August 2013

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.

In this issue

Message from the Coordinator	1
Award – Kidsmart products	2
Consumer issues - The Checkout	3
Fire in the blood	3
News from the Region	
Update on TPP negotiations	4
Issues	
Can FDA be trusted	5
Doctors urged to Boycott dextropropoxyphene	5
Features	
War-torn Somalia eradicates polio – again	7
Two decades of struggle – Novartis, India	8
Feature article	
Legislation an essential tool for ensuring access to medicines policy goals	11
APCNMP Report	6, 13

Message from the Coordinator

After an absence of 10 years I attended this year's 66th World Health Assembly (WHA) in Geneva from 20 – 28 May at the UN Palais as part of the TWN team but also wearing the HAI, and by extension, the PHM hats. As a lead up the WHA, the TWN office in Geneva was abuzz with activity when a team of WHO Watchers from PHM met there daily for four days to discuss interventions on specific WHA resolutions. I learnt that other groups too were carrying out similar workshop-type activities in Geneva. One such group was the International Federation of Medical Students Associations or IFMSA, a dynamic, resourceful and energetic global network of young medical students, which later went on to organise a meeting on the Health Rights of the Girl Child during the WHA itself.

These lead-up activities reminded me of a time, in the 80s and 90s, when HAI and its regional offices at the time – HAIAP, HAI Europe, HAI Latin America and the Caribbean and HAI Africa too, organized similar activities – some of which I was part. The HAI team would meet prior to the event to plan interventions and in the evenings to evaluate the day's proceedings and strategise for the next day's activities. It was a time of great excitement and wonderful interaction, when relationships were forged and still stand strong today. I am informed by HAI pioneers that, in the early 80s Consumers International (IOCU at that time) and TWN organized seminars/workshops prior to the WHAs to discuss contentious issues and strategise and plan interventions. It was at one such workshop that HAI in fact was born!

For the future, some serious consideration should be given to organizing workshops around specific resolutions and emerging health concerns and inviting participation from young and energetic groups such as IFMSA and Médecins Sans Frontières, WHO partners

and activists and country delegates, either in the lead up to the WHA or as side events during the WHA itself. Having attended several similar events in this last 66th WHA, my experience is that delegates, whether government or non-government, will participate if the workshop is relevant, topical or unusual, controversial, and the speakers diverse.

And while the WHA itself can appear like a big mad carnival, it is in the spaces in between the proceedings that actual work takes place – when public health interest groups have an opportunity to meet, lobby, advocate and network with country delegates and each other. What was it that is said about 'the corridors of power'? Oh yes, places were deals are made.....

Shila Kaur, HAIAP Coordinator

Award

We are introducing an 'Award' section. We look forward to members letting us know who has received an award, or who deserves one.

We would like to share award winning achievements of members and others.

However, this edition features an Award of a different sort - the 2012 ***Choice*** 'Shonky' Award – conferred on *Nature's Way Kidsmart* by – the Australian Consumer Organisation, ***Choice.***

http://www.choice.com.au/checkout-tv/guilty-mum/shonky-kidsmart.aspx

Choice 'Shonky' Award conferred on Nature's Way Kidsmart

[Kidsmart claim their products are 'based on the healing principles of homeopathy, a natural and therapeutic system that stretched back over 200 years'. Ed]

The idea of selling water for upwards of $1000 per litre and claiming it is medicine represents the very essence of shonkiness. But convincing anxious or desperate parents they can use it to treat their children's ailments takes it to a whole new level. Introducing the Nature's Way Kids Smart Natural Medicine range, with variants for colds and flu, hay fever and runny nose, pain and fever, and for calming kids down. Already feather-whipped by the TGA for making unsubstantiated claims about the uses and effectiveness of the products, the company has done nothing to temper its assertions that the products might actually do something.

Most of the homeopathic 'ingredients' – and given the dilution factor, we use the term loosely – feature plant extracts, including strychnine and insecticidal *Sabadilla*, and arsenic. Stop. Rewind. Was that *strychnine*? They're giving kids *strychnine*? Sure enough, the 'Nux vomica 6C' in the 'Calm' liquid is the homeopathic term for strychnine, in a dilution of one in a trillion.

To picture this 6C dilution in real terms, imagine you have an Olympic-size swimming pool full of water. Now take 20 such pools, and join them all together. Now put one drop of the strychnine 'mother tincture' (the original liquid containing the now-discarded strychnine) in this mega pool, stir, and you have a 6C Nux vomica swimming pool. Worried? Well don't be: this is further diluted in the bottle by a further one-thousandth.

Clearly the harm is not from the stuff itself – it's effectively water with blackcurrant flavour. The harm comes from it doing nothing for your children in the expensive and mistaken belief you're doing something.

As public health campaigner Dr Ken Harvey points out, 'Symptoms like 'restlessness, anxiety, irritability and agitation' the '*Calm*' claims to treat can be the symptoms of potentially serious childhood infectious diseases for which a homeopathic remedy is entirely inappropriate. Such misguided treatment might make a parent postpone seeking more appropriate medical advice to the child's detriment. 'In my opinion, such promotion is dangerous and an affront to public health and medical science.'

The claims have been referred to the Australian Competition & Consumer Commission (ACCC) for investigation. NSW Fair Trading has written to the ACCC and offered to assist.

……

Kidsmart record

It has been noted that Kidsmart products had been the subject of numerous upheld complaints and the sponsor (Pharmacare Laboratories) had a long track record of non-compliance with Complaints Resolution Panel determinations.

In a determination dated July 31, 2013 (made available August 19, 2013) the Panel noted that representations at a number of Internet pharmacy sites were essentially subsets of the representations at the website operated by Pharmacare. Moreover, only Pharmacare, the sponsor of the advertised product, submitted evidence in relation to the complaint.

A number of Internet pharmacies responded that they had relied upon material provided by Pharmacare for website content.

Pharmacare stated that they 'have no control about third party advertising'. The Panel was therefore satisfied that it was necessary and appropriate for corrective information to be placed before the public. The Panel requested that Pharmacare publish a retraction, and that each of the retailer advertisers publish corrective statements. See the retraction requested for the sponsor - next page.

