



December 2013

# HAI AP News

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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**

Public interest pressure groups, also known as Civil Society Organizations or CSOs are increasingly being challenged by lack of resources and many have downsized programmes and operations for continued functioning. Many now operate with skeletal staff and on specific programmes with limited funding. The

challenge is not just global but also local and HAI is no different.

The ramifications of HAI Global's unsuccessful funding effort two years ago have been damaging and the regional offices have had to face closure or work with a skinny staff. On 10 November 2013, HAI Global's Director, Dr Tim Reed and the Asia representative of its Governing Board, Dr Prem Chandran John flew into Bangkok to meet with the Chair of HAIAP's Governing Council, Prof Niyada Kiatying-Angsulee and the HAIAP Coordinator, Ms Shila Kaur to discuss the future of HAI and its operations, in view of existing funding challenges.

The team met for a day's discussions on 11 November 2013 at Chulalongkorn University during which Tim presented a possible new model for HAI's future operations. The meeting with HAIAP was the first leg in a series of similar consultations by Tim with the other regional offices. The meeting was also a good opportunity for HAIAP's Chair and Coordinator to reconnect and discuss project possibilities for HAIAP.

On 12 November 2013 Prof Niyada and Shila met for a brief HAIAP planning meeting and agreed on three possible project areas for the immediate future: antibiotic resistance, national medical drug policies and the Trans-Pacific Partnership Agreements.

Meanwhile attempts at fundraising are continuing; I submitted a project proposal to a German funder

following a lead from Tim; whether this is successful or otherwise remains to be seen.

Well, the year draws to an end; how the days have flown! Despite the challenges and the uncertainties, HAIAP continues to draw inspiration from its supporters, near and far, young and not-so-young! HAIAP wishes to acknowledge the kind and generous support of the Third World Network; the synergy has been incredible! So much remains to be done and true, solid partners are the vital cogs to ensure that the wheel of life turns smoothly, not just professionally but also personally, you will agree? So let's carry on!

Happy New Year and a Merry Christmas!

Viva HAIAP! Viva HAI!



## Award

### Winners of the 2013 Prix Prescrire

French edition of

#### ***Understanding and Responding to Pharmaceutical Promotion: A Practical Guide.***

At the beginning of October, Health Action International, together with the World Health Organization, were pleased to become one of three recipients of the 2013 'Prix Prescrire' for the French edition of our book, *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide*.

This juried prize is awarded annually to noteworthy books in the field of health. According to Prescrire, the Guide 'is a precious resource for understanding the promotional influence of pharmaceutical companies... and offers pragmatic solutions to help health professionals and students to deal with them.'

To download a free copy of the Guide - also available in English, Spanish and Russian-please visit Health Action International's website:

[www.haiglobal.org/03\\_other.htm](http://www.haiglobal.org/03_other.htm)<[http://www.haiglobal.org/03\\_other.htm](http://www.haiglobal.org/03_other.htm)>.

Health Action International would also like to congratulate our fellow Prix Prescrire winners for their exceptional works: N. Oreskes and E.M. Conway for their book, *Merchants of Doubt* (Bloomsbury, New York), and S. Fainzang for her book, *Self-medication or the Mirages of Autonomy* (PUF, Paris).

For more information about all three books, follow this link to Prescrire's reviews:

<http://english.prescrire.org/en/81/168/48735/0/NewsDetails.aspx>.

Originally published in 2009, this manual is intended for use by medicine, pharmacy, nursing and other health discipline instructors and students at universities around the globe. It includes actual examples of pharmaceutical marketing, like:

- common marketing techniques used by the pharmaceutical industry;
- the negative influence that pharmaceutical promotion has been found to have on prescribing and dispensing decisions;
- skills to critically assess pharmaceutical promotion; and
- alternative sources of unbiased, independent and better quality information about medicines.

*Editors: Barbara Mintzes, Dee Mangin, Lisa Hayes, World Health Organization / Health Action International, 2010*

180 pp. 19.5 MB

[http://www.haiglobal.org/10112010/DPM\\_ENG\\_Final\\_SEP10.pdf](http://www.haiglobal.org/10112010/DPM_ENG_Final_SEP10.pdf)

Hard copies of the manual are also available from our Coordinator - Shila Kaur - in Penang. The manual is a great resource for developing awareness among students and professionals about pharmaceutical marketing activities.

### ***What is Prescrire?***



Prescrire is a non-profit continuing education organisation, based in France, committed to better patient care.

Prescrire and Prescrire International provide independent information, by and for healthcare professionals.

Prescrire publishes a monthly journal in French, and an international edition in English 11 times a year, plus a yearly supplement in French devoted to drug interactions. It is a fully accredited continuing education organization that offers continuing education and professional practice improvement programs specifically adapted for healthcare professionals. A non-profit organisation, it is wholly financed by its subscribers, and accepts no advertising or other outside support.

Prescrire has the editorial and research capabilities necessary to ensure the accuracy of its reviews. Its editors are healthcare professionals, specially trained in Prescrire's editorial methods and free from conflicts of interest. Exacting quality control procedures are applied to all editorial content.

<http://english.prescrire.org/en/82/170/0/0/About.aspx>

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# Feature: Development of a Medicines Registration System in Fiji

Compiled by Beverley Snell and Frances Cameron

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## **The Pacific Island Countries**

Twenty two independent island countries in the Pacific region with populations ranging from less than 2000 to almost 1,000,000 (except PNG with almost 6 million) are dispersed through an area around 10 thousand kilometres square. In such small populations the workforce is limited and qualified professionals have wide ranging tasks.

