



December 2012

HAI AP News

Penang, Malaysia

Email: kaur_shila@yahoo.com Web: <http://www.haiasiapacific.org>

HAI AP Est. 1981

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

On 27 September 2012, HAIAP and the Asian Institute of Medicine, Science and Technology (AIMST) cemented links with the signing of a Memorandum of Understanding, allowing HAIAP's significant health and pharmaceutical resources to be housed in the AIMST library. AIMST will have access to HAIAP's considerable

expertise. AIMST is located in the northern state of Kedah which adjoins Penang on the mainland peninsula of Malaysia.

The event was further enhanced with the hosting of the HAIAP-AIMST *International Workshop on Prescribing in the 21st Century* at the School of Medicine, AIMST. Dr Ken Harvey and Dr Niyada Angsulee, as Chair and member of the General Council respectively, played key roles in the signing of the MOU and participation at the International Workshop.

Ken's wish to pass the baton of Chairpersonship of HAIAP was met with disappointment – the GC and membership voted that they want Ken to continue in this capacity - a clear indication of a winning leadership style and capability. Ken reiterated his wish to pass the baton of Chairpersonship of HAIAP but to-date no one else has volunteered.

We are at year's end and I have two wishes for the New Year: One is for HAIAP to enlarge its pool of expertise and resources through the recruitment of younger members into the HAIAP family; and two is for us to contribute time, ideas and expertise to fund raising. The current membership is greying but the issues loom larger than ever and if we are to continue, we need the energy, enthusiasm and empathy of like-minded younger folks. Between us, Dr Manuj Weerasinghe and I worked hard on a concept paper to WHO earlier this

year, without success, unfortunately. However, the process of developing the concept paper engendered rapport, cemented relationships and demonstrated care and support for the network. HAIAP needs you!

Happy New Year 2013!

Shila Kaur, HAIAP Coordinator

Future of WHO hangs in the balance

*David Legge - scholar emeritus
School of Public Health, La Trobe University, Bundoora,
Victoria 3086, Australia*

[An analysis of the current position of WHO by David Legge was published in the British Medical Journal in October 2012. Extracts are reproduced here as fair use. Readers are encouraged to read the complete article.]

BMJ 2012;345:e6877 doi: 10.1136/bmj.e6877 (Published 25 October 2012)

WHO is in crisis. Unless member states can be persuaded to 'untie' their donations and give the organisation leeway to control its budget and set priorities WHO will slide further into irrelevance with disastrous consequences for global health, warns David Legge.

Summary

A substantial shortfall in the funds available for basic administrative functions led WHO's director general, Margaret Chan, to initiate another reform of the WHO in 2010. Although the reform programme has expanded to include priority setting, governance, and management,¹ financing is the fundamental problem. The process of reform is also bedevilled by the same problem that led to the funding crisis in the first place — a switch in power from the assembly of member states to donors (including some member states as well as other donors) with specific interests. This article outlines the problems and what the reforms are trying to achieve.

When WHO was formed in 1948 its main funding came from its member states, who paid according to the size of their population and economy (their 'assessed contributions'),² but since its founding the large rich countries (the United States in particular) have sought to control WHO's agenda by restricting its funding.³ Since the 1980s assessed contributions have been frozen, and the WHO has become increasingly reliant on voluntary contributions from member states, intergovernmental bodies, and various philanthropists. Assessed contributions as a proportion of total revenues have declined from 80% in 1978-79 to 25% in 2010-11. The budgetary gap has been met through the growth in voluntary contributions, 91% of which are earmarked for particular projects and programmes. As a consequence,

WHO's work is controlled by the donors rather than by its assembly of member states, distorting priorities and the coherence of its programmes.

Success of the current reform programme depends on resolving the contradiction between member state priorities and donor control and requires the freeze on assessed contributions to be lifted. To achieve this, member states must be persuaded to prioritise global health over parochial interests.

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Dr Legge explored the challenges faced by WHO under the following headings

- *Global health crisis requires a strong and effective WHO*
- *WHO's budgetary and organisational disabilities*
- *Donor dependence*
- *Staffing*
- *Member state accountability*

He described Margaret Chan's Programme of reform

Margaret Chan's attempt to tackle these challenges is made doubly difficult by the fact that the reform programme suffers from many of the problems that need to be tackled. Some progress is being made in all areas, but financing remains the central issue. Chan made it clear in May 2011 that her preferred option would be increased assessed contributions.⁸ Once it became clear that this was not going to happen in the short term, her fallback position has been 'stable and predictable financing.' She has urged donors to untie their donations — or at least to tie them at the highest level of budgetary allocation — to give the organisation greater flexibility in responding to the agenda of member states. In fact, four of the top 10 member state donors (US, Japan, Canada, and France) do not give any untied voluntary funding.⁹

As this was also met with a lack of enthusiasm she has argued for a more cooperative, transparent, and centralised process for negotiating funding for the priorities agreed by member states. She has proposed various organisational models for achieving this objective, the latest of which is a 'funding dialogue.' However, member states are concerned that this will institutionalise the control of the donors. Particularly controversial at the May 2012 World Health Assembly was the timing of the funding dialogue in relation to the meetings of WHO's governing bodies. At present the funding dialogue is scheduled for the first quarter of the calendar year, after the January meeting of the executive board and before the World Health Assembly in May. Under this arrangement the executive board will adopt a draft budget in January, and donors will then be asked to fund various elements. The outcomes of this funding dialogue will then come to the assembly in May, where member states will be invited to accept the

budget as funded (or adopt a different, unfunded, budget).