Given previous non-compliance by Pharmacare with the Panel's determination it will be interesting to see if this latest one is complied with.

RETRACTION

An advertisement for four Nature's Way Kids Smart products, which we published on this website, should not have been published. The four products were Nature's Way Kids Smart Natural Medicine Pain & Fever, Nature's Way Kids Smart Natural Medicine Cold & Flu, Nature's Way Kids Smart Natural Medicine Runny Nose & Hayfever, and Nature's Way Kids Smart Natural Medicine Calm.

In the advertisements we unlawfully made claims that the products could have therapeutic benefits in relation to a range of conditions and ailments in children and infants including anxiety, irritability, colds and flu, congestion, and hayfever.

A complaint about the advertisement was recently upheld by the Complaints Resolution Panel. We provided no evidence that the advertised Nature's Way Kids Smart products are effective, and relied exclusively on evidence about traditional homeopathic ingredients contained in the products. Consumers should be aware that traditional homeopathic ingredients are ingredients that are traditionally dispensed by homeopathic practitioners, and generally contain only insignificant or undetectable quantities of any active ingredients.

The Panel found that the claims were unlawful, misleading, and unverified and breached the Therapeutic Goods Advertising Code. The Panel also found that the advertisement abused the trust and exploited the lack of knowledge of consumers.

The Panel therefore requested that Pharmacare Laboratories Pty Ltd publish this retraction.

Australian TV Comedy *Checkout* looks at consumer issues

http://www.abc.net.au/tv/thecheckout/

Australian comedy group known for their production of 'The Chaser', in collaboration with *Choice,* had an indepth look at many consumer issues in a series on National ABC TV called ***The Checkout***. Thanks to the producers, we have been able to make a selection available for you to see.

The first episode looked at complementary medicines

https://www.youtube.com/watch?v=QMYXKSy2fb8

and https://www.youtube.com/watch?v=_vPha4usTtI

Here are segments of some others

Chronic Pain…

https://www.youtube.com/watch?v=tfNqBP900L8

Craig impersonating Nicole Kidman in her *Swisse* ad: https://www.youtube.com/watch?v=12ww26sQF7E

Fire in the Blood: A moving documentary of real heroes and villains

Shila Kaur, Penang, July 2013

On the sidelines 66th World Health Assembly (WHA) held in Geneva from 20 – 28 May 2013, Medecins Sans Frontieres (MSF) hosted the screening of Fire in the Blood, a groundbreaking and provocative documentary on the global fight for access to life-saving medicines with particular reference to HIV infection. Held at the Swiss Press Club on 21 May 2013, the screening which began at 6.30 pm in the evening, was exclusive to participants at the WHA and invited guests. Present at the screening were its director Dylan Mohan Gray and a panel including Mohga Kamal-Yanni from Oxfam, Rohit Malpani from MSF's Access Campaign and James Love, Director at Knowledge Ecology International, USA.

With almost a full house of 150 people, it was obvious that viewers came with a knowledge base of the issue and expectations of meeting some of the lead players in the documentary and possibly hosting similar screenings either in their home countries and workplaces or for advocacy and educational activities.

The website for ***Fire in the Blood***, [1]calls it 'An intricate tale of medicine, monopoly and malice' – how Western pharmaceutical companies and governments aggressively blocked access to low-cost HIV drugs for the countries of Africa and the global south in the years after 1996 – causing 10 million or more unnecessary deaths – and the improbable group of people who decided to fight back.

Fire in the Blood was shot on four continents and includes global figures such as Bill Clinton, Desmond Tutu and Joseph Stiglitz. It tells a tale of 'the remarkable coalition which came together to stop 'the Crime of the Century' and save millions of lives in the process.'

The film critiques the system by which medicines become subject to monopoly, and in that respect can be regarded as being 'political' in its aim. According to Dylan, 'The biggest obstacle to reforming the current system is the dogged intransigence of the international pharma industry, which has almost unfathomable financial resources and political clout. 90% of the billions upon billions of pounds this industry spends on marketing every year is directed at doctors, whose relationships of trust with their patients the companies seek to leverage for commercial gain.'

[1] http://fireintheblood.com/

Some of the leading figures depicted by Dylan in ***Fire in the Blood*** are medical doctors who stood up against systems that devalued patients lives. 'To me, these people are true heroes, and embody the very best ideals of your profession,' writes Dylan in his blog.

Like others in the audience ***Fire in the Blood*** moved me to tears – it is a story of courage and empowerment amidst hopelessness and injustice, about small people fighting big battles when the stacks are high against them and the unbearable loss of unlived lives that mothers must bear. It is about power and cruelty on one hand and humanity and goodness on the other. I came away with admiration and respect for those unsung heroes, which ***Fire in the Blood*** made immortal on the screen so that the world can witness and partake in their bravery and rejoice in the human spirit to fight for what is right and just, irrespective of the outcome. This was a story that needed to be told and Dylan did a marvellous job of it.

For those of us in the international health community working on rational use of medication, you will see and hear familiar faces and voices. The message always hits closer to home when it is spoken by familiar and loved ones.

Update on the Trans Pacific Partnership negotiations and Public Health

Deborah Gleeson, PHM Australia, 7 August 2013

Status of the negotiations

Round 18 of the TPP negotiations, was held in Kota Kinabalu, Malaysia on 15-25 July 2013.

At this negotiating round there was a strong sense that the TPP countries are attempting to conclude as many areas of the text as possible before the self-imposed deadline of October 2013. But it was also clear that some controversial areas of the text, including particularly the intellectual property, state-owned enterprises and environment chapters, will not be concluded by then. Some other chapters where there are major unresolved areas include labour, investment and government procurement. There is likely to be some technical work remaining after October, and some issues that cannot be resolved at the technical level will be pushed up to the political level for resolution.

Japan joined the negotiations for the last two days of the round. At this stage it is unclear what impact Japan's entry will have on the timelines for completion. Japan may not be so willing to accept text that has already been agreed by the other Parties.

