

# **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

It's that time of the year – work winds down, festivities begin and family time takes precedence. We all begin to take longer and deeper breaths (some of relief, others of expectation) and we allow ourselves the luxury of not checking our emails obsessively!

A lot happened in 2014 with particular regard to antimicrobial resistance. The 67<sup>th</sup> WHA in May 2014 saw the tabling of Resolution WHA67.25 on AMR, after a deafening silence of more than 10 years; the Global Action Plan will roll out next year in 2015. Several global processes have kicked in following the adoption:

the ReAct/Dag Hammarskjöld Foundation meeting held in June 2014: the 'One health' meeting was held in the Netherlands also in June 2014; the Antibiotic Use in Humans meeting was held in Norway in Nov 2014; the SEARO AMR meeting held in Jaipur, India in Nov 2014 and the Surveillance of AMR meeting in Sweden in Dec 2014. The other global process is the initiation of the Global Health Security Agenda by the US which gives AMR topmost priority.

Other events that have taken place recently in the Asia Pacific region include the ASEAN Antibiotics Awareness Day event, 18 – 19 November 2014 held in Bangkok, Thailand; the ReAct SEA Regional Meeting on Community, Hospital and Policy Interventions to Manage and Control Antibiotic Resistance, 21 – 23 November 2014 held in Penang, Malaysia and the 5<sup>th</sup> Asia Pacific Tripartite Meeting of WHO-FAO-OIE on zoonoses, 24 – 26 November 2014 held in Bangkok, Thailand.

I had the opportunity to participate at all three meetings and interact with a range of participants on AMR, representing international organizations, ministerial officials, health professionals, researchers, academics, farmers, artists, writers, journalists, and civil society. The work on AMR is gathering momentum, the pace is quickening and there is a sense of urgency to take action at all levels. The One Health Approach adopted by the tripartite WHO-FAO-OIE has clear merits; what

was glaringly missing was the lack of involvement of civil society in that process.

The Lancet Commission on Essential Medicines Policies (EMPs) which was launched in October 2014 and aims to reconfirm the relevance of EMPs and formulate recommendations for future global essential medicines policy for the next 20 years. The Commission will report its findings in the November 2015 issue of The Lancet to commemorate the 30<sup>th</sup> Anniversary of the Nairobi Conference on Rational Use of Drugs. mentioned in the feature in this issue, the Lancet Commission welcomes input and involvement from relevant people to strengthen its report. HAIAP members have much to contribute so if you have time, do contact one of the Commissioners mentioned on the website: They include many of our friends and colleagues. http://www.bu.edu/lancet-commissionessential-medicines-policies/get-involved/. commission is chaired by Dr Hans Hogerzeil, now at the University of Groningen, Netherlands.

There have been significant struggles for HAIAP since its inception and 30 years on we see the face of struggle resurrected in specific areas like AMR where irrational use and accessibility combine to make a global public health crisis; and in IP areas where we must be ever vigilant and energetic. Our work is never done; it just takes on different hues, at times more intense and angry; at other times paler and less dramatic.

After three successive meetings – tail-to-tail – my one day off to handle personal business in the capital city of KL began with a night's sleep of disjointed thoughts of AMR, WHO, FAO, OIE, ASEAN, Civil society and campaigns on AMR! We continue to 'work' even during our supposed time of rest.

Have a Blessed New Year! And Merry Christmas to all who celebrate this joyous occasion!

Viva HAIAP!

Shila Kaur, December 15, 2014

### WORLD AIDS DAY: What does HIV teach us about access to medicines for Ebola?

By Mohga Kamal-Yanni

We need to change the present monopoly ownership system to allow public funds their proper place in stimulating accessible and affordable technologies that make our world a safer and more humane place.

Nov 28th, 2014 In Access To Medicines, Ebola, HIV and AIDS

In 2001, I stood in the UN building in front of a huge picture of a woman dying with somebody next to her holding her hand. The writing under the poster read:

'you mustn't die alone'. I wanted to shout: 'she mustn't die full stop'. At that time the new antiretroviral medicines had started to work miracles, bringing people from their deathbeds back to life. Yet as a Ugandan doctor truly said: 'the medicine is in the North but the disease is in the South'. The pharmaceutical industry was happy to sell the medicines at very high prices in rich countries while turning a blind eye to the rest of the world.