How is WHO funded?

- WHO's main budget is funded through mandatory assessed contributions by member states and voluntary contributions (from member states, other intergovernmental bodies, and private foundations)
- Assessed contributions, the spending of which is untied, totalled \$945m (£590m; €734m) in 2010-11. The amount paid is based on a country's population and GDP using a formula fixed in 1982
- Voluntary contributions comprised around \$2898m in 2010-11, of which \$248m was untied and \$2649m was earmarked for projects chosen by the donors
- The five member state donors making the biggest voluntary contributions in 2010-11 were the US (\$438m, 100% tied), UK (\$289m, 84%), Germany (\$189m, 100%), Canada (\$182m, 100%) and Norway (\$114m, 58%)⁷
- The proportion of WHO's revenue gained from assessed contributions has fallen from 80% in 1978-79 to less than 25% in 2010-11¹¹

Assessed contributions are drawn on to supplement funding provided through donor grants because many donors refuse to pay the full cost of overheads

The formula for assessed contributions, which WHO can spend as it wishes, has been frozen since 1982 (box) after US opposition to WHO's essential drugs policy^{4, 5} and the code for the marketing of breast milk substitutes.⁶ As a result, WHO is now largely dependent on voluntary contributions, earmarked for specific purposes, from a variety of state and non-state donors. This makes it hard to follow the agenda of the member states, as expressed at the World Health Assembly.

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Member states who oppose increasing assessed contributions or the untying of their donations advance two main arguments: firstly, that WHO needs to attend to problems of efficiency and effectiveness before funding is revisited and, secondly, that WHO should live within its means through better priority setting. The paradox is that the shortfalls in efficiency and the problems of programmatic incoherence are largely the consequences of the donor chokehold.

While priority setting has been a leading theme in the discussions of reform, a robust methodology for doing so is lacking.¹⁰ The director general has promised that the 'cross cutting issues' (social determinants, gender equity, human rights, and primary healthcare) will not be neglected, but no clear procedures have been advanced for ensuring this or for working across silos generally.

The reform package (box) is at its weakest in relation to member state accountability. Indeed, the concept has not been identified as a problem in any of the official papers prepared by the secretariat. However, there have been some minor initiatives directed at streamlining discussion at governing body meetings and providing better briefings for member states.

Elements of reform¹⁰

- Funding dialogue—a more cooperative, transparent, and centralised process for negotiating funding for member state determined priorities plus an appeal to donors to untie their donations
- Priority setting—new categorisation of programmes and a new approach to priority setting based on the problems identified in country cooperation strategies
- Governance reforms—includes a review of the sequencing of governing body meetings; aligning the work of regional committees more closely with that of the executive board; harmonising the procedures of regional offices; streamlining governing body meetings; and clearer policy development around relations with stakeholders
- Managerial reforms — includes staffing practices, clearer conflict of interest policies, improved evaluation, and a more strategic approach to public relations

The article ends with exploration of the role of civil advocacy

Civil advocacy

There is no clear endpoint that would define the completion of the reforms. Some progress will be made on some of the issues. Debate will continue on others. Currently, the regional committees are meeting and discussing the full reform package. In early December there is a closed meeting of member states to further consider reform in the budget process. However, there is a serious risk of stalemate. If member states are not willing to address the root problem of donor dependence and lack of flexible finance, WHO will slide further into irrelevance, with disastrous consequences for the global health crisis. Paradoxically, the unnamed disability — the lack of accountability of member state representatives and the limited engagement of civil society in holding WHO to account — may provide the most promising strategy for driving successful reform. Public health advocates need to make rich countries accountable for privileging corporate interests over global health. In low and middle income countries governments must be persuaded to agree in advance to increasing assessed contributions so that their representatives can speak with authority regarding the

need for adequate untied funding. Organisations such as WHO Watch (www.ghwatch/who-watch), which has been working to build stronger links between international decision making at WHO's governing bodies and grassroots networks addressing local and national needs, could help to strengthen WHO and member state accountability.

1 WHO Director General. A65/5 WHO reform. 2012. http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_5-en.pdf.

2 Farley J. Brock Chisholm, the World Health Organization and the cold war. UBC Press, 2008.

3 Godlee F. WHO's special programmes: undermining from above. *BMJ* 1995;310:178-82.

4 Godlee F. WHO in retreat: is it losing its influence? *BMJ* 1994;309:1491-5.

5 Laing R, Waning B, Gray A, Ford N, Hoen Et. 25 years of the WHO essential medicines lists: progress and challenges. *Lancet* 2003;361:1723-9.

6 Walt G. WHO under stress: implications for health policy. *Health Policy* 1993;24:125-44.

7 WHO. Voluntary contributions by fund and by donor for the financial period 2010–2011.

8 WHO Director General. A64/4 The future of financing for WHO. 2011. <http://apps.who.int>

9 WHO. Financial report and audited financial statements for the period 1 January 2010 to 31 December 2011. http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_29-en.pdf.