The next round – perhaps the last formal round - of negotiations is coming up very soon on 22-30 August in Brunei. Much of the remaining technical work may be completed via 'inter-sessional' meetings or other means before or after the next round.

Update on key public health issues of concern

Access to medicines

The extreme US proposals on intellectual property and pharmaceuticals that would severely constrain access to medicines continue to be opposed by all of the other TPP Parties.[2] According to a report by Gordon Campbell (http://www.scoop.co.nz/stories/HL1307/S00122/gordon-campbell-on-the-tpps-risk-to-national-sovereignty.htm), World Trade Online reported on 17 July 2013 that six countries, including Australia, Canada, Chile, Malaysia, New Zealand and Singapore had tabled a principles or discussion paper at Round 17 of the negotiations that presented an alternative to the US proposal. While this paper is likely to be far more moderate than the US proposal, Vietnam is not involved. Vietnam is the most vulnerable party in terms of access to medicines.

The healthcare annex to the transparency chapter, which contains provisions directed at pharmaceutical pricing and reimbursement schemes, specifically targets national reimbursement schemes such as Australia's PBS and New Zealand's PHARMAC but could also have implications for other countries that have national formularies and/or price controls of some description. All countries appear to remain opposed to the draft text tabled by the US. Public health advocates are comcerned that the US has not tabled a more acceptable proposal, as it seems likely that the annex will become a political issue towards the end of the negotiations, where trade-offs between different sectors are likely.

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

[2] MSF analysis of the US proposals see annex at http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Letter_MSF-TPPOpenLetterGeneral_ENG_2013.pdf

Issues

Can the FDA be trusted?

From E-drug with thanks to Donald Light, Resident Fellow, Edmond J. Safra Center for Ethics, Harvard University Professor, Rowan University-SOM Visiting Researcher, Center for Migration & Development, Princeton University

During this year as a Fellow at the E J Safra Center for Ethics at Harvard University, I have been part of a team on 'institutional corruption' in how prescription drugs are tested, approved, and marketed. Our research shows that the FDA cannot be trusted to carry out its historic mission to protect patients from harmful and ineffective drugs.

For years, the FDA has allocated less than 10 percent of its budget to monitoring prescription drugs for harmful side effects, and 90 percent to approving new drugs. However, independent expert teams of physicians and pharmacists have found that most new drugs are little better for patients than previously approved new drugs. They may be technically innovative and better than a placebo, but not clinically better for patients. The small percentage of clinically superior new drugs help patients and add to the large medicine chest of effective drugs.

The Harvard Center has just posted a blog about this research. It focuses on how FDA officers are proposing to approve new drugs for 'early stage Alzheimer's disease' when no such disease exists and they admit there are no biomarkers or clinical symptoms that differ from people misplacing something or saying 'I've forgotten what I was going to say... '

See the text and links:[3]

http://www.ethics.harvard.edu/lab/blog/312-risky-drugs.

In effect, the FDA is acting as a market-maker to legitimate drugs for a non-disease fear of incipient Alzheimer's disease, using even less evidence that the drugs are safe or effective than they use now.

The FDA has played this role before, legitimising a widespread non-disease and approving drugs for them. 'Osteopenia' as a constructed disease is a good example, designed to expand sales. While most new drugs approved by the FDA are slightly better than a placebo or substitute measure, they may be worse (or better) than drugs approved in previous years for the same condition. But all of them are under-tested for harmful side effects. Prescription drugs are the fourth leading cause of death, on a par with stroke. One in every five new drugs is likely to cause serious harm. There is an epidemic of harmful side effects from prescription drugs, about 80 million a year in the United States alone. (See the linked article) [4]

The FDA's new array of post-market surveillance measures to detect harmful side effects, we find, is not yet doing that job. It may, after years of pilots and ramp-up; but for now there are about 2460 deaths and 53,000 hospitalizations every week of the year from serious adverse reactions.

Simple reforms could make new drugs safer and more effective than they are now. But the FDA is going the other way, by lowering criteria for approval, less is known about whether new drugs are better or safer, leaving it to drug sales representatives to tell us that they are, based on no solid evidence. Are we returning to the era of hucksterism of the 1890s?

Doctors urged to boycott dextropropoxyphene

Cate Swannell

MJA Insight Issue 31, 19 August 2013

[Copied as fair use]

TWO leading pharmacologists have called for a boycott on prescribing dextropropoxyphene after its manufacturer successfully appealed the drug's removal from the Australian Register of Therapeutic Goods.

Dextropropoxyphene, an opioid, was approved for mild-to-moderate pain more than 30 years ago. Since then evidence has accumulated that it is no more efficacious than paracetamol.

A 'For Debate' article in the *MJA* said the drug also carried a significant risk of sudden death from cardiotoxicity in patients with renal impairment, drug interactions and accidental or deliberate overdose. (1)

Despite this, dextropropoxyphene remains on the market in Australia after an appeal to the Administrative Appeals Tribunal (AAT) by the drug's manufacturer against the Therapeutic Goods Administration (TGA) decision to delist it, the authors wrote.

The drug has been banned in the UK (2004), EU (2009), US (2010), New Zealand (2010) and elsewhere, they wrote.

The TGA delisted dextropropoxyphene in 2011, with the decision reaffirmed in January 2012. (2)

The AAT upheld the appeal by the manufacturer, Aspen Pharmacare, allowing dextropropoxyphene to remain on the market provided 'conditions were put in place directed at minimising the risk'. (3)

[3] http://www.ethics.harvard.edu/lab/blog/312-risky-drugs

[4] http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2282014

In its judgment, the AAT said that 'the Tribunal has concluded that the quality, safety and efficacy of both Di-Gesic [dextropropoxyphene/paracetamol] and Doloxene [dextropropoxyphene napsylate] is not unacceptable. In consequence, the products will remain on the [Australian Register of Therapeutic Goods]'.

Professor David Henry, CEO of the Institute for Clinical Evaluative Sciences and professor in the Department of Medicine at the University of Toronto, told *MJA InSight* that more attention needed to be paid to Aspen's role.