It was largely thanks to a huge global mobilisation of civil society led by people living with HIV that leaders and pharmaceutical companies started to feel embarrassed about denying access to life-saving medicines to millions of people. But it was only after generic competition kicked in that access to medicines became something policymakers talked about. An offer by an Indian company to sell a cocktail of the three basic medicines for one dollar a day slashed the prices of antiretrovirals, meaning that today over nine million people are on treatment, including over seven million in Africa.

Generic competition was possible because India had not at that time implemented the Trade Related Aspects on Intellectual Property Rights (TRIPS) and thus was able to manufacture the medicines. Since adopting TRIPS, India's ability to produce medicines has been limited. Yet the country has been under immense pressure from multinational pharmaceutical companies, the US and the EU to tighten its IP rules even further and thus to limit access to medicines to those who need them.

It seems that the world is obsessed by granting more and more monopoly power to pharmaceutical companies rather than by investment in research and development (R&D) for medicines and vaccines that are needed for public health.

#### What lessons should we learn for Ebola?

The profit from treatment of HIV infected people in rich country provided the necessary market that has stimulated R&D for antiretroviral medicines. This is not the case for the Ebola market, which consists of small numbers of people in poor countries. Clearly these people are too poor to pay the price of new medicines and vaccines. Pharmaceutical companies had no commercial incentive to enter into R&D for vaccines or medicines for Ebola – or any other haemorrhagic fever.

For this reason Ebola is the other side of the coin to HIV as the intellectual property rights system allows the market to shape R&D priorities, rather than public health needs. That same system allows companies to charge high prices that are unaffordable in developing countries as the HIV crisis taught us.

The fear of Ebola crossing borders and affecting people in the US and Europe has changed the situation – clearly there is now a market for travelers, but more importantly the threat of a global epidemic means that donors may be willing to pay for products that contain the spread of Ebola and other haemorrhagic fevers.

#### E-Drug and Books on Pills

E-DRUG celebrates its 20<sup>th</sup> birthday in February 2015. It was launched in Boston in February 1995, by a group of volunteer moderators as the English language electronic discussion group on essential drugs and the first message was posted on February 3.

Messages have been archived since June 1995 <a href="http://www.essentialdrugs.org/edrug/archives.php">http://www.essentialdrugs.org/edrug/archives.php</a> and by the end of 1995 communications from Netherlands, Italy, Australia, Madagascar, Spain, Denmark, South Africa, USA, Philippines, Pakistan, Brazil, Canada had already been recorded.

Around the world, E-DRUG is used by health care professionals, researchers and policy makers to obtain and discuss current information on essential drugs, policy, program activities, education and training. Members also use E-DRUG to announce and learn of upcoming conferences or courses in their field.

Discussions focus on topics such as rational use of drugs, drug policy, economics and financing, supply and marketing, legislation and regulation, quality assurance and safety, and training. E-DRUG is especially targeted to health workers in developing countries, and is based on simple off-line e-mail technology. If you are not a member already and would like to join go to

http://list.healthnet.org/mailman/listinfo/e-drug

#### **Books on Pills**

Over the years E-DRUG subscribers have discussed the idea of having a list of 'books on pills'. So many valuable essential-drug-related 'activist' books have been written and it was considered very important that we remember these books and the contributions they have made to the movement for access to essential medicines.

As E-DRUG's 20th birthday and the 30th anniversary of the Nairobi Conference approach, and with the 40th anniversary of the birth of the essential medicines concept not far off, it is timely to revisit these books.

E-DRUG Moderators collated the titles contributed by members and shared the results at the end of 2013. What started out described as the 'List of books on pills', and was initially intended as a list of 'activist' books about Big Pharma, grew to cover a wider range of books related to essential medicines such as rational

use of medicines and essential medicines policies and issues. We all know the importance of Charles Medawar, Virginia Beardshaw, Ellen t'Hoen, Mike Muller, Diana Melrose and so many more. The list is much longer than envisaged and now the intention is that it will become a resource not just of 'activist' style literature related to Big Pharma, but also of key texts touching on the 'essential drugs movement' from its early roots to the present day.