The work of pharmacists in the Pacific Island Countries (PICs) covers everything from the selection of the right medicines, making sure they are available and ensuring their quality, good storage and distribution, to the prescribing and actual use of the medicines.

In this setting, it is important that appropriate policies and structures are in place to support and maintain the system together with a reliable supply of essential medicines ensured through efficient procurement, storage and rational use within a strong health system.

Maintaining a reliable supply of essential medicines is linked to selection of the right medicines by the National Medicines and Therapeutics Committees; controlling the medicines allowed into the country and their quality; procurement procedures, storage, distribution and use; and education of the whole work force concerning those aspects, as well as education about the rational use of the medicines. A National Medicines Policy defines the issues and the goals. Legislation and regulation must be in place to cover all the issues.

## **The Fiji setting**

Fiji has a population of less than one million and is made up of two main islands, Viti Levu and Vanua Levu, and 30 smaller islands. The Capitol, Suva is situated on the main island.

The Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) is the peak body within the Ministry of Health responsible for all pharmaceutical-related activities in line with national regulatory mechanisms for a total of 221 Fiji MoH health facilities, and 125 retail outlets. Its function and scope are defined by legislation in the Medicinal Products Decree 2012.

The Fiji National Medicinal Products Policy was revised in 2012. But a policy, no matter how carefully formulated, has no value if it is not implemented. Therefore, the first national Pharmaceutical Sector Strategic Plan was developed in 2013 to link with the revised National

Medicinal Products Policy. It includes short- medium- and long-term strategies and plans to be implemented throughout the sector in the next five years.

There are few staff and they are already over-burdened but the recent endorsement of the revised Policy together with the development of the Strategic Plan for its implementation have provided the will and impetus to begin activities including putting a full registration system in place within the Fiji Medicines Regulatory Authority (MRA).

The Medicines Registration Unit (MRU) within the MRA is responsible for the Registration of appropriate manufacturing companies as well as the individual products that will be imported. It is responsible for registration of medicines, medical devices and cosmetics; issuing of licenses for import/export and for pharmaceutical facilities; for the regulation of any business pertaining to the pharmaceutical practices. Until now it has not been possible to set the complete Registration process in place.

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***In September 2013 Frances Cameron, a young Australian pharmacist had the opportunity to work in the MRU as part of her MPH degree; assisting Fijian staff to develop a framework for medicines registration.***

*Frances acknowledged the warm friendship and professional support from Fijian supervisors Ilisabeta Pesamino and Apolosi Vosanibola when she explained her project in a presentation to fellow MPH students:*

## **Background to the project**

Registration of medicinal products is a vital regulatory process that protects consumers from exposure to substandard products.

- Substandard/Spurious/Falsified/Falsely-labeled/Counterfeit (SSFFC) medicinal products are a serious and growing concern worldwide, endangering public health.
- Ineffective products – untreated/uncontrolled medical conditions
- Toxic/contaminated products – adverse reactions and fatalities

Example case – in 2001 contaminated paracetamol caused the death of 200,000 people in China

Pre-qualification for procurement in the Fiji public sector currently provides quality assurance but the Private sector is completely uncontrolled.

The need for registration has been recognised by the:

- Medicinal Products Decree 2011
- National Medicinal Products Policy (NMPP) 2013
- Strategic Plan for Implementation of the NMPP

#### **Activities in relevant section of the Strategic Plan**

- Develop a registration procedure for registration of manufacturers that satisfy international GMP standards. It will involve standardized documentation matched with appropriate assessment software.
- Maintain a list of prequalified suppliers including a system for review and renewal of registration every two years.
- Develop a registration program for medicinal products (including complementary and traditional medicines and devices) in Fiji

Action in the form of designing, implementing and maintaining a registration system was urgently required so that all medicinal products imported into Fiji would be verified for quality, safety, efficacy and GMP and the public would be protected from exposure to SSFFC products and the associated negative health and economic consequences.

The goal would be a feasible, comprehensive, sustainable and enforced system to regulate all medicinal products imported to Fiji together with an implementation plan and commencement process.

The method involved a literature search, examination of MRAs from other small countries; and consulting experts and local staff to design the model. A local situation analysis was undertaken, opportunities recognised and needs identified.

A protocol for the registration of medicinal products – concept paper – was developed for the Fiji Medicinal Products Board and accepted by them.

An implementation plan was developed in five phases: Preparation for implementation, trial and optimisation, national rollout, maintenance, ongoing work plan. And an implementation manual was developed.

Challenges included the need for detailed understanding of the current situation and processes in Fiji - much of which is not documented; so many discussions with local counterparts were needed.

The limited human resources needed to be considered when designing the implementation plan and proposed timeframe. Though recruiting new staff was approved, the MRA, including the MRU, currently only had one staff member

There was a limited timeframe for the activity and many areas where work could be done, so staying focused and prioritising activities were important.

#### **After four weeks - outcomes and products**

In four weeks a tailored medicinal products registration system was designed and a step-by-step implementation plan was developed.

- A manual for applicants was produced (forms and procedures) and an Instruction Manual for FPBSC was drafted. Software was selected and installed.
- Plans for a pilot activity focusing on the import of diabetic medicines were developed.
- Focus group questions were developed (for use in the pre and post pilot surveys).
- A medicines scheduling system was incorporated into the design of the data base.
- The concept paper was presented to the Medicinal Products Board and accepted.
- Support in terms of human resources was requested.
- An information session for importers was held.
- Volunteers were recruited for a pilot trial.