If the TGA and AAT were not able to protect the public, 'doctors and pharmacists should take matters into their own hands and stop using this dangerous and useless drug', Professor Henry said.

He said doctors might also consider whether to use other products from the same manufacturer.

Professor Andrew Somogyi, professor of clinical and experimental pharmacology at the University of Adelaide, said he was convinced the only way to keep the public safe from dextropropoxyphene was if Aspen now voluntarily removed it from the market.

'And the only way the company will remove it is if there are no sales', Professor Somogyi told *MJA InSight*.

He called on medical educators to educate their students and peers about therapeutic guidelines that advised against prescribing the drug. 'That's the only way.'

A spokesperson for Aspen Pharmacare told *MJA InSight* the company's policy was not to speak to the media.

Professor Somogyi said the AAT decision set 'a very dangerous precedent' as well as damaging Australia's reputation internationally.

'I'm quite embarrassed about it, actually', he said. 'Internationally, people are looking at us and saying 'what's going on?'. The TGA is being viewed as foolish and naïve, and the clinical investigators are being made to look foolish as well.

'I feel very sorry for the TGA', Professor Somogyi said. 'They're doing the best they can to protect the public. They made a very good decision about dextropropoxyphene and then they get this ludicrous decision [from the AAT].'

A spokesperson for the TGA said each party would have an opportunity to consider an appeal to the AAT finding.

The authors of the *MJA* article said the case highlighted the need to reform the appeal process by drug manufacturers for the sake of public safety and interest.

'When registration can be contrary to TGA advice and based around civil court proceedings rather than scientific interpretation of evidence, the international reputation of Australia's drug regulatory system could be at stake', they wrote.

'[The case] should clearly highlight to our government the urgent need to revise the legal appeal processes that in our view inappropriately burden the TGA when it decides to take action to protect the Australian people.'

1. MJA 2013; 199 (4): 257-260 Trials and tribulations in the removal of dextropropoxyphene from the Australian Register of Therapeutic Goods

2. TGA 2012; Media release: Update on TGA decision to cancel prescription pain-killers, 6 Sept

3. Administrative Appeals Tribunal of Australia 2013; Aspen Pharmacare Australia Pty Ltd and Minister for Health and Ageing [2013] AATA 197

Note from HAI AP News editor: Comments attached to the article were for and against removal of the drug. See https://www.mja.com.au/insight/2013/31/doctors-urged-boycott-dextro

.

From the APCNMP report – see back page:

Bangladesh: A long history of national medicines policy: where are we now?

Dr Zafrullah Chowdhury reflected on the pioneering work on national medicines policies with the introduction of the National Drug Policy in Bangladesh in 1982. Activities at that time included the import of raw materials on international competitive tender, price fixation of all essential medicines by government and a ban on the manufacture of antacids and oral vitamins by foreign companies. Over 1700 harmful

or unnecessary medicines were deregistered and destroyed. Most drug prices dropped by 50–75% in two years. Drug registration procedures and the quality of medicines improved. Since then, Bangladesh has achieved near self-reliance in the manufacture of quality essential medicines. However, some of the early gains have been lost.

While the prices of some essential medicines are reasonable, others are not. The government introduced the Indicative Price System, violating procedures in the drug policy. Under these revised processes, the prices of 117 drugs and vaccines are fixed by the Drug Regulatory Authority and the rest by manufacturers. In the absence of continuing education for practising physicians, irrational prescribing is common. Pharmaceutical company representatives have taken the role of teachers for doctors. An excellent drug policy will fail to protect patients without ongoing support and commitment of politicians and bureaucrats to rigorous and transparent processes and regular, high quality continuing education for medical practitioners.

Feature: War-torn Somalia eradicates polio – again

Compiled by Beverley Snell from a range of news sources

Somalia has been torn apart by war and violence since 1991 and has no central government or detailed medical data. The country is run by war lords and a significant proportion of the population is living as 'internally displaced persons'.

Yet a team of UN health workers have been able to repeatedly achieve eradication of polio. The last case of indigenous polio was reported in 2002 but re-infection occurred three years later with a virus originating from Nigeria and again this year.

In February 2006, cases were found again. The local polio eradication coordinators shared their troubles in a meeting. In one district, population 200,000, nine clans were at war. Each clan has a warlord. Each warlord had rifles and at least one anti-aircraft gun mounted on the back of a truck. When the campaign coordinator started the polio campaign, one warlord's men twice riddled his house with bullets. The issue: He hadn't hired members of that clan for the $5-a-day jobs to vaccinate children.

The coordinator explained 'The elders in the village can't manage the militiamen. Everyone wants a job, and they'll do anything to get it.'

The world's last small pox victim helps eradicate polio

One of the 10,000 volunteers was Ali Mao Moallim who was the last person on earth to contract smallpox more than 30 years ago.

Ali Mao Moallim, (also known as Ali Maalin) from Merka in southern Somali, was recorded as being the last person in the world to be infected with smallpox in 1977. He was born in 1954 and during the smallpox campaign he was working as a hospital cook. He escaped vaccination – covering his arm and pretending he had been vaccinated already because he thought the vaccine would be painful. After he was infected he was sick for 50 days with smallpox but recovered completely.

Moallim used his battle with smallpox and the story of how he contracted it to show the importance of vaccination. He became an instrumental advocate in the fight against polio in Somalia and helped lend a hand to its defeat in 2008.

'Somalia was the last country with smallpox. I wanted to help ensure that we would not be the last place with polio too,' he said.

> Let's hope he's the last real hero of global health who gets forgotten. No Facebook profile. No Klout score. No Linkedin. No awards by institutions who seem to give them out all over the world.
>
> Ali Maow Moallin survived into stateless land, living a life given anonymously to his community. A footnote celebrity in the halls of academia and public health. Let's not ever let that happen again.
>
> If you read one story about global health people this year, read about Ali Maow Moallin, who died from malaria complications in July. Why this man didn't get more recognition, awards, and respect defies logic. A global health tragic hero that lived on in the in the footnotes of public health lectures and Power Points but who should have deserved much more. *

2013 - Somalia is again battling an outbreak of the virus.