10 World Health Assembly. WHA65(9) WHO reform. 2012. http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_DIV3-en.pdf.

Feature: The MARVI Workers of HANDS In Pakistan

Compiled from information provided by the Health and Nutrition Development Society (HANDS), Pakistan, a HAIAP member organisation

HANDS was founded by Prof. A. G. Billoo (Sitara-e-Imtiaz) in 1979. HANDS has evolved over 33 years into one of the largest Non Profit Organizations of the country based on the integrated development model. It has a network of 29 offices across the country and has access to more than 25 million people in nearly 42000 villages / settlements in 29 districts of Pakistan. HANDS strength is 15 volunteer Board Members, 12 Districts Patrons, more than 1400 full time staff and more than one million community based volunteers covering 3531 medium and small size organizations. HANDS is certified by Pakistan Centre for Philanthropy (PCP) and tax exempted by the Income tax department of government of Pakistan. It has met the qualifications of the Institutional Management Certification Program (IMCP) of USAID for management standards and is accredited with the European Union; and is a member of the Humanitarian Accountability Partnership (HAP).

HANDS has developed 19 policy manuals which include Operation, Finance, Human & Institutional Development, Human Resource Management, Social Mobilization, Social Marketing, Disaster Management, Health Promotion, Social Protection, Monitoring Evaluation & Research, Resource Mobilization, Education & Literacy, Information Technology, Information Communication Resources and Advocacy, Knowledge Management, Infrastructure Development Energy, and Water & Shelter, Gender And Development, Livelihood Enhancement and Suggestion and Complaints (Whistle Blowing).

The April 2012 issue of HAI News described the role of HANDS in the response to the floods in Pakistan in 2010 and its rehabilitation and reconstruction activities.

The HANDS TAMEER (The Appropriate Measures For Early Recovery and Early Rehabilitation) strategy focused on family and village holistic development, transforming 1000 villages into model villages, in collaboration with 14 Union Councils and 50,000 families: building houses; developing small businesses; reviving live stock activities; constructing village streets, water channels, roads; installing hand pumps and drainage; and strengthening health and education services. The strategy included MARVI workers - women who provide the link between communities and the HANDS Primary Health Care program.

In this edition we highlight the role of the HANDS MARVI Workers.

Marginalized Area Reproductive Health Viable Initiative (MARVI)

HANDS recognised that there were women who remained marginalised and cut off from the PHC services. In addition there were areas with no Lady Health Workers (LHWs) – the community health workers who provided the crucial links between the Primary Health Care program and the community. There was a need for another level of health worker to ensure links with marginalised women and to support their access to the PHC program. The concept of MARVI workers was born.

Case study

Kumari, lives in a remote desert village named Sadoori in district Umarkot, Sindh Pakistan. She is a housewife with three children. Her husband Mithan is a driver. Her family income is so limited that most of the time they sleep on an empty stomach.

Her life was limited only to her family and household chores, cooking, fetching water for home, etc., and when she got any time, it was spent gossiping with neighbourhood women. One day a few NGO workers came into her village. They introduced themselves as NGO workers from HANDS and explained the purpose of their visit.

The HANDS team visited the village again and initiated the formal process of formation of men's and women's organizations. The team asked them to nominate a few women to interview to work as Health Worker and few Dais. Finally Kumari was selected by the committee for the health worker position along with Dai Kari. Later HANDS workers trained her for the role of Community Health Worker and Dai Kari in exclusive Trained Traditional Birth Attendants Training.

Kumari became a MARVI worker after getting this training and she feels that Dai Kari and she can bring lot of change in women's lives of her village. She started her work as per her assigned job, to register married childbearing age women, pregnant women, and children under 3 years old of the village with the assistance of Dai Kari. The HANDS Lady Health visitor started visiting her regularly and assisting her to verify the cases for contraceptives, and for referral of high risk women and malnourished children.

This model works on the same pattern as the Lady Health Worker (LHW) model where the health worker has a static centre at her residence and makes home visits as well for service delivery. LHWs are mostly young women, from the local communities, with at least eight years of formal schooling, trained for 15 months to deliver care in community settings and be responsible for a population of about 1000–1500 providing general preventive care and advice, antenatal care, contraceptive advice, growth monitoring, and immunisation services as well as simple therapeutic services and referrals.

Like the LHW, the MARVI worker is supported by a health committee and women's group - voluntary boards formulated by her for assistance in providing health services in the target area. Each health worker is assigned an approximate population of 1000 and is named as 'MARVI' worker.

The objectives of this model are to improve Reproductive Health and Family Planning status in marginalized communities of the country and to provide basic health services in non-LHW areas.