So the preparation phase was completed and thoughts turned towards commencement of the implementation phase and anticipated future outcomes.

#### **Anticipated future outcomes**

Feedback from the pilot will optimise the system and the National phased rollout will begin according to prioritized categories of medicines, and hopefully with additional staff.

Auditing will occur, and penalties enforced to ensure compliance (Inspectors are being trained).

The registration system will make a big contribution to strengthening the pharmaceutical sector.

Ultimately, all medicinal products imported into Fiji will be registered. Quality will be assured and there will be better use of resources. Consumers will be confident in the quality of medicinal products.

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#### ***Transferability to other Pacific Island Countries in need of a registration system***

To date none of the PICs have been able to establish an authority to register medicines being imported. With small capacity and no national quality control body, they rely on the strong regulatory authorities in countries like Australia and New Zealand. Companies and products registered in those countries are accepted. Some PICs, eg Tonga, have prepared for a registration system by Listing the medicines approved for import.

## Update on the Trans Pacific Partnership negotiations and Public Health – no conclusion

December 12. From Deborah Gleeson and Brigitte Tenni

*Deborah Gleeson is a member of the Public Health Association of Australia and active in the People's Health Movement. Brigitte Tenni is affiliated with Public Health Association of Australia, which has been advocating for a more just trade agreement.*

HAIAP has been actively following developments of the the Trans Pacific Partnership Trade agreement with updates in HAIAP news. Countries involved in the trade negotiations include Singapore, Malaysia, the United States, Australia, New Zealand, Brunei, Peru, Chile, Japan, Canada, Mexico and Vietnam. The Agreement is in the final throes of three years of negotiations.

The Trans Pacific Partnership agreement is potentially the most damaging trade agreement covering public health ever to be signed.

Trade ministers from the negotiating countries had hoped to wrap up the three-year talks in Singapore between 7 and 12 December 2013, by making decisions on the major outstanding issues, despite significant conflicts over many of the 29 or so chapters of the agreement. They failed to meet this self-imposed deadline. A short statement issued at the end of the meeting said ministers had 'decided to continue our intensive work in the coming weeks...' and that they intend to meet again in January.

The countries involved have signed an agreement to keep the text confidential until after negotiations have concluded and the agreement has been signed; and to keep negotiating documents secret until four years after the agreement is concluded or the negotiations are abandoned.

### Growing secrecy

The negotiations had always been shrouded in secrecy until mid-November when Wikileaks published the leaked text of the Intellectual Property Rights (IP) Chapter of the agreement that confirmed fears of US demands that will restrict market entry of affordable generic medicines.<sup>1</sup>

In Singapore, stakeholders had no role as participants and no avenues for interacting with negotiators except through personal contacts and it was even more difficult than usual to get any information about what was happening. But there were reports that small groups of ministers met to hammer out compromises on the stickiest issues, and that these were then put to the rest of the countries.<sup>2</sup>

### Health and medicines

Extremely worrying were suggestions that the group negotiating the highly sensitive IP chapter included only one of the countries advocating for a fairer proposal on medicines (it is not known which of these countries was involved).<sup>3</sup>

The draft of the IP chapter leaked to Wikileaks in November showed the United States has continued to push for expanded and extended patent protection and exclusive rights over clinical trial data, among other provisions, that could delay access to affordable medicines.<sup>4</sup>

Several countries have put forward a fairer counter-proposal. While Australia was reportedly involved in the early development of this counter-proposal, its current position is unclear.

The Australian government has maintained that it will not accept anything in the agreement that would undermine the Pharmaceutical Benefits Scheme or the health system. But on the third day of the Singapore talks, a leaked memo showed Australia had collaborated with the United States and Japan to revise the 'healthcare transparency annex', the part of the agreement that will affect the Australian Pharmaceutical Benefits Scheme (PBS).

On the final day of talks, an article in Washington Trade Daily (WTD) cast further doubt on the Australian government's claims about protecting the nation's health and medicines policies.

It reported that:

*Australia, New Zealand and Canada, among others, dropped their objections to the high-standard disciplines in intellectual property and came on board by agreeing to the modified text. Effectively, there is consensus on the intellectual property dossier except for one developing country, WTD was told.*

The 'High-standard disciplines' proposed refers to the extremely high level of intellectual property protection proposed by the United States. It calls for patents for new uses of existing drugs. If a new use is found for an old drug that is out of patent, the drug can be granted a new patent. Medicines like those for HIV-related disease, and cancer drugs are already priced out of reach for many people in countries like Vietnam,<sup>5</sup> and the US proposals for the TPP would make this scenario much worse. Even in wealthy countries like Australia, a significant proportion of those on low incomes already postpone purchasing or go without necessary medicines due to the cost.

The US seeks clinical trial data exclusivity, which prohibits generic medicines companies from using that data to register drugs for five years. And it wants mandatory patents on most medical, surgical, and

diagnostic procedures, which will increase their cost. These are only some of the US intellectual property demands, and they far exceed the World Trade Organization (WTO) rules governing patent protection enshrined in the 1994 Trade Related Aspects of Intellectual Property Rights (TRIPS).<sup>6</sup>

## In Australia

On the same day as the memo was leaked, the Australian government blocked an order by the Senate to reveal the Trans Pacific Partnership text before it's signed.

In addition, 44 prominent academics and public health experts wrote to the health minister to express their concerns and to urge the government to honour the Senate order.<sup>7</sup>

The Senate has passed a motion noting the letter and reiterating its call for the release of the text.