According to the Global Polio Eradication Initiative,[5] there were 45 cases of polio in Somalia this year as of 9 July, nearly half the cases occurring worldwide in 2013. So Moallim got to work again, out in the field. And then he got sick - this time with malaria. Two days after being in the field he was hospitalised and died on July 22. [6]

Ali Moallim leaves behind a wife and three children. The thoughts of everyone at the Global Polio Eradication Initiative are with his family at this time. [7]

A tribute to him in ***Rotary Voices*** July 18, 2013 by George R. Camp, a Rotary Foundation Cadre technical adviser had described him as one of the true heroes of polio eradication.

'Because of his brush with smallpox, Moallim became committed to the effort to rid his country of another virus, polio.

He became heavily involved in the polio eradication efforts in his country joining more than 10,000 volunteers, who were eventually successful in getting Somalia declared polio-free in 2008.

Moallim, as a local coordinator for the World Health Organization (WHO), was responsible for social mobilization, and traveled extensively throughout

[5] http://www.polioeradication.org/tabid/488/iid/316/Default.aspx
[6] http://www.polioeradication.org/tabid/488/iid/316/Default.aspx
[7] http://www.polioeradication.org/tabid/488/iid/316/Default.aspx#sthash.MjSTOxAU.BGgCPvhR.dpuf

Somalia encouraging parents in communities to immunize their children against polio.'

The Boston Globe, in a 2006 article on polio, described him as one of WHO's 'most valuable' coordinators. He explained his effectiveness by saying 'Now when I meet parents who refuse to give their children the polio vaccine, I tell them my story. I tell them how important these vaccines are. I tell them not to do something foolish like me.'

The WHO described the eradication of polio as a 'landmark victory' and a testimony to the efforts of the more than 10,000 volunteer workers.

'This truly historic achievement shows that polio can be eradicated everywhere, even in the most challenging and difficult settings,' the WHO's Hussein Gezairy said. 'This repeated success in Somalia indicates the disease can be stopped even in areas with no functioning central government.'

See also

http://news.bbc.co.uk/go/pr/fr/-/2/hi/africa/7312603.stm

* Posted by Jose Gomez-Marquez on the website of Little Devices @ MIT August 1, 2013

Feature:
Two decades of struggle: The *Glivec* precedent *

Amit SenGupta

The Supreme Court judgment in the Novartis case is important as it vindicates the entire process leading to health safeguards being incorporated in the Indian Patents Act. The article discusses this process, from the General Agreement on Tariffs and Trade and popular mobilisation in India to the enactment of and amendments to the Act, in the backdrop of the judgment.

The judgment by the Supreme Court of India, denying the claim of a patent on the anti-leukaemia drug Glivec (imatinib) by the Swiss multinational Novartis, is important at many levels. In this article we discuss, in the backdrop of the judgment, the long and protracted course leading to the enactment of the Indian Patents Act of 2005.

The Uruguay Round

In 1986, a new round of negotiations was initiated under the General Agreement on Tariffs and Trade (GATT), otherwise known as the Uruguay Round of negotiations. In the Uruguay Round, developed countries introduced a number of issues on the agenda – which were hitherto not considered trade issues – related to intellectual property (IP) rights, investment and services.

Initially, developing countries led by India and Brazil were able to stall the introduction of these new issues (Shukla 2000: 14-15), while the US continued to press for their inclusion. The latter's position was dictated by the state of the US economy. Having lost its competitive edge in the manufacturing sector and with its own agricultural exports threatened by state-subsidised agricultural exports from Europe, the US was keen to open up the services sector – especially for financial services. At the same time, the US had an interest in protecting its IP-dependent industries where it still had an advantage, specifically in pharmaceuticals, software and audiovisual media (ibid: 20-21).

India had a clear interest in not agreeing to these new demands. India's pharmaceutical sector had flourished in the wake of its 1970 Patents Act, which did not allow product patents on medicines and agro-chemicals. India only allowed process patents on pharmaceuticals, and had leveraged on this to develop capacity in process technologies.

By the beginning of 1989, the resistance by developing countries was broken down. Enormous pressure exerted by the US resulted in the two main hold-outs changing their position. India went to the extent of replacing India's chief negotiator at GATT, S P Shukla, because of his strong opposition to the inclusion of IP issues in the negotiating agenda (Marcellin 2010: 87).

The significance of the negotiations was not clear to most popular movements and civil society groups in different parts of the world. A key to the development of the resistance in India was the formation of the National Working Group on Patent Laws (NWGPL). In spite of its relatively small numbers, the NWGPL was hugely influential in shaping opposition to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, right from the late 1980s. It was composed of a group of former civil servants, lawyers, scientists, representatives of the domestic pharmaceutical industry and representatives of trade unions in the pharmaceutical industry.[1]

The NWGPL, itself not a mass movement, became a catalyst for advocacy and mobilisation. It was the principal source of evidence-based arguments against the proposed regime on IP. Strong support from the domestic industry found resonance among a wide range of political actors. Over the next decade, the NWGPL organised the 'Forum of Parliamentarians', which had representation from virtually the entire political spectrum. Several political and social movements, non-

governmental organisations and mass organisations in India formed alliances against the GATT negotiations. Many subsequent developments had their roots in the popular mobilisations between 1990 and 2005.

Tortuous Path

The path towards the final formulation of India's Patents Act was also increasingly informed by, from 1991, the formal introduction of neo-liberal reforms. From an earlier position that India was forced to concede to in the GATT negotiations, there was now an attempt to argue that strong IP protection would promote domestic interests. However, popular sentiment continued to be hostile. The TRIPS Agreement provided a three-stage time framework for developing countries: introduction of a 'mailbox' facility and Exclusive Marketing Rights (EMRs) from 1995; provisions on rights related to term of patent protection, compulsory licensing, reversal of burden of proof, etc, by 2000; and introduction of product patent protection in all fields from 1 January 2005.