Establishment of MARVI and support for the program

- Identification of a MARVI worker by the Community Based Organization (CBO) following initial nomination and interview together with the HANDS team.
- Signing of Memorandum of Understanding (MoU) with CBO and MARVI.
- Training of MARVI
- Establishment of MARVI Markaz (Health House).
- Supplies to MARVI - Equipment and essential medicines and social marketing products

- Initiation of health services including home visits and health awareness sessions
- Monitoring and supervision
- Monthly meeting with HANDS and CBO for progress sharing
- Development of Monthly Progress Report (MPR)

The Services Provided by MARVI include:

- Mobilization of pregnant women for antenatal services
- Mobilization of pregnant women for postnatal services
- Demand creation and sale of social marketing products (Family Planning methods, safe delivery kit, iodised salt, oral rehydration salt, essential medicine)
- Treatment of common ailments
 - Acute Respiratory Infection (ARI)
 - Diarrhea
 - Malaria
 - Common skin diseases
- Growth monitoring of children under three years old.
- Referrals of complicated cases to nearby health facility
- Facilitation for Expanded Program on Immunization
- Health awareness sessions and health education during community home visits.

Achievements

Four hundred and forty seven MARVIs were trained in six districts of Sindh which included 350 in Umerkot, 25 in Thatta, 25 in Badin, 25 in Karachi Rural, 11 in Jamshoro, 10 in Jacobabad and one in Sanghar.

The assessment of MARVI workers showed that:

- 83% of MARVI Workers know the recommended number of two ante-natal checkups.
- 100% of MARVI workers know the recommended number of two post-natal checkups.

- 51% MARVI workers have knowledge of at least four danger signs of the ante-natal, natal and post-natal periods.
- 87% of the MARVI workers were able to identify the three delays.
 - 83% could identify the first delay
 - 93% identified the second delay and
 - 83.3% identified the third delay.
- 100% MARVI workers have knowledge about Family Planning methods
- 70% are able to generate some profit - the average income of MARVIs from the sale of RH-FP products is Rupees 1700 per-month.
- MARVI workers referred nearly 54, 255 women and 8, 594 children with complications to secondary care facilities and saved their lives.

Feature: Controlling counterfeit medicines In South East Asia - science and collaboration

Beverley Snell

In 2001 Paul Newton and colleagues in Lao PDR published a letter in the Lancet detailing the extent of the problem associated with counterfeit artesunate in the Mekong countries.¹ Artesunate is the key ingredient in anti-malarial treatment. Dr Newton had discovered that the ampoules he was using for the treatment of severe malaria were not effective and tests proved that they actually contained no artesunate. They were counterfeit. Further investigations showed that of 104 shop-bought 'artesunate' samples from the region, 38% did not contain artesunate.

Other dangers of fake anti-malarials are that some contain small amounts of active product, to fool chemical detection systems, and exposure to low levels of a drug promotes the development of resistance - a particular concern in malaria. Signs of resistance to the leading anti-malarial drugs - artemisinin-based compounds - have been seen in South East Asia.²

Fakes also include many other types of medicines. In 2004 it was estimated that 10% of the medicines available in South East Asia were counterfeit.³

An issue with counterfeit medicines is that they are sometimes confused with generic medicines. Several countries have introduced legislation to control counterfeits but lack of awareness of the difference has meant that the laws have also affected the import of legitimate generic medicines. In 2009⁴ Customs

misunderstanding led to blocking transit of good generics through Schipol airport.⁵

Generic medicines are legitimate copies of patented (branded) pharmaceuticals. They can be produced after patent protection has expired or under certain flexibilities of Intellectual Property law. The same GMP and quality standards apply to generics as to branded medicines.

What are counterfeit pharmaceutical products

Counterfeit products are illegal imitations of legitimate products that are meant to deceive buyers. They demonstrate several criteria.

- They are deliberately and fraudulently mislabeled with respect to identity and/or source
- They can be branded and generic
- They can include products:
 - With correct ingredient(s)
 - With wrong ingredient(s)
 - Without active ingredient(s)
 - With insufficient quantity of active ingredient(s)
 - Or with fake packaging
- Worse – products may contain other ingredients that are harmful. For example in 2001, diethylene glycol in paracetamol preparation led to some 200, 000 deaths in China; in the USA, fake heparin may have led to more than 60 deaths in 2008.⁶

In 2005 Prof Mohamed Ibrahim Izham presented the details of the WHO Rapid Alert system that was being introduced, to the HAIAP Regional Consultation in Penang.

¹Newton P et al. Fake artesunate in southeast Asia. The Lancet Vol. 357 June 16, 2001

²Dondorp AM et al. Artemisinin resistance in Plasmodium falciparum malaria. N Engl J Med 2009;361(5):455–67.

³ WHO Fact Sheet
http://www.wpro.who.int/media_centre/fact_sheets/fs_20050503.htm

⁴Court ruling in Kenya a victory for access to medicines
<http://www.essentialdrugs.org/edrug/archive/201004/msg00036.php>

⁵India may drag EU to WTO on seizure of drugs in transit
<http://www.essentialdrugs.org/edrug/archive/200903/msg00057.php>

⁶Izham M. Combating Counterfeit Drugs: Counterfeits Kill. Presentation to HAIAP Regional Consultation Penang, April 2005.

Rapid Alert System for Combating Counterfeit Medicines

This system serves as a rapid alert mechanism for WHO, Member States, and partner organizations for combating counterfeit medicines in the Western Pacific Region. When counterfeit medicines are detected in the Region and reported through the Rapid Alert System, relevant authorities are alerted immediately and time-sensitive actions are taken.