There is hope that the delay in concluding the negotiations at a time when there's rising concern among the Australian public will mean there is time to persuade the government to take a stance that's conducive to a healthy agreement, a healthy country and a healthy region.

It is also hoped that the Senate is successful in its efforts to make the text of the agreement available for public scrutiny before the Australian government commits to its terms.

<sup>1</sup> <http://wikileaks.org/tpp/>

<sup>2</sup> <http://www.scoop.co.nz/stories/PO1312/S00100/heavy-handed-tactics-in-tppa-talks-aim-to-isolate-dissenters.htm>

<sup>3</sup> <http://www.keionline.org/node/1826>

<sup>4</sup> <https://wikileaks.org/tpp/pressrelease.html>

<sup>5</sup> <http://www.oxfam.org/en/pressroom/pressrelease/2013-03-04/us-trade-policy-putting-public-health-risk>

<sup>6</sup> [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm)

<sup>7</sup> <http://www.phaa.net.au/documents/131003%20Letter%20to%20Tony%20Abbott%20TPPA.pdf>

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## Global Technical Meeting on R&D

*Tessel Mellema Policy Advisor, Health Action International (HAI) Europe; Michelle French, Communications Officer MSF Access Campaign.*

### The Status Quo Wins Again: Selected R&D

demonstration projects disappoint, offer little progress.

On December 4-5, 2013, in Geneva, experts at a Global Technical Meeting, hosted by the World Health Organization (WHO), selected biomedical research and development (R&D) 'demonstration projects' to go forward and receive financing. Representatives of HAI Europe and Médecins Sans Frontières (MSF) Access Campaign attended the meeting. The purpose of demonstration projects are to test new R&D approaches

that enhance needs-driven R&D and access to results that can be used on a large scale.

The Global Technical Meeting was the result of a process that reflected a compromise; the demonstration projects would provide an initial step away from the R&D framework status quo, which has been identified as failing global health, towards a multilateral framework that is just, inclusive and driven by health needs, rather than monopoly profits and ensures worldwide access to innovative medicines. A key element of this compromise process was that the demonstration projects would be used to validate alternative mechanisms to incentivise needs-driven R&D, which would ensure product affordability and access to the results of R&D, but avoid market exclusivity through intellectual property rights rewards.

At the World Health Assembly in May 2013, Member States agreed that demonstration projects should incorporate two core principles identified as key to the enhancement of needs-driven, affordable innovation: firstly, open knowledge innovation and, secondly, the de-linkage of the costs of R&D from the price of the final product.

The eight projects that have now been selected, although perfectly scientifically sound, do not divert from the R&D status quo and will demonstrate little, at best, and, nothing, at worst, in terms of establishing new innovation models that use alternative incentives to the current monopoly driven model.

Innovative proposals, disruptive to the status quo, including two proposals submitted by MSF, one on developing new tuberculosis regimens, and a second on developing a multiplex, open source fever diagnostic, did actually make the 22-proposal shortlist, but were eliminated in the final selection exercise in Geneva and will not go forward. At first sight, this appears to be the direct result of the criteria used for selection; however, whether the demonstration project would test a new approach to R&D was only used as a third-level criterion for selection. Although HAI and MSF were disappointed with the outcome, they are primarily concerned that the process has failed to achieve the fundamental and principal mandate of this initiative and of the larger Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) process, which is to test new models of innovation that challenge the status quo, and, for example, incorporate the principles of open innovation and de-linkage.

HAI and MSF agreed that it is difficult to imagine what lessons the selected demonstration projects will offer the current system of global health R&D. They will certainly not contribute to the search for a structural solution to the current failure of global health R&D.

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## News from the Region

### ***Philippines – After the typhoon Haiyan (local name Yolanda), November 2013***

#### **Health disaster group: All is not yet well -- call for comprehensive rehabilitation plan**

At its press conference, November 27, the Philippines Disaster Health Group *Samahang Operasyong Sagip* (SOS) criticized the government anew for its inefficiency and inept leadership in responding to typhoon Yolanda's backwash after seeing for themselves the real situation of the super typhoon aftermath and its survivors.

After a relief mission, the 40-staff team of experienced SOS volunteers including nine medical doctors with different specializations, fifteen nurses, two medical interns, and four health workers, reported that massive economic dislocation occurred in the fourteen barangays of Hernani and Gen. McArthur of Easter Samar and Basey of Western Samar.

Rosalinda C. Tablang, president of SOS said that the main sources of livelihood were all gone. The strong floods swept away or destroyed fishing boats, felled coconut trees, and submerged crops so the people are left with nothing and survivors see no light at the end of the tunnel.

Based on stories from some barangay officials, Tablang said it is 'not clear' what the local and national governments are planning for the rehabilitation of communities. 'As to how long the makeshift tents in Brgy. Batang in Hernani Eastern Samar will stand to provide shelter to the survivors, nobody knows. No serious government aid or rehabilitation plan is apparent'.

SOS convenor and medical doctor Darby Santiago warned that because of poor sanitation, lack of clean water sources, and absence of latrines, other epidemics may soon take over if immediate health intervention is further delayed.

SOS also slammed the Department of Social Work and Development's (DSWD) pronouncement to end the food relief provision in December and implement the 'cash-for-work' and 'food-for-work' program for the survivors of typhoon Yolanda. Tablang cited an interview aired by a news program to a woman who said she is taking part in the DSWD repacking of relief goods in a DSWD managed warehouse because she hopes to take home 6 kilos of rice given to volunteers like her. The woman said she needed the rice to feed her family because they only received a relief pack once since the typhoon hit.