The political instability in India, post- 1996, meant that further discussions on amendments to India's 1970 Act resumed only in 1998 after the installation of the Bharatiya Janata Party (BJP)-led National Democratic Alliance (NDA) government. Indian Parliament enacted two legislations through the Patents (Amendment) Act of 1999 and 2002, which addressed the first two requirements of the TRIPS Agreement. After assuming office, the NDA government was clearly subsumed by the neoliberal logic while engaging with public policy on a range of issues.[2] The NDA government then circulated the draft Third Patents (Amendment) Bill in 2003, but it could not be discussed because of the change of government in 2004. In 2004, there was a clear consensus between the two principal parties in India – the Congress and the BJP – and the United Progressive Alliance (UPA) government circulated an almost unchanged version of the NDA's Third Patents (Amendment) Bill draft. In the then political spectrum only the left parties (along with some regional parties) stood firmly against the draft Bill. But towards the end of 2004, the BJP started voicing opposition to the draft Bill. While this is in the realm of speculation, BJP's volte-face had little to do with any opposition to the substance of the Bill (given that this was identical to the Bill they had circulated) and more to do with an intent to embarrass the UPA government. With support for the bill now unsure, the UPA government decided to beat the 31 December 2004 deadline by promulgating an ordinance on 26 December 2004 (The Patents (Amendment) Ordinance 2004). Patents Ordinance of 2004.

The Ordinance, if ratified by Parliament, would have made it impossible for Indian companies to continue producing cheaper versions of new drugs. In early 2005, with the BJP engaged in a bitter tussle with the Congress in Bihar and Jharkhand over formation of ministries, it became clear that the Ordinance would be defeated in Parliament and the Congress was now forced to seek the left's support.

In the consequent negotiations between the left and the government, the left largely depended on advice provided by people associated with the NWGPL. These negotiations also allowed other interested parties to suggest new language. At the end, several important amendments were made to the 2004 Ordinance (ICTSD 2005), including the insertion of Section 3(d), which has been the subject of much discussion after its use by the Supreme Court to strike down the appeal by Novartis.

The negotiations were held in the backdrop of protests across the country, as well as in different parts of the world – all demanding that the 'pharmacy of the South' should not be jeopardised. By 2005, the global Access to Medicines campaign was a powerful force and organisations such as Médecins Sans Frontières (MSF) and others were able to organise support across the globe. Protest letters were sent to the prime minister, including one where the co-signatories included Jim Yong Kim, the present World Bank chief (then director, Department of HIV/AIDS, World Health Organization) (Khor 2013).

Important Amendments

While there has been considerable focus on Section 3(d) of the amended Act, many important amendments to the 2004 Ordinance were adopted, including:

(1) Restrictions on Patentability: The amendments clarified that an 'inventive step' means a feature of an invention that 'involves technical advances as compared to the existing knowledge or having economic significance or both'. It incorporated a new definition for 'new invention': any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i e, the subject matter has not fallen in public domain or that it does not form part of the state of the art. It also provided a definition for 'pharmaceutical substance' as being 'a new entity involving one or more inventive steps'.

(2) Restoration of Pre-grant Opposition to Patents: The amendments restored all the original grounds in the previous Act for opposing grant of a patent and also provided that: 'the Controller shall, if requested by such person for being heard, hear him'. The time for filing such opposition was extended from three to six months.

(3) Export to Countries Without Manufacturing Ability: The amendments clarified that a country could import from India if it 'by notification or otherwise allowed

importation of the patented pharmaceutical product from India'.

(4) Continued Manufacture of Drugs with Applications in Mailbox: The amendments clarified that Indian companies that were already producing drugs that were the subjects of mailbox applications could continue to produce them after payment of a royalty, even if the drug was subsequently granted a patent.

(5) Time Period for Considering Compulsory Licence Application: Concerns that the process of granting compulsory licences could take too long were addressed by specifying that the 'reasonable time period before the Patents Controller considers issuance of a compulsory licence when such a licence is denied by the patent holder shall not ordinarily exceed six months'.

(6) Export by Indian Companies of Patented Drugs: The amendments provided that when patented drugs are produced under compulsory licence in India 'the licensee may also export the patented product'.

Several of the amendments are being used today by different groups to try to safeguard access. In particular, the pre-grant opposition provisions have been used extensively by domestic companies and civil society groups, and combined with restrictions on patentability, the provisions have allowed many important drugs to be kept off patents. Further, a number of drugs introduced in the transition phase (1995-2005) were not patented as the amended Act allowed generic companies to manufacture and sell drugs introduced in this period.

The language for Section 3(d) was provided by the Indian Drug Manufacturers' Association (IDMA). The left parties had asked for a more stringent definition of patentability by limiting grant of patents for pharmaceutical substances to 'new chemical entities' or to 'new medical entities involving one or more inventive steps'. Section 3(d) was a compromise and the government had agreed to refer the matter to an expert panel.

Subsequently, the government constituted a Technical Expert Group under the chairmanship of R A Mashelkar, former director general, Council of Scientific and Industrial Research. The Group, in its report in 2007, opined that restriction of patents to new chemical entities would be incompatible with the TRIPS Agreement. Evidence surfaced that parts of the report had been plagiarised from a study by the UK-based Intellectual Property Institute, funded by Interpat, an association of 29 drug companies including Novartis (Padma 2007: 392).

The report was withdrawn and press reports indicated that Mashelkar had resigned from the committee (ibid). Yet, the same committee resubmitted a new version with the same conclusions in 2009. These recommendations were expeditiously accepted by the government.

Vindication of Struggle

The Supreme Court judgment in the Novartis case, thus, needs to be read not just as an instance of the application of one section (Section 3(d)) of the Indian Patents Act. The judgment is important as it vindicates the entire process that led to health safeguards being incorporated in the Indian Act.

The judgment, in fact, refers clearly to this process by noting (in para 26):[3] …to understand the import of the amendments in clauses (j) and (ja) of section 2(1) and the amendments in section 3 it is necessary to find out the concerns of Parliament, based on the history of the patent law in the country, when it made such basic changes in the Patents Act. What were the issues the legislature was trying to address? What was the mischief Parliament wanted to check and what were the objects it intended to achieve through these amendments?