Some additional features are included in the database: keywords and classifications are given to aid in searching the list, ISBNs, some French and Spanish titles are represented, some related films, and a list of useful links including electronic source where available.

Due to the scope of the list, it is made available as an Excel file with multiple worksheets (as well as a Word file with just the list) and can be downloaded from the E-Drug website: http://www.essentialdrugs.org/documents.php

An Excel file version sorted by date will download to your desktop if you click here.

If you are searching for references for your thesis on the activities of the pharmaceutical industry that have had an impact on the use of essential medicines, this resource could be what you have been waiting for. (Missing titles can be added – send suggestions to Beverleyfsnell@gmail.com)

# Intellectual Property Issues and access to medicines – the TPPA

#### Critics Say Trans-Pacific Partnership Agreement Favours Big Pharma, Forgets Patients

International Business Times

Kathleen Caulderwood . October 22 2014 http://www.ibtimes.com/critics-say-trans-pacific-partnership-agreement-favors-big-pharma-forgets-patients-1710426

In early October, WikiLeaks released a 77-page document showing a draft of proposed rules debated behind closed doors. The proposal called for stronger patent protection for pharmaceutical companies. While some observers argue the measures will help boost business and trade, others worry about what it means for poorer nations. Critics say that the lack of transparency and heavy influence of corporate players is a dangerous combination.

Intellectual property rights are one of many issues being discussed, and one particular part related to the pharmaceutical industry has been especially contentious: compulsory licensing, which allows a generic drug producer to copy a patented product without permission in times of great need. Proponents

say this is a necessary feature that ensures patients' access to essential medicine if the need is great, regardless of cost. But members of the pharma industry fear the regulation is being misused, and they say it's infringing on their legal ownership rights.

The rule is included in <u>articles 30 and 31</u> of the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, signed in 1994.

'The proposed TPPA would give an advantage to the pharmaceutical companies at the expense of patients,' said Peter Maybarduk, program director of the Global Access to Medicines Program. Vietnam, for example, is one of the poorest countries and doesn't have the same intellectual property regulation as its American or Australian counterparts. 'In exchange for a trade agreement, they're being asked to trade away a number of safeguards in their economy.'

#### TPPA still under challenge

November 21, 2014

During the G20 held in Australia in late October, it was disconcerting to hear broadcasts of President Obama singing the praises of the proposed TPPA and saying how he looked forward to it being finalised. Fortunately it has not been finalised. As recorded in Public Citizen, below, 'the message of citizens across the globe is clear: we are not willing to accept a 'trade' deal negotiated in secret in the interest of corporations and at the expense of our rights to safety, democracy, and health'.

#### Public Citizen Eyes on Trade

While leaders from the 12 countries negotiating the controversial Trans-Pacific Partnership (TPP)

Agreement met around the margins of the Asia-Pacific Economic Cooperation (APEC) summit in China, more than 10,000 **New Zealand**ers took to the streets in 17 locations to protest the TPP. Protesters were joined by lawmakers from a number of political parties.

Meanwhile in Japan, 50 activists staged an action outside of Prime Minster Shinzō Abe's official residence in opposition to the TPP. More than 100 individuals representing farmers, labor groups, consumer organizations, medical advocates, lawyers, and university professors met with Japanese lawmakers to discuss concerns related to the TPP.

A number of flash mobs were organized around **Australia**. A few days later, concerns about the TPP were represented during G-20 educational forums and protests which attracted thousands.

#### CHOICE report calls for fair trade

http://tinyurl.com/kw6dem9

- Are you concerned about increasing cost of medicines?
- Would you worry if Australians could be jailed for illegally downloading an episode of Game of Thrones?
- Do you want to know if your muesli bar contains palm oil?