The system was to be used only for reporting cases of counterfeit medicines and to discuss and share information on the particular case of counterfeit medicine. All reported cases would be delivered to the Public Health unit in WPRO for confirmation with the country focal point; and the report sent to all members in the electronic communication network. This initiative intensified surveillance – upgrading it from a passive to an active surveillance system. It could detect cases of counterfeit drugs and help increase knowledge of the magnitude and nature of the problem.

It was found that reporting had a significant effect - products immediately disappeared from the market after being identified.

The system was not easy to implement fully, largely due to the difficulties in stimulating reporting from within member countries.

Since 2005 significant developments have resulted in more successful control of counterfeit pharmaceuticals. In 2005 WHO had teamed up with Interpol and the world customs organisation to develop multi country operations in collaboration with the Health Ministries, Customs, Drug Regulatory authorities and the Police in each participating country.

Operation Jupiter – South America

Operation Jupiter conducted in collaboration with Interpol in South America between November 2004 and April 2005 led to thousands of arrests; and seizures of millions of counterfeit cigarettes, hundreds of thousands of counterfeit or recordable CDs and DVDs and thousands of fake pharmaceutical products, computers and electrical goods.

<http://www.inta.org/INTABulletin/Pages/InterpolReportonOperationJupiter.aspx>

Operation Storm in Southeast Asia

Operation Storm was initiated to build on 'the intelligence dividend' that arose from Operation Jupiter for conducting investigations concerning counterfeit pharmaceuticals in South East Asia. Counterfeit medicines are a much more serious issue than CDs or T Shirts.

As part of the Operation, Inter-country and country trainings were undertaken on GMP, quality assurance and surveillance techniques. Officials from Customs, Drug Regulatory Agencies and the Police (who have basic or no experience dealing with crime involving counterfeit pharmaceuticals) were trained; and key people from focal points were trained in sampling. Communities were also provided with information about counterfeits and education on what to look for.

- A protocol was established so that countries would be able to submit samples for testing through the INTERPOL Liaison Office in Bangkok (LOBANG).
- The Health Science Authority (HSA) Criminalistic Laboratory in Singapore offered their forensics analysis services (including forensic botany) to participating countries.

Meetings were held to design the plan and get approval and cooperation for involving the necessary participants and the private sector. Representatives from national agencies, together with the Operation Storm Coordination Team, established protocols for lines of communication. It was also agreed that countries should aim for medium-level targets. These were realistic targets that were achievable during the first year of Operation Storm.

The overt phase of Operation Storm would last for six months, commencing on 15 April and closing on 15 September 2008.

Priority focus drugs were chosen

- Anti-Malaria medication;
- Anti-Tuberculosis medication;
- Anti-HIV drugs;
- Antibiotics, specifically those for pneumonia and child-related illnesses.

A total of 110 samples from 20 million pills were submitted to the HSA Criminalistic Laboratory in Singapore for testing. These samples came from six countries (Cambodia, Indonesia, Laos, Myanmar, Thailand and Vietnam). The 20 million seized pills included antimalarials (22 different kinds) representing 66% of the samples; erectile dysfunction drugs -16% of the samples; and antibiotics, antipsychotics and anti-platelets 18% of the samples.

Of these 20 million pills, more than 12 million were counterfeit, while nearly eight million pills were expired, not registered or diverted medical products. 240,000 blister packs of fake artesunate were found.

Use of Forensic Science

Minute quantities of foreign materials can be found within the packaging as well as anomalies within the product itself. Forensic testing was able to identify the

probable source of pollen grains and plant materials in the seized products and the results led to factories in southern China, and their subsequent closure and arrests of owners.

More than 100 pharmacies and illicit drug outlets closed and at least 33 suspects were arrested.

Interpol Flagship operations⁷ – Storm (Southeast Asia), Mamba (Eastern Africa) and Pangea (targeting the Internet) – continue to go from strength to strength.

Successive raids on licit and illicit markets have shown improved results in terms of seizures, arrests, convictions and the closure of illicit websites.

In addition there have been strengthened

- Network for regulators and law enforcement agencies
- Technical support for medicines registration in China, Cambodia, Mongolia etc.
- Pharmaco-vigilance centre in Cambodia and Vietnam

There have been Inter-country and country training courses on pharmaco-vigilance in Manila (Sept 08), Singapore, Hanoi (Dec 2010), Cambodia; Medicines surveillance involving consumers in Malaysia and Philippines; and training on GMP in China, Laos and Vietnam.

Customs authorities have been trained and supplied with rapid detection devices. Although Customs points cannot be the only solution - some countries have many border points - Customs operations are a key component and need to be part of multiagency teams tackling the counterfeit medicine trade. Customs must know the difference between generic and counterfeit.

Regional focal points have been strengthened with mobile laboratory units (Minilabs) for the identification of counterfeit drugs provided to trained and supported focus health workers. Suspect samples are sent for forensic testing. A total of 270 laboratory units for protection from counterfeit drugs are already in operation in 65 countries worldwide, mainly in Africa and Southeast Asia.

Some other outcomes of Operation Storm:

Intelligence from Myanmar led to the discovery that counterfeit anti-malarials sold in Myanmar were produced in Thailand and that the cross border area was also a transit point for amphetamine-like stimulants and other common cough remedies produced in the same area.