The judgment is a vindication not just of a legislative process, but of popular resistance and mobilisation – in India and across the world – that challenged corporate power. Small victories such as this become inspirations for larger battles.

Notes:

1 For more information about the formation of the NWGPL, see Sen Gupta (2010).

2 See, for example, Arulanantham (2004).

3 Text of final judgment is available at: http://ju- dis.nic.in/supremecourt/imgs1.aspx? filename=40212 (viewed on 20 June 2013).

References

Arulanantham, David P (2004): 'The Paradox of the BJP's Stance Towards External Economic Liberalisation: Why a Hindu Nationalist Party Furthered Globalisation in India', Asia Pro- gramme Working Paper, December, Royal Institute of International Affairs, Chatham House, London.

ICTSD (2005): 'Indian Parliament Approves Con- troversial Patent Bill', *Bridges Weekly Trade News Digest*, 9(10), International Centre for Trade and Sustainable Development,

Khor, Martin (2013): 'A Victory for Patients' Access to Medicines', Global Trends Series, Third World Network,

Marcellin, Sherry S (2010): *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO* (Farnham, England: Ashgate Publishing).

Padma, T V (2007): 'Plagiarised Report on Patent Laws Shames Indian Scientists', *Nature Medicine*, 13(4): 392.

Sen Gupta, Amit (2010): 'B K Keayla: A Personal Reminiscence', *Economic & Political Weekly*, 45(51): 25-26.

Shukla, S P (2000): 'From GATT to WTO and Be- yond', Working Papers No 195, United Nations University/World Institute for Development Economics Research, Helsinki, Finland.

* Published in *Economic and Political Weekly* Vol - XLVIII No. 32, August 10, 2013. Copied as fair use with thanks.

Feature article

Legislation an essential tool for ensuring access to medicines policy goals

Michelle Forzley, Jane Robertson, Anthony Smith.
WHO South-East Asia J Public Health 2013;2:69-71.
[Copied as fair use – with thanks]

Effective national legislation is critical to support the activities of a Medicines Regulatory Authority. However, the law is an under-recognized mechanism for managing issues in the implementation of access to medicines and other medicines policy goals. Regulations are a more flexible tool, have legal effect and the advantage that they can be created or changed without the need to go to the Parliament. Closer collaboration between the health and legal sectors is important as is political commitment for enforcement of the law. Some regional case studies illustrate the opportunities to use the law as an effective tool to implement medicine policies and to meet access to medicine challenges.

Background

Effective medicines legislation and regulations are critical to establishing the framework for and supporting the activities of a Medicines Regulatory Authority (MRA). The value of law to achieving health objectives has been demonstrated in a few areas such as tobacco control.[1] In some cases, misapplied or inadequate laws can act counter to good health outcomes, for example, laws limiting access to narcotic analgesics may deny patients effective pain relief or palliative care.[2] Some of the key requirements for effective legislation and the importance of greater collaboration between the legal and health sectors to achieve good medicines law were discussed in a symposium at the Asia Pacific Conference on National Medicines Policies.[3] In this symposium, solutions available to all MRAs and grounded in law and regulation were demonstrated as key to solving several MRA challenges. These are reported in this article along with some observations on ways forward to making the law an explicit component of medicines policy work.

The Role Of Legislation

Three key legal concepts and their application are relevant for medicines law – legislation, regulation and governance. Legislation includes all forms of laws including international treaties, national legislation and sub-national laws. The law (legislation) defines the universal principles and establishes the MRA, creates the legal mandates and the infrastructure, processes and authority for the MRA to perform its functions. Regulations are used as a legal tool to amplify legislation, to provide more detail and to define the processes, annex schedules or other practical elements required to support MRA activity. Regulations are a more flexible tool, yet still have legal effect and have the advantage that they can be created or changed without the need to go to the Parliament. Policies, standards, codes, models and guidelines can have the effect of law and are useful to support the implementation of medicines policies. Governance is the manner of governing and management; good governance is effective, equitable, accountable, transparent and follows the rule of law. However, having medicines law is not enough. There must be political will to respect and enforce the law.

Country experiences and lessons learned about good practices

Three different country experiences were presented and these demonstrated the value of legislation and administrative regulation to solving medicines regulatory and access issues. Though each problem was different, legal tools were part of the solution. These included suspension of a law through the use of an administrative regulation, the segregation of tax revenue by a law to fund medicines purchases and the integration of non-health sector law to combat corruption.

Bhutan

In the case of Bhutan (population 750 000), a supplier default on a 3 year contract for pharmaceuticals led to an acute shortage of medicines in 2010-2011. The MRA established under the Bhutan Medicines Act (2003) requires that all medicinal products are registered by it. There is currently no local manufacturing capacity in Bhutan apart from a single manufacturer for traditional medicines. So all medicines are imported, mainly from India and to a lesser extent Bangladesh. Faced with the acute shortage of essential medicines, a solution had to be found and it was found in the law. The application of the law was effectively suspended through a regulation that created an exemption from registration requirements if a product had been approved by selected reputable MRAs in another country. This legal solution could be effective in any country with limited capacity and facilities for medicine evaluation.

Palau

The challenges in Palau (population 20 000) related to medicines financing. While the law of Palau obligates

the government to provide essential medicines, it had been difficult to obtain enough money from the legislature to purchase them as funding for medicines must compete with other demands on the national budget. Two solutions were implemented. The first was to create a minimum inventory list of medicines. In effect this was an essential medicines list, an important tool for medicines regulation and prioritisation for purchasing. This dramatically reduced the number of different medicines to be purchased and consequently the total medicines bill which had been higher than the funds available. While this reduced the amount of money required from the legislature, it did not deal with the issue of not having the money available when needed to buy medicines. In response, through legislation, the Government created a hospital trust fund in parallel with the introduction of compulsory health insurance and medical savings. These were financed through a 2.5% tax on all citizens, which were designated by law to the trust fund for the purchase of medicines. This guaranteed access to funds has dramatically increased the availability of essential medicines in Palau.