Then you really should care about the <u>Trans-Pacific Partnership</u> (TPP), a trade agreement being negotiated in secret between Australia, Brunei, Chile, Canada, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. In this CHOICE report you will find information on:

- The <u>secrecy</u> surrounding the TPP and details of how the media is being locked out of briefings
- How the Australian government could become more vulnerable to <u>lawsuits from multinational</u> corporations
- Why food labelling in Australia is in danger
- How draconian <u>copyright provisions</u> could significantly curb our freedom online
- How new <u>patent provisions</u> could make medication costs skyrocket
- CHOICE's campaign on the TPP

CHOICE is calling for the TPP text to be released before a final agreement is signed. CHOICE has produced a Video: CHOICE investigates the Trans-Pacific Partnership (TPP) and the impact it will have on your consumer rights and privacy. Why all the secrecy?

The video and links to many other resources concerning the TPPA can be found here

http://tinyurl.com/kw6dem9

### New Zealand Doctors call for independent Health assessment of TPPA

 $\underline{\text{http://www.itsourfuture.org.nz/doctors-support-call-for-independent-health-assessment/}}$ 

Senior NZ doctors and dentists are formally throwing their weight behind growing calls for a formal

independent health assessment of the Trans Pacific Partnership Agreement (TPPA).

They voted overwhelmingly in favour of an independent health assessment, to be based on the draft of the TPPA and carried out prior to the TPPA being signed.

### TPP conclusion in 2015 still 'challenging', says new NZ-US Council chair

http://www.itsourfuture.org.nz/tpp-conclusion-in-2015-still-challenging-says-power/

By Pattrick Smellie <a href="http://businessdesk.co.nz/">http://businessdesk.co.nz/</a>

Nov. 14 (BusinessDesk) – Although Simon Power, the newly appointed chair of the NZ-US Council told BusinessDesk. 'We don't know yet when the next round of negotiations will take place or when Ministers will meet again,' *it was found December 10, 2014, that TPP talks resumed this week*, with negotiators meeting in Washington, but no major breakthroughs are expected given this weekend's elections in Japan.

Wrapping up a TPP deal in the first half of 2015, before the US 2016 presidential elections started consuming American political focus, 'would require significant progress.' 'That's what leaders say recent meetings have achieved. We're keen to see progress, but that timeline looks challenging.'

#### Controlling Counterfeit medicines update

http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Storm

IN HAIAP News December 2012, we described initiatives that were being undertaken to control counterfeit medicines including the partnerships between WHO and Interpol that were having considerable success finding and controlling the sources of counterfeit medicines.

http://www.haiasiapacific.org/?page\_id=70

http://www.haiasiapacific.org/wpcontent/uploads/2014/03/HAI APNews4Dec2012.pdf

**2014 update:** activities in South-East Asia of *Operation Storm*; and *Operation Pangea* that focuses on the internet.

#### **Operation Storm**

Operation Storm targets counterfeit medicines in Southeast Asia, a region particularly affected by the problem.

Storm V Dates: July-August 2014

Participating countries: Cambodia, China, India, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

Results:

Seized quantity: 3,849,718 units and 3,454 kg

Estimated value (USD): 2,724,065

Number of arrests: 35
Prosecutions: 58
Investigations: 36

Number of searches: 157

Outlets closed: 1

#### Operation Pangea - targeting the internet

http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea

Combating the sale of illegal medicines online



Operation Pangea is an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the dangers of buying medicines online. Coordinated by INTERPOL, the annual operation brings together customs, health regulators, national police and the private sector from countries around the world.

Activities target the three principal components used by illegal websites to conduct their trade – the Internet Service Provider (ISP), payment systems and the delivery service.

The operation has gained significant momentum since its launch in 2008. The first phase of the operation brought together 10 countries; a number which has now risen to more than 100.

Pangea VII Dates: 13-20 May 2014

Participating countries: 113
Participating agencies: 198

Results:

- 9.6 million fake and illicit medicines seized, including slimming pills, cancer medication, erectile dysfunction pills, cough and cold medication, anti-malarial, cholesterol medication and nutritional products;
- · Seizures worth more than USD 32 million;
- 434 arrests;
- 1,249 investigations launched;
- 22,800 adverts for illicit pharmaceuticals removed from social media platforms;
- More than 11,800 websites shut down.