Similarly, in Vietnam it was learnt that counterfeit pharmaceuticals are usually bought and sold in the border areas.

Through the private sector, large quantities of counterfeit Duocotexcin and Cotexcin (anti-malarials) were found in Kenya and traced to southern China. There is a strong belief that there is a link with Chinese Taipei and further investigation is underway.

Conclusion

The final report of Operation Storm concluded that the operation was able to use the intelligence gained from previous operations and to convince countries in the greater Mekong region of the importance of banding together to control the danger counterfeit pharmaceuticals pose to public health and safety.

'Operation Storm is unprecedented at the national, regional and international levels. This is the first time that three national agencies – Customs, the Drug Regulatory Agencies, and the Police – are working together to conduct joint operations for counterfeit pharmaceutical crimes. Also for the first time, seven Asian countries have recognized the common threat that counterfeit pharmaceuticals pose and have come together to tackle this problem. Also unprecedented, at the international level, is the cooperation among INTERPOL, WHO and WCO to fund and to coordinate operations'.⁶

In countries that have no drug registration system, quality assurance measures must be built into the procurement process to ensure safety, efficacy and quality of pharmaceutical products. In addition, a system for monitoring and maintaining product quality throughout the product's shelf life should be in place. If these procedures are followed counterfeit products will be excluded.

It is worth reading 'A Collaborative Epidemiological Investigation into the Criminal Fake Artesunate Trade in South East Asia Newton P, Fernandez F et al in PLoS Medicine | www.plosmedicine.org 0218 February 2008 | Volume 5 | Issue 2 | e32. The author's summary follows the references.



⁷ Operation Storm final report <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Storm>

News from the region

India: Novartis vs India update - Supreme Court hearing comes to an end

E-Drug: December 4. Joanna Keenan, Press Officer Médecins Sans Frontières - Access Campaign

Novartis vs India - Supreme Court hearing comes to an end After 12 weeks of hearings in India's Supreme Court, Médecins Sans Frontières (MSF) has learnt that final arguments into the Novartis v Union of India case challenging the interpretation of Section 3d of India's patent law have today come to an end.

During the hearings, which started on 11 September, the two judges presiding over the case heard arguments from Novartis as to why they deserved a patent on the mesylate salt of the blood and intestinal cancer drug imatinib. In recent weeks, the judges heard the counsel for the Indian government, and then representatives for the Cancer Patient Aid Association on arguments to defend India's stricter patentability criteria that discourages patenting of new forms of known medicines. The judges have now retired to consider their verdict; there is no indication at this stage to suggest when the judges may hand down their findings.

MSF responded: 'With this precedent-setting case nearing its end, we sincerely hope that the integrity and intention of India's patent law, and Section 3d in particular, is upheld. India's ability to continue production of affordable medicines for the developing world depends a great deal on the country's patentability standards and how they are interpreted by the courts in India. We will now wait for the judges' verdict to be released'.

Background

Section 3(d) led to Novartis being denied a patent for imatinib mesylate (marketed by Novartis as Glivec). Novartis is contesting the Indian patent office's and appellate body's decisions to reject the company's application for a patent on the salt form of imatinib. A win for Novartis would set a dangerous precedent, severely weakening India's legal norms against 'evergreening', a common practice in the pharmaceutical industry. A single medicine can have several applications pending for separate patents, each relating to a different aspect of the same medicine. In this case Novartis is pushing for an interpretation of patentability standards that would inevitably lead to patents being granted far more widely in the country, blocking the competition among multiple producers

which drives down prices, and restricting access to affordable medicines for millions in India and across the developing world.

Further information on the case can be found here:

Q and A: <http://www.msfaaccess.org/content/qa-patents-india-and-novartis-case>

Timeline: <http://www.msfaaccess.org/content/timeline-key-events-novartiss-attack-pharmacy-developing-world>

Briefing document:

<http://www.msfaaccess.org/content/what-novartis-says-and-why-its-wrong>

Malaysia: Challenges for Community Pharmacy

Shila Kaur (HAIAP Coordinator) and Gan Ber Zin (Community Pharmacist, Malaysia)

[Many countries are regulating the separation of prescriber and dispenser roles – a separation that has been the norm in Great Britain, Australia and most developed countries. Many Asian countries too have adopted this separation of prescribing and dispensing functions. Malaysia remains one of the countries where medical practitioners prescribe and supply medicines. A related issue is the sale of prescription only medicines – without prescriptions – by pharmacists in some countries where doctors prescribe and dispense. Pharmacists are reluctant to ask patients to go to the doctor for a prescription for 'prescription only' medicines. They know that patients who visit the doctor for a prescription will also be supplied with the medicine and the pharmacist will lose. Regulated separation of the roles would seem to be the solution. It might help some of Malaysia's problem too. This article describes some of the other problems faced by Malaysian Community Pharmacists. B Snell Ed.]

Where are the professional ethics?

Malaysia is a 'dispensing market'. Medicines are mostly promoted and sold to retailers (clinics & pharmacies) with inducement of official free goods, at times with additional unofficial free samples.