'Despite millions of donated cash and goods to the affected populations, skewed government policies make it more difficult for the survivors to receive immediate relief. Amidst the people's loss and empty stomachs, the government should provide livelihood and house reconstruction support instead of making people work for donated goods,' Tablang said.

They called on the Filipino people, as well as health professionals, to share their resources and lend their talent and time to the affected families.

The SOS provided a comprehensive report detailing their findings concerning the living conditions and health status of the people they visited

#### **General Observations and Findings:**

1. Many barangays especially those far from town centers have received little or no relief assistance from any group, whether government or private. One example is Barangay Cacatmonan in the municipality of Hernani, where the typhoon destroyed all but one out of 35 houses. The barangay captain and several counselors, carrying a list of survivors in the barangay, requested that their barangay be given relief goods.

Other survivors lament that only those with high numbers of casualties are prioritized so that their barangays are not given support or seldom included as beneficiaries.

2. Some cadavers and debris are still not retrieved and cleared in the barangays.

3. The survivors are living in most vulnerable conditions:

- Some are staying in evacuation center in public schools (some barangays in Basey), some in tents made from tarpaulins.
- Lack of electricity make night time pitch black and movement in the areas difficult and dangerous.
- Survivors have difficulty cooking food in tin cans using firewood from debris.

4. Major health risks which could lead to serious disease outbreaks were noted:

- Lack of shelter.
- Lack of water supply.
- Lack of toilet facilities.
- Irregular provision of food.
- Crowded condition in evacuation areas.

5. Common illnesses include: upper respiratory tract infections, hypertension, arthritis, error of refraction, diarrhea, wound and injuries, skin diseases.

6. Other expressed needs: need to reconstruct houses and desire to start livelihood activities. The people lined-

up for construction materials such as nails, saws and hammers.

### **SOS Recommendations:**

1. Development and implementation of a systematic strategy to reach out to far-flung areas and provide urgently-needed relief and assistance. Medical and relief teams and service groups must reach far-flung areas not only those in town centres.
2. Immediate retrieval of cadavers and clearing of debris, both for faster relief efforts and health and psychological recovery of survivors.
3. Immediate and comprehensive health interventions to address potential sources of outbreaks and epidemics. These include immediate clearing of debris, provision of water sources, construction of shelter, construction or provision of latrines, provision/assistance in food production.
4. Start reconstruction and rehabilitation efforts: provision of construction materials, livelihood, food production, and economic activities.

SOS demands that the government immediately and decisively (1) continue food and relief distribution; (2) act on rebuilding the lives and livelihood of the affected population; (3) address the immediate health problems and concerns of the affected families; (4) institute and implement a comprehensive disaster risk reduction program geared at building the capacities of communities in preparing and responding to disasters; (5) increase the budget for disaster risk reduction.

Dr. Edelina P. Dela Paz of the People's Health Movement in the Philippines, and a co-convenor of SOS, calls on the government to provide leadership to develop ownership of the response in coordinating the activities of international donors and as a priority to develop a disaster preparedness and response strategy that can be in place in all provinces. This will not be the last disaster in the Philippines.

(SOS teams will continue to be mobilised to the affected areas).

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## **Bangladesh: Hunger Strike**

### **HAIAP members declare their solidarity with the Freedom Fighters of Bangladesh.**

HAIAP elder Dr Zafrullah Chowdhury was among the group of more than 50 freedom fighters who were on a three-day hunger strike at the capital's Central Shaheed Minar from Monday December 2, demanding peace in the country. 'We are very much disturbed by the present situation when crude bombs are being blasted frequently and police are opening fire without magistrate's orders,' said Dr Zafrullah. 'Bangladesh is undergoing a politics of terrorism and looting at present.

It will stop only when people take to the street,' said another participant Maj (retd) Syed Munibur Rahman. Group spokesperson Ali Ahmed Ziauddin said, 'We want a real democratic state. People are falling victim for the election system stated in the present constitution. For this, we want a new constitution to be formulated.'

The hunger strike ended after three days. Dr Zafrullah stated 'We freedom fighters have seen the horror and cruelty of war. We do not want to see our motherland fall prey to a suicidal civil war. We are now at the doorstep of such a disaster. The main reason for this situation is an undemocratic state run by rent seekers and looters. We want a truly accountable, corruption free and war criminal free democratic state. Towards that goal let us unite against all forms of violence, be that unleashed by the state or by any political party....'

The current political impasse is the result of the 15th Amendment to the constitution which did away with the provision for a three month caretaker regime to conduct parliamentary elections. This provision was introduced in 1996 in order to cope with the corruption and rigging of votes that is common place in many third world countries. The present government having 90% seats in Parliament more than the 2/3 majority required to bring any fundamental changes in the constitution was able to introduce the 15th Amendment, although this was not part of their election manifesto nor was it recommended by the Parliamentary Committee formed by this government to formulate recommendations on the issue.

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## **Thailand - Anti-tobacco Laws: Philip Morris sues over loss of sales**

[Copied as fair use]

<http://www.trefis.com/stock/pm/articles/193927/philip-morris-sues-thai-government-over-anti-tobacco-law/2013-06-28>

Philip Morris International (NYSE:PM) has sued the Thai government over a new anti-tobacco law requiring larger graphic warnings on cigarette packs. The Thai government has decided to extend health warnings from 50 to 85% on each side of every cigarette pack sold in the country. Philip Morris is not the only one to take a legal action against the government, as Japan Tobacco Inc. and the The Thai Tobacco Trade Association (TTTA), which represents 1,400 retailers across the kingdom, have also filed separate cases against the health ministry. This new rule is somewhat similar to the plain packaging law implemented by the Australian government last year. Philip Morris also sued the Australian government against the law and was defeated in the local court however, the case is still going on in International courts. (See: Philip Morris Earnings Face Headwinds From Anti-Tobacco



Laws) Going by what happened in Australian local court, we believe, the tobacco companies might meet the same fate in Thailand as well.