Corruption

The third country experience discussed was that of corruption, an activity affecting both developed and emerging economies. An example came from an Asian country where high medicines prices were in part due to 'informal' payments that encouraged doctors to prescribe and institutions to purchase particular generic products. It was estimated that around 40% of the generic medicine prices went as incentives to doctors to prescribe. These payments resulted in the purchase of medicines of lower quality, as well as influencing prescribing practices, sometimes towards less appropriate medicine choices. This situation is more likely to occur in environments where there are low salaries for health professionals, an acceptance and rationalisation of 'informal' payments as a professional norm and few consequences for corrupt practices. There are practical, policy and legal responses in these situations. The practical is to ensure appropriate remuneration for doctors and other health professionals. Policy options include efficient, supervised health system management practices for quality assurance of medicines and procurement; legal responses include collaborating with the justice and law enforcement sectors to enforce existing laws. Sometimes it may be necessary to enact new legislation to define illegal and criminal behaviours such as bribery, unjust enrichment or other abuses. The United Nations (UN) Convention against Corruption is available to guide countries on best practices.[4] Countries ratifying the convention must follow it by aligning national laws and practices with those required by the convention. Anti-corruption work being undertaken in other sectors of government may provide a framework and model for similar activities in the health sector.

Building legal capacity and strengthening systems with legislation

The absence of lawyers from the work of the pharmaceutical sector in some countries is a real barrier to the use of effective legal tools and therefore effective regulation. Greater collaboration between the legal and health sectors on medicines law is required. The medicine and health sectors need to work together to learn how to access legal tools and resources; the legal community need to understand good practice in the medicines sector so that good legal practices can be applied. Appropriate legislation jointly drafted needs to be enacted and relevant laws and regulations enforced.

A practical example of this lack of collaboration is found in the example of inspection of medicine facilities. Conference participants reported that often, medicines inspectors do not have sufficient authority to act under the law or there is insufficient evidence obtained to sustain successful prosecution in the courts. In some cases, new or amended legislation may be required to provide the necessary authority to inspectors and regulators. Along with this, there should be training on how to use the powers such as those to seize suspect materials and products, or to shut down manufacturing plants.

Regulators (usually with pharmacy/life sciences but no legal background) must know how to work with law enforcement agencies and also learn the information that must be collected to aid police and prosecutors to take action under relevant laws. Effective enforcement requires political commitment and well-functioning legal institutions and strong co-ordination between various government agencies. Increasing civil society engagement in matters related to health in general, and to the availability and affordability of good quality medicines in particular, will be an important means for maintaining the pressure on politicians and giving voice to the concerns of patients. This will help ensure accountability and transparency in the development of medicines legislation and avoid the perception of undue influence of lobby groups such as the pharmaceutical industry on policy development.

Ways forward

Capacity building and sharing of knowledge and experiences are important to strengthen the use of legislation as a tool for medicines policies development and implementation in the region; working collaboratively with the legal sector is essential. Best practice legal models and tools from other parts of the world should be identified and disseminated. There is considerable scope for increased use of more flexible administrative regulations to support MRA functions and activities. Regular meetings and sharing of best practices could be an effective strategy. A model best practices template for least developed countries with no manufacturing capacity may be useful. It is important that the law is respected and upheld, and that the civil and criminal sanctions available are applied. In some jurisdictions, there are mismatches between breaches and the penalties that can be imposed; these need to be addressed. Well publicized legal action may serve as an effective deterrent to infringements of medicine-related law by others. Local legal capacity may need to be increased and building teams with international experts may assist. An example of an effective model is the Access to Opioid Medication in Europe (ATOME) project in which local lawyers are trained on international standards on opioid medicines practice after which they assess national laws to identify legislative barriers to access to opioid medicines and recommend solutions.[2] Efforts are being made to raise awareness of corrupt practices in the pharmaceutical sector and programmes such as the World Health Organization's (WHOs) Good Governance for Medicines programme[5] and the Medicines Transparency Alliance (MeTA)[6] promote good governance, transparency and accountability.

The recognition of law as an essential tool for medicines policy is overdue. This conference was an important step towards putting legal processes firmly on the regional agenda to support national medicines policies and their implementation.

1. World Health Organization. WHO framework convention on tobacco control. Geneva: WHO, 2003. Available from: http://www.who.int/fctc/text_download/en/index.html [Last accessed on 2013 May 3].

2. Access to opioid medication in Europe (ATOME). Available from: http://www.atome-project.eu/[Last accessed on 2013 May 3].

3. Asia Pacific conference on national medicines policies: Better health through national medicines policies, Sydney, Australia, 26-29 May 2012.

4. Available from: http://www.apcnmp2012.com.au [Last accessed on 2013 May 3].

5. United Nations Office on Drug and Crime. United Nations convention against corruption. UNODC. Available from: http://www.unodc.org/unodc/en/treaties/CAC/[Last accessed on 2013 May 3].

6. World Health Organization. Good Governance for medicines. Geneva: WHO. Available from: http://www.who.int/medicines/ggm/en/ [Last accessed on 2013 May 3].

7. Medicines transparency alliance. London: MeTA. Available from: http://www.medicinestransparency.org/

Proceedings of the Asia Pacific Conference on National Medicines Policies (APCNMP2012)

The report of the Asia Pacific Conference on National Medicines Policies (APCNMP2012) held in Sydney, Australia, on 26-29 May 2012 is now available. The Conference report is published as a supplement to Australian Prescriber and is available online free of charge at

www.australianprescriber.com/supplement/36/1/1/56<http://www.australianprescriber.com/supplement/36/1/1/56>
More detailed summaries of the symposia, workshop discussions and presentations in the plenary sessions are available on the Conference website at www.apcnmp2012.com.au<http://www.apcnmp2012.com.au/>.

HAIAP News is produced three times a year.

We need feedback, suggestions, and contributions for inclusion. Please send them to:

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