More often than not, favourable offers of sales are given only to clinics where the doctors diagnose, prescribe and dispense for a profit on medicines. For example, a drug 'A' is sold to pharmacies at maximum of 'buy 10 units gets 4 units free' but clinics are offered with a starting base of 'buy 10 units get 6 units free' up to 8 or more units free at bulk purchases.

This discriminatory inducement has fostered a middleman-network called 'runners', driven by greed and made possible by a sales-target-commission. As a

result consumers are confronted with great variation in prices of medicines at the pharmacies, with certain outlets known to sell medicines way below the cost price of most pharmacies; while other individual pharmacies are being blamed by unsuspecting consumers for 'price-hiking'.

Discriminatory pricing

Pharmacies are only able to dispense but not allowed to prescribe and/or switch the brand of what is prescribed. In addition, they face major discrimination, particularly with access to medicines from drug companies at competitive prices. Doctors and clinics in general are given multiple quantities of units of free commercial goods with their medical supplies as well as free samples to tie-in with sales. For example, for most anti-hypertensives /anti-lipids, doctors/clinics get from 50-100% free goods while independent community pharmacies get only up to maximum of 30-40%.

This profit inducement promotion in favour of one party against the other is termed as discriminatory pricing. On certain specific occasions, companies even offer cheaper prices directly to doctors/clinics out right, or refuse sales of certain products/packings/strengths to pharmacies, entrenching the monopoly of doctors/clinics.

Consumers are at the end of this medicines chain and the ultimate victims of this unhealthy alliance. If blame has to be assigned, it's the drug industry that has to be called to account. The 'runner' system is the direct result of the discriminatory pricing policies of the drug companies in Malaysia. 'Runners' sell medicines at special reduced prices to GPs or even their own or partner outlets, and to some pharmacists.

Drug companies in Malaysia also sell certain medicines at reduced prices only to clinics or only to certain parties, or provide financial supports to outlets that take part in sales promotion; paying undisclosed bonuses or even direct financial kickbacks as well as 'listing fees'. The big retail chains not only have economic might to bargain for deals, they also demand that drug companies pay a listing fee for each of their brand to be put on the shelves of their chains of outlets; about +/- Rm 500 per outlet per brand.

Advertisement support

Advertisement support is often negotiated directly between the drug company and the outlet, usually the chain-pharmacies with direct or indirect payments; usually in the form of costs of running a special promotion for the company's brand, or a special sales promotion in the press, with shared cost of advertisement or full sponsorship. Such information may be open in the market but are discrete with details kept

only in the books of the parties involved unless investigated by the authorities.

Industry and Pharmacy Codes of Conduct

The right thing would be for the drug companies to put an immediate stop to the inducements that are currently being offered to health practitioners and to ensure that its members adhere to the Industry Code of Conduct.

The Pharmaceutical (Industry) Association of Malaysia (PhAMA) has its own Code of Conduct - Marketing Practices for its 46 or so member (mostly Multi-National companies) but regrettably their members are openly infringing their own Code of Conduct. The Code of Conduct is available at their website <http://www.phama.org.my/>

Clearly the Malaysian Pharmaceutical Society, which is the professional body responsible for the actions of its members, is not doing its job of ensuring that the profession adheres to a strict Code of Conduct and Good Pharmacy Practice. The Pharmacy Board has a Code of Conduct for Pharmacists - available at <http://www.mps.org.my/index.cfm?&menuid=57&parentid=52#TOC>

Pharmacists, especially independent community pharmacists have had to face the Pharmacy Board for unethical practices like displaying of improper advertisement/leaflets (provided by the drug companies). However the authorities have not hauled up the pharmacists working in those drug companies which have discriminatory and unethical practices.

This Pharmacist Code of Conduct covers in detail professional responsibility and ensures the highest level of professional and ethical conduct. It also covers the relationship with the Pharmaceutical Industry and prohibits the acceptance of any financial or material inducement that would compromise pharmacists' professional judgement on the choice of drug for his patient or client.

To sustain public confidence in the profession, a pharmacist shall not only choose but also be seen to be choosing the drug which, in his professional judgement and having due regard to economy and rational drug use, will best serve the interest of his patient or client. A practitioner shall not sell or supply with prior knowledge any drug or medical device which is defective or is incapable of serving the purpose it is intended for or is falsely or fraudulently labelled or presented.

Honesty is promoted by the Code and a practitioner shall be liable to disciplinary proceedings if he is convicted of criminal deception, forgery, fraud, theft or of any other offence involving dishonesty.

The Code verifies that a practitioner shall not act for improper motives. A practitioner's motive is considered

improper if he sells or supplies any drug or medical device purely for his financial or material benefit, or if such act is motivated by his acceptance of an improper inducement from the supplier of the drug or medical device. Fee-splitting, or any form of kick back arrangement as an inducement to refer patients or clients to other members of the allied profession, may be regarded as unethical. A practitioner shall not recommend a particular member of the allied profession or a medical practice unless so requested by his patient or client seeking medical advice.

The Task Force Formation

Early 2011, a Facebook group named MEDI GROUP was set up to assist fellow Community Pharmacists (C.Ps) in their practice of community pharmacy. Datuk Nancy Ho agreed with the proposal to set up a Task Force to look into and address the problems confronting community pharmacists.

