00
Ung Whitfield 25 gm	Tk 10.00	Terbinafine tube 5 gm	Tk 50.00
Benzyl benzoate lotion 100 ml	Tk 18.00	Crotamiton 60 ml	Tk 66.00
Tab paracetamol 500 mg	Tk 0.60	Tab paracetamol 500 mg + caffeine 65 ng	Tk 1.80
		Tab paracetamol 665 mg extended release	Tk 2.50

Teaching of clinical pharmacology and pharmaco-economics is of the utmost importance to protect people's health from the greed of the pharma industries.

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The full story has been documented by the author in his book 'The Politics of Essential Drugs - The Making of a Successful Health Strategy: Lessons from Bangladesh', Zed Press, London, 1995.

SI	Product	RM+PM	MARKUP	MRP without VAT
1	Repacking	100	50	150
2	Oral preparation except antibiotics and FP preparations	100	125	225
3	Antiviral, anti-infective, antifungal	100	130	230
4	Oral antibiotics	100	130	230
5	Sustain Release tabs/capsules	100	180	280
6	FP Pills	100	180	280
7	Dispersible tablets	100	200	300
8	Steroids & Hormones	100	240	340
9	Aseptic preparations	100	240	340

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