# Feature: The Lancet Commission and 30 years of Essential Medicines memories

Compiled by Beverley Snell

In October 2014 a new <u>Lancet Commission on Essential Medicines Policies</u> was established with the goals of:

- Re-confirming the ongoing relevance, and the crucial need of comprehensive essential medicines policies to achieve broader global health and sustainable development goals, especially universal health coverage
- Formulating recommendations for global essential medicine policies for the next two decades

The work of the Commission will result in a report in *The Lancet* planned for November 2015, to commemorate the 30th anniversary of the 1985 Nairobi Conference on the Rational Use of Drugs.

*Lancet* has recognised that 'Access to essential medicines globally is a highly charged political issue that is often about trade, policies, and protest.' <sup>1</sup>

These issues are not new to HAIAP members. HAI activities in support of the essential medicines concept have been documented in detail in publications such as HAI-Europe's 25th anniversary publication <u>Pills Politics Practice</u> and HAIAP's <u>Fast Flexible and Furious</u>, 2006, and in our regular <u>HAIAP News</u>. Here we just touch some stepping stones along the journey from the launching of the essential medicines concept on the medicines that were

'of the utmost importance to satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford'

to the challenges of using the TRIPS flexibilities to maintain access to essential medicines.

#### The Essential Drugs (Medicines) Concept

'While drugs alone are not sufficient to provide adequate health care, they do play an important role in protecting, maintaining and restoring the health of people ... It is clear that for optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential' drugs, indicating they are of the utmost importance and are basic, indispensable and necessary for the health needs of the population.' WHO 1977

### **Essential Medicines and Primary Health Care:** Background

Until the 1960s, the medicines that were used to treat health problems were mainly from plants; or were salts like potassium iodide, potassium bromide, potassium citrate. People living in the main towns in developing countries (mostly colonies of European powers), who consulted western doctors, were prescribed those sorts of medicines. Aspirin had been synthesised in 1897 so there was an effective drug to relieve pain that was not an opium derivative.

There were limited antibiotics to treat infections and few new drugs to treat many other common conditions. People living in rural areas in the colonies relied mostly on their traditional medicines.

Soon after the Second World War things had begun to change. Sulphonamides and penicillins were developed. Barbiturates were produced and used as sedatives; and drugs to treat a wide range of problems including cardiovascular problems, epilepsy and allergies were developed and made available.

The 1960s witnessed enormous developments in the production of modern drugs. Newly independent countries became rapidly expanding markets for transnational drug companies or for local traders who imported medicines from other countries.

Some countries had legislation to control the import and distribution of pharmaceuticals, but the range and scope of products increased faster than the understanding of potential dangers and ahead of expanded legislation. In any case, the means to implement existing legislation was mostly not well developed.

During the next 20 years, a huge number of potent substances became available in non-regulated markets for anyone who could afford to pay for them. Untrained drug sellers gained status almost equal to doctors. The new medicines prescribed by health professionals and sold by drug sellers were often seen as magic cure-alls but unfortunately there were dangers and side-effects with many of the new products.

The wealthier people in the less developed countries spent a lot on self-medication through over-the-counter purchase of uncontrolled substances for real and imagined problems including modern life-style problems. At the same time, poorer people in urban

areas, and most people in rural and remote areas had no access to even the most essential medicines.

During the 1960s and 1970s several countries or regions of countries had initiated successful programs to deliver a basic but comprehensive program of primary care health services, including access to a limited range of essential medicines, to cover poor rural populations. Among them were Tanzania, Mozambique, Papua New Guinea and in the Asia Pacific region, areas of Bangladesh and the Jamkhed area of India. The concepts behind the initiatives were recognised by the World Health Organization (WHO) and UNICEF.

#### Dr Halfdan Mahler

Dr Halfdan Mahler from Denmark, had joined the WHO in 1951 as a senior officer for the National Tuberculosis Programme in India. After a range of appointments, in 1970 he was made Assistant Director-General of the WHO. In 1973, he was elected as the third Director-General and he was re-elected for two successive five-year terms in 1978 and 1983 respectively. His leadership was extremely significant in the development of the essential medicines concept.