Based on a similar litigation in Australia related to the Plain Packaging Act, a positive outcome for the tobacco industry or Philip Morris is not expected in this case. This is not good news for Philip Morris as Thailand is one of the four primary growth markets for the company in Asia, the other three being Indonesia, Philippines and Vietnam. In 2012 Philip Morris reported a shipment volume growth of 4.2% in Asia, which was primarily driven by market share gains in these four growth markets, partially offset by volume declines recorded in Japan and Korea. If the new law, scheduled for implementation on October 2<sup>nd</sup> 2013, is effective in reducing adult smoking rates in Thailand, it will have a direct impact on Philip Morris' top-line growth from Asia and might also inspire other countries in the world to take similar measures.

## Issues

### **Antimicrobial resistance activities**

#### **Community engagement on rational use of antibiotics - Malaysia**

Following the written agreement between Action on Antibiotic Resistance (ReAct) South East Asia, USM School of Pharmaceutical Sciences and Yayasan Bina Ilmu (YBI), a civil society organization, an introductory workshop was launched at the 1 Malaysia Community Hall in Sungai Pinang, Penang on 18 July 2012.

The workshop aimed to engage the local community members, who are predominantly from the lower to middle income group, on managing antibiotic resistance. YBI serves 8 villages within the area and focuses on various aspects of education, health and community welfare.

By highlighting the issues related to antibiotic use and resistance, the workshop marked the first step towards awareness raising on antibiotic use and resistance among the community. Thirty YBI leaders were guided on ways they can play an 'ambassador role' in spreading the message to others within their community. Key themes that were used during the program include:

- Do bugs need drugs?
- Save the pill for the really ill
- Antibiotics: Not a magic bullet
- Bacterias are smart....treat them smartly

The duration of this project is 3 years.

### **Training-of-the-Trainer (TOT) Workshops**

In November, a three-day series of 'Train-the-Trainer' workshops was organized for 30 community members /leaders from 9–11 November 2012 at the same community hall.

Participants were provided information training materials (teaching guidelines and a module, '*What you should know about antibiotics*', books and pamphlets) on antibiotics and antibiotic resistance that they can disseminate to fellow community members and other interested communities.

Following the success of this event, the participants were motivated to organize their own antibiotic smart use campaigns.

In 2013, monthly sessions were set up with the trainers to ensure a smooth and up-to-date knowledge transfer to community members. All the materials were also translated into Bahasa Melayu and made available for public use.

### **Knowledge Sharing**



A series of focus group discussions were undertaken by Ms. Nadja Trygg, a Master of Public Health Sciences student from the Medical Management Centre of Karolinska Institute, Sweden, doing a case study on civil society organization projects in Malaysia.

The focus group discussions revealed that community leaders want better engagement between health personnel and its community for health knowledge and successful empowerment of the public.

In view of the study findings, policy recommendations will include:

1. A better understanding of the population's social and environmental context by health educators and
2. Enhanced public education on issues related to antibiotic resistance (ABR) at the grass root community level.

The results were presented as reports and the recommendations were embedded into the working plan of the project.

In October 2013, Mr. Sharrieffuddin represented USM to present the findings and a progress update at a conference organized by ReAct in Ecuador, Latin America.

Back in the homeland, 40 community leaders from all over Penang Island were invited to attend a forum on ABR. The progress on the project will be presented and plans are in line to expand it to another community.

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## **Syria's polio outbreak is a global public health emergency**

*Michael Toole, AM, Professor of International Health at Burnet Institute and member of the Independent Monitoring Board of the Global Polio Eradication Initiative.*

*The Conversation 7 November 2013*

<https://theconversation.com/syrias-polio-outbreak-is-a-global-public-health-emergency-19779>

As if the children of Syria had not suffered enough, the news of an outbreak of polio (poliomyelitis) signals that even more suffering lies ahead. The polio virus invades the nervous system and can kill or cause lifelong paralysis. Wild poliovirus had not been detected in Syria since 1999. But on 17 October a cluster of 22 cases of 'acute flaccid paralysis', the signature symptom of clinical polio, was reported from Deir Al Zour province....

Wild poliovirus had not been detected in Syria since 1999. But on 17 October a cluster of 22 cases of 'acute flaccid paralysis', the signature symptom of clinical polio, was reported from Deir Al Zour province.

Since then, wild poliovirus type 1 (WPV1) has been found in 10 of the cases under investigation, all in children under the age of two years.

### **Eradication so close**

The world has come tantalisingly close to eradicating polio. In the 1980s, the virus killed or paralysed around 350,000 people annually. Then Rotary International launched a global vaccination campaign, in partnership with the World Health Organization and UNICEF and more recently, the US Centers for Disease Control and Prevention and the Bill and Melinda Gates Foundation.

In 2012, there were just 223 cases in five countries. Only three countries – Afghanistan, Nigeria and

Pakistan – have never interrupted transmission of the wild poliovirus.

But this year, there have been severe setbacks.

In Somalia, 180 cases of polio have been reported so far this year in areas controlled by the Islamic militants group Al Shabab, which has banned vaccination. That outbreak has spilled into neighbouring countries with 14 cases in Kenya and seven in Ethiopia.