'Say No To Inducement to Medical Prescribers' was subsequently set up by the Task Force and Medi group members to start voicing their grievances through a series of letters to the leaders of the Malaysian Pharmaceutical Society and to the Ministry of Health officials.

On 12th April 2012, The Task Force members and Terms of Reference (T.O.R) were announced in the MPS-iBulletin. The Task Force 1st Assignment was to investigate the discriminatory pricing practices (and policies) of pharmaceutical companies against community pharmacies.

- Differential/Double Standard Pricings
- Exclusively of certain products/ Packaging
- Undisclosed incentives & manipulation.

The Task Force agreed that Instead of blaming anyone, it is more important to make sure that the 'runner' network and discriminatory practices do not continue.

The past cannot be changed but if we work together, we can ensure a better future.

The Task Force asked the Malaysian Pharmaceutical Society to provide all its resources available to the MPS Task Force for Community Pharmacists in its efforts to seek an end to the discriminatory pricings against Pharmacies.

Some Council members appeared to be ambivalent in their stand on this issue. The Task Force had to expand considerable effort to first 'convince' the MPS Council. There was a feeling that efforts would be better used to by putting a 12 Points Proposals To PhAMA

1. Have a standard pricing structure for all
2. Abolish pre-price increase loadings
3. Provide in print, the official Price-List

4. Discourage all forms of price based advertisements without stating the recommended selling price (RSP)
5. Provide formal announcement of any price increase
6. Limit quantity purchase units to the level of meeting minimal delivery amount
7. Prohibit all other guises of inducement '1 Malaysia, 1 Price, No inducement'
8. Make newly launched products and samples available to both doctors and pharmacists
9. Prohibit inadequately qualified sales promoters
10. Exert good judgement on sales and marketing, that '10 x 1 is the same as 1 x 10'
11. Consider price reduction for all patent expired medicines
12. Put in practise electronic territorial management tools

The Task Force suggested five easy steps to do immediately with least disruption to sustainable sales for fair trade and equitable access to Fair and Affordable Priced Medicines for the members of the public from all health care outlets.

1. put a stop to the source of original goods to the 'runner trade' from the original point of supply
2. extend the same price and bonus scheme to all independent community pharmacies (IPs)
3. curtail the needless upper tiers of bonuses and samples on large quantity loading
4. discourage all forms of undisclosed subsidy-incentives to 'must buy' advertisements without stating the RSP
5. have a standard pricing structure for all groups of health professionals and all types of outlets with the official Principal's Price-List which was in practice before.

HAI Global Network

HAI Global

Overtoom 60/III 1054 HK Amsterdam The Netherlands
Email: info@haiweb.org Web: www.haiweb.org

Health Action International Asia Pacific

Penang Malaysia Email: kaur_shila@yahoo.com

HAI Africa

P.O. Box 66054 - 00800 Nairobi Kenya Email: info@haiafrica.org Web: www.haiafrica.org

HAI Europe

Overtoom 60/II 1054 HK Amsterdam The Netherlands Email: info@haiweb.org Web: www.haiweb.org

HAI Latin America (AISLAC)

Accion Internacional Para la Salud Apdo 41 – 128 Urb Javier Prado Ca. Mario Florian Mz 3 Lote 22 San Borja, Lima 41 Peru Email: ais@aislac.org Web: www.aislac.org

Other news

International Drug Price Indicator Guide MSH 2011: additional information available

The *International Drug Price Indicator Guide* contains a spectrum of prices from pharmaceutical suppliers, international development organizations, and government agencies. The *Guide* aims to make price information more widely available in order to improve procurement of medicines of assured quality for the lowest possible price. Comparative price information is important for getting the best price, and this is an essential reference for anyone involved in the procurement of pharmaceuticals.

Management Sciences for Health (MSH) has published the *International Drug Price Indicator Guide* since 1986 and updates it annually.

International Drug Price Indicator Guide is available at <http://erc.msh.org/pricguide>. Two new downloads are available on the site. You can download a pdf file containing the print edition of the Guide. You can also now download a spreadsheet with the buyer and supplier median prices.

Julie E. Frye Editor, International Drug Price Indicator Guide Center for Pharmaceutical Management Management Sciences for Health <http://www.msh.org>

Where There are no Pharmacists– available in French



Là où il n'y a pas de pharmaciens, the French translation of *Where There are no Pharmacists*, has gone to press and will be available from TWN in early January. The text was translated by Elisabeth Coffin and Anke Meiburg of Ecumenical Pharmaceutical Network (EPN), with the support of the German Institute for Medical Missions (DIFAM).

The book was prepared for publication by Beverley Snell from HAIAP and Lean Ka-Min from TWN.

HAIAP New Website

We are grateful to Ken Harvey and Manuj Weerasinghe for sorting out the problems with our previous website and establishing a new one at <http://www.haiasiapacific.org>. It will soon be formatted in line with the other HAI family websites and needs to be populated with relevant documents and information. Please send any material that would be good to include to Ken Harvey or Shila Kaur.

We would like to produce HAIAP News at least 3 times a year.

Please send feedback, suggestions, and contributions for inclusion to:

Beverley Snell bev@burnet.edu.au or Shila Kaur kaur_shila@yahoo.com