#### The birth of the essential drugs concept

By the 1970s, it was recognised that causes of poor health in less developed countries such as inadequate or poor nutrition, poor housing and sanitary conditions and inadequate water needed to be addressed. However, it was realised at the same time that the right modern drugs were very important for health care.

In 1975, Dr Mahler, in his report to the WHA<sup>2</sup> identified national pharmaceutical policies as a means of meeting health needs and economic priorities in developing countries. He also referred to experiences with carefully selected drug lists in Chile, Cuba, Mozambique, Papua New Guinea and Sri Lanka, which had led to improved access to drugs. This report was a major step in the campaign for access to essential medicines.

Before representatives of WHO Member States at the World Health Assembly, Dr Mahler insisted on the need to develop national pharmaceutical policies based on the affordability, quality and availability of drugs. National policies must cover all aspects from selection, procurement, quality assurance, legislation and regulatory control, to the use of drugs.

Primary Health Care and the first Model List of Essential Drugs

With Dr Mahler at the helm, the World Health Organisation began promoting the concept of essential drugs in 1975. The initiatives were supported by a World Bank Policy paper in 1975.

The Primary Health Care (PHC) approach was launched at Alma Ata (now the capital of Kazakhstan) in the former Soviet Union in 1978 and the place of Essential Drugs Programs was secured within the framework of PHC. Primary Health Care, as defined at Alma Ata, is

essential health care based on scientifically sound and socially acceptable methods and technology, made universally accessible to individuals, families and communities by their full participation.

This initiative took place in an era where the role of government in the provision of health, education and welfare services was taken for granted in most developed countries.

The emphasis in PHC is on the importance of preventive measures such as safe water supply, breast-feeding, immunisation against vaccine-preventable diseases and good nutrition associated with production of adequate good food but the need for appropriate curative care and access to essential medicines is recognised. The slogan 'Health for all by the year 2000' was launched.

#### The first model list of essential drugs

In support of the concept of Essential Drugs, a model list of essential drugs which included about 200 generic drugs and vaccines was prepared by an 'Expert Committee' in 1977. Mrs Margarethe Helling Borda's memories of the First Expert Committee meeting were recorded in the Essential Drugs Monitor.

All products were called by International Nonproprietary Names (INNs) (or generic names) rather than the brand names given by the companies producing them. Safety, affordability, need and efficacy (SANE) were the criteria for selection of drugs in the WHO Model List. Essential drugs were defined as 'those that satisfy the health care needs of the majority of the population; they should be available at all times in adequate amounts and appropriate dosage forms'. Although the list has been revised and updated several times. the definition has remained unchanged. Countries were encouraged by the WHO to develop their own standard drugs lists, using the WHO list as a model.

The move by WHO in support of the essential medicines concept influenced many member states. Most WHO member states welcomed the new approach to medicines. But there was opposition some medical associations argued that the concept of essential drugs was a threat to the freedom of prescribing, while the pharmaceutical industry particularly the research-based industry, supported by some Western countries — argued that it would

endanger the industry as well as jeopardize its future research efforts.

By 1979 the Alma-Ata Declaration had already generated criticisms and reactions worldwide. The goal 'Health for All by 2000' was not considered possible, implementation of PHC as formulated was far too expensive and the declaration did not have clear targets. As result the Rockefeller а Foundation sponsored the Health and Population Development Conference just a year after Alma-Ata. Selective Primary Health Care (SPHC) was introduced with the view that most lives could be saved by focussing on low-cost solutions that addressed very specific and common causes of death. The focuses would be

**G**rowth Monitoring,

Oral rehydration for diarrhoea in children,

**B**reast-feeding and

Immunisation - GOBI. This acronym later expanded and became GOBI-FFF after recognition of the need for **f**ood supplementation, **f**emale literacy and **f**amily planning.

Essential medicines received no attention. However it was becoming clear that access to essential medicines was being ruthlessly challenged by vested interests. In the early 1980s authors such as Charles Medawar, Diana Melrose, Mike Muller and Milton Silverman published works implicating pharmaceutical companies in the abuse of people's health in developing countries. More authors followed with more accounts of continuing unethical activities by large pharmaceutical companies.

A list of these books has been published by E-DRUG<sup>3</sup>.