Worldwide, there have already been 332 cases this year – almost 50% higher than last year's total.

### **Types of vaccinations**

There are three types of wild poliovirus: 1, 2, and 3. There have been no cases of WPV2 since 1999 and the last case of WPV3 occurred in Nigeria almost 12 months ago. All cases of polio this year have been caused by WPV1. In theory, this trend makes it easier to control the disease.

The most commonly used vaccine is trivalent oral polio vaccine (OPV) which produces immunity in the mucosa (soft tissue) of the gut to all three types, preventing the virus from entering the bloodstream. But newly developed monovalent vaccines more efficiently induce immunity against a single type.

The downside is that on rare occasions the live vaccine virus mutates into a paralytic form, is excreted from the gut, and may circulate in communities where immunity is low. This is called circulating vaccine-derived poliomyelitis and is the reason why most developed countries such as Australia have switched to inactivated polio vaccine (IPV). This injectable vaccine induces immunity in the bloodstream but not in the gut.

### **Latest outbreaks**

Final genetic sequencing results are pending to determine the origin of the viruses isolated in Syria. The big surprise is that the source may be Israel.

Since February 2013, more than 100 samples of sewage have been positive for WPV1 in southern and central Israel, and more recently samples have tested positive in Gaza and the West Bank. There have been no cases of paralytic disease during this "silent" outbreak.

A stool survey in southern Israel found that almost 5% of Bedouin children and almost 1% of Jewish children tested positive for WPV1.

More than 95% of children in Israel, Gaza, and the West Bank have been vaccinated with IPV which explains the absence of clinical disease. But if children with WPV in their gut come in contact with children who do not have adequate immunity, they may transmit the virus which may then cause paralytic disease. Given the mobility of

the Bedouins, the virus may spread through Jordan, northern Egypt, and quite possibly Syria.

This spread has implications for Australia, where the anti-vaccination lobby has led to many parents not vaccinating their children, making them vulnerable to virus.

Other than Israel, the remaining reservoirs of WPV are all in conflict-affected countries: Afghanistan, Northwest Pakistan (where the Taliban has banned polio vaccination in North and South Waziristan), Somalia, Northwest Nigeria (where the militant Boko Haram has murdered vaccinators), and now Syria.

### **One step forward, two steps back**

Afghanistan has employed innovative methods to reach children in insecure areas and has had just eight polio cases this year, all in the Eastern region neighbouring Northwest Pakistan. While President Hamid Karzai has exhibited strong leadership holding provincial governors accountable for vaccination campaign performance, he has maintained a low public profile to avoid opposition to vaccination by anti-government elements.

The Grand Imam of Al-Azhar Mosque in Cairo (the Sunni equivalent of the Vatican) has issued fatwas demanding that Islamic mullahs remind parents that vaccinating their children is an obligation. This has had some effect on countering the anti-polio vaccination propaganda of the armed militants.

Nevertheless, armed conflict coupled with negative propaganda remains the major obstacle to achieving the goal of ridding the world of this devastating disease. We are facing a global public health emergency that demands action at the highest level of the world's diplomatic community.

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### ***Is basic scientific research skewed to support the pharmaceutical industry?***

*MJA Insight December 2, 2013*

*Jane McCredie, Sydney based science and medicine writer*

<https://www.mja.com.au/insight/2013/46/jane-mccredie-basic-flaws>

We've heard much in recent years on the potential for clinical researchers' relationships with industry to skew published research findings, with flow-on effects on prescribing and other aspects of clinical practice.

This [Cochrane review](#)<sup>1</sup>, for example, last year found industry-sponsored trials of drugs and devices were

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<sup>1</sup>  
<http://onlinelibrary.wiley.com/doi/10.1002/14651858.MR000033.pub2/full>

more likely to report favourable results for both efficacy and harms and to reach overall positive conclusions about the treatment being studied.

But what about industry involvement in basic scientific research?

On the face of it, you might think basic research would have little impact on clinical practice, but Dr Adriane Fugh-Berman, who researches industry-physician relationships at Georgetown University in the US, argues it is widely used to support pharmaceutical marketing.

Animal and even cellular studies are used by manufacturers to promote off-label prescribing, to reduce concern about side-effects and to create a buzz about forthcoming drugs, she writes in *PLOS Biology*.

A former pharmaceutical executive, communicating on condition of anonymity, told Dr Fugh-Berman about some of the ways preclinical work is used by the industry to support clinical messages.

'The work of basic scientists is used for indirect and sometimes direct marketing to highlight a therapy's mechanism of action, to suggest surrogate markers of safety and efficacy, and to differentiate a product from competitors' [products]', he writes.

Dr Fugh-Berman describes her own experience as a doctor in the early 2000s, facing the marketing push to prescribe hormone replacement therapy (HRT) to postmenopausal women off-label for possible prevention of cardiovascular disease and dementia.

'No randomized controlled trials with disease endpoints supported this use', she writes, 'so [physicians paid by the company] invoked observational studies, studies with surrogate endpoints (ie, cholesterol-lowering), experimental animal studies, and even cell-culture studies.'

One industry slide shown at medical meetings compared brain cells grown in media with and without oestrogen, she writes.

'Brain cells grown in estrogen-free media were shriveled and dying, a pathetic counterpoint to the vigorous confluence of cells grown in estrogen-containing media.'

Whatever your take on the whole HRT debacle, it would seem unwise to assume the results of that kind of study would be automatically replicated in living human brains.

There has been little focus so far on whether industry funding of basic research has the potential to skew results in a similar way to clinical research, but Dr Fugh-Berman believes there certainly should be.

She cites evidence suggesting industry sponsorship may indeed encourage positive findings in basic research as well as discouraging publication of less favourable results.

The anonymous pharma executive told her: 'It is to industry's advantage to selectively support particular researchers whose point of view supports marketing goals, and to encourage selective publication of articles.'

Unsurprising perhaps, but the bottom line is any research used to market drugs or other treatments needs to be subjected to rigorous scrutiny, whether it's a full-blown clinical trial or a few cells in a Petri dish.

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## **Universal Health Coverage:**

### **Beyond rhetoric**

Municipal Services Project Occasional Paper No. 20 –  
November 2013

Amit Sengupta

*The complete pdf can be downloaded here:*

<http://www.municipalservicesproject.org/publication/universal-health-coverage-beyond-rhetoric>

### **About the project**

The Municipal Services Project (MSP) is a research project that explores alternatives to the privatization and commercialization of service provision in electricity, health, water and sanitation in Africa, Asia and Latin America. It is composed of academics, labour unions, non-governmental organizations, social movements and activists from around the globe who are committed to analyzing successful alternative service delivery models to understand the conditions required for their sustainability and reproducibility.

### **Executive Summary**

*'There is a rich man's tuberculosis and a poor man's tuberculosis. The rich man recovers and the poor man dies. This succinctly expresses the close embrace between economics and pathology.'*

*Norman Bethune, circa 1930*

This paper raises critical questions around the wide and growing enthusiasm for Universal Health Coverage (UHC), which is increasingly seen as a silver-bullet solution to healthcare needs in low and middle-income countries. Although confusion still exists as to what UHC actually means, international development agencies typically define it as a health financing system based on pooling of funds to provide health coverage for a country's entire population, often in the form of a 'basic package' of services made available through health insurance and provided by a growing private sector.

Global health agencies such as the World Health Organization, and international financial institutions such as the World Bank, are promoting this approach in response to the rise in catastrophic out-of-pocket expenditure<sup>1</sup> for health services, and in the face of crumbling public health systems in the global South

(both of which were precipitated by the fiscal austerity imposed by these same international financial institutions in the 1980s and early 1990s). In this new model, UHC prescribes a clear split between health financing and health provision, allowing for the entry of private insurance companies, private health providers and private health management organizations.

The logic is that healthcare challenges require an immediate remedy, and since the public system is too weak to respond, it is strategic to turn to the private sector. In short, the UHC model is built on, and lends itself to, standard neoliberal policies, steering policy-makers away from universal health options based on public systems. Building and improving the public healthcare system is not part of this mainstream narrative, with the state generally confined to the role of system manager.

Although these programs are now zealously promoted by global health agencies, the evidence to support their implementation remains extremely thin. Reliable data upon which to evaluate their performance are hard to come by (Giedion et al 2013) and methodologies designed to collect good evidence are singularly lacking, illustrated in this paper by the highly contested data of some early health reforms based on universal insurance in the South, eg Chile, Colombia and Mexico, which have nonetheless been used to legitimize the current UHC agenda.

The paper argues that secure finances for health care are a necessary but insufficient condition for systems that are equitable and provide good quality care. We analyze the reasons why finances need to be channeled through well-designed public systems if they are to be spent efficiently. We further argue that, in glossing over the importance of public provisioning of services, many proponents of UHC are actually interested in the creation of health markets that can be exploited by capital.

To contextualize the UHC debate, we look at Europe's experiences in constructing similar models, whereby health becomes a marketable commodity. We also present the cases of Brazil, India and Thailand to illustrate how this trend has become global, reinforced by the implementation of new UHC initiatives. Our analysis shows that despite policies in favour of universal public health care, the neoliberal ethos has become dominant in these countries' health systems. Thus, even in the case of widely acclaimed reforms, equity and efficiency tend to be compromised because ideological pressures prevent the adoption of an entirely **public** system of care provision. The challenges of high quality and equitable health care are most acute in low and middle-income countries because of faster growing populations, higher prevalence of infectious diseases,

and growing burdens of non-communicable illnesses. Re-imagining public health care – rather than the private sellout of health systems via UHC – is argued to be the only way forward in building truly **universal** health outcomes.

organized by the UN Standing Committee on Nutrition and then in the FAO/WHO prep meeting for the 2014 upcoming International Conference of Nutrition +22 (ICN2).

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## News

### PHM

#### **Claudio Schuftan has been busy**

Claudio recently visited Morocco where he was invited to present at a conference on Social Protection and the Right to Health. He also had a successful meeting with PHM sympathizers in Morocco to get them organized. Together they discussed a possible IPHU course in Morocco on sustainability which could be organized by them in 2014.

Claudio went on to Rome where he participated first, in a one day seminar on nutrition and sustainability

#### **French Where There are no Pharmacists in Vanuatu**

*Là où il n'y a pas de pharmaciens*, the French translation of *Where There are no Pharmacists* was published by TWN and HAIAP in January 2013 with the support of the Ecumenical Pharmaceutical Network (EPN), and the German Institute for Medical Missions (DIFAM) – mainly for distribution in francophone Africa.

We were delighted when the balance of the French copies were purchased in October for distribution in Vanuatu. Vanuatu is a Pacific Island Country where the French language is commonly used as well as English and the indigenous languages. In colonial times, Vanuatu was a condominium, run jointly by France and Britain.

### **HAI Global Network**

#### **HAI Global**

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