#### The birth of HAI

Following the World Health Assembly in May 1981, Health Action International (HAI) was founded at a meeting in Geneva after the baby food activists had successfully lobbied for a code of conduct at the Assembly. At this meeting Civil Society Organizations (CSO) from 26 countries came together and established this network of world specialists in medicines policy, to counteract the increasing influence of the pharmaceutical industry on public health and to represent the interests of consumers in healthcare policy debates. The network was later established across all continents as HAI-Africa, HAI Asia Pacific and HAI Latin America. It is worth revisiting the HAI publication Pills Politics Practice -25 years of promoting people-centred medicines policy 1981-2006 to appreciate the birth and life of HAI.

In 1982 Dr Zafrullah Chowdhury, one of HAI's founding members, experienced first hand the battles that would

need to be fought in order to gain essential medicines for the people of Bangladesh.

By developing Bangladesh's National Drug Policy in 1982 he challenged the might of the international pharmaceutical industry by establishing a just and affordable health strategy based in part on the local manufacture of a relatively small number of essential generic drugs.

His book *The Politics of Essential Drugs – The Making of a Successful Health Strategy: Lessons from Bangladesh,* published by Zed Press, London, in 1995, tells the story of this initiative, including its achievements and limitations. He sets it in a global context, discusses the pressures mobilized (both now and at the time) by the pharmaceutical corporations and others to reverse the new strategy, and reflects on the relevance of Bangladesh's experience for other countries.

#### The 1985 Nairobi Conference

Despite strong resistance from the pharmaceutical industry, WHO convened, in 1985, the Conference of Experts on the Rational Use of Drugs - the so-called Nairobi Conference - which brought together specialists from different disciplines and perspectives, includina industry, consumer groups, donors, academics and national policy-makers. conference agreed on important issues relating mainly to drug information, drug regulatory programs and prescribing practices. The Nairobi conference reached a consensus over the need to develop national medicines policies as the basis for promoting rational use of drugs.

In November 2014 Dr Mira Shiva wrote in a message to HAIAP colleagues:

'I cannot believe 30 years have passed since the WHO's International Conference of Experts on Rational Use of Drugs in Nairobi 1985. For the first time Consumer activists involved with Rational Use of Drugs had been invited. I recall Dr Zafrullah, Dr Andrew Herxheimer, Charles Medawar, Diana Melrose and I were there. The Nairobi meeting was immediately followed by a meeting in Chennai of drug activists from the Asian region called 'Drugging of Asia'. It was co-organized by IOCU-ACHAN, VHAI (where I was coordinator) and Low Cost Drugs and Rational Therapeutics. Dr Bala and Dr Prem John were there. We had been infiltrated by a 'plant' from the drug industry as the High Dose Estrogen Progesterone campaign was on and we had a PIL (Public Interest Litigation) in the Supreme Court'

That conference gave an impetus to the Revised Drug Strategy that would be adopted by the World Health Assembly in 1986. The overall goal of the strategy

was to rationalise drug use in cooperation with the health professions, academia, the pharmaceutical industry, NGOs, and the public and to expand access to good quality affordable essential medicines. The scope of the strategy was extended to cover, for example, access to newer drugs for HIV and other life threatening conditions, control of counterfeit products and inclusion of traditional medicines. Meanwhile, the struggle to implement PHC and essential medicines programs continued.

#### The Bamako Initiative

The cost of implementing PHC and providing essential medicines was becoming a major concern. In 1984, James Grant, then Director of UNICEF, at a meeting in Bamako in Mali, launched the idea of payment for medicines as a way to help finance Primary Health Care. The idea became known as the Bamako Initiative and was presented to WHO in 1987. Implementation was attempted in some countries, particularly in Africa. However, there were many concerns. For example, as described by Kanji (1989)<sup>4</sup>,

'administration of user fees requires management skills and time that might not be available; medicines might be provided only to those who are prepared to pay for them; and the revenue generated from the sales of medicines may be insufficient to have much impact on supporting the cost of more medicines or the PHC program in general. There could be preference for providing more expensive medicines and rational use of medicines could be less of a priority.'

#### The next years

The List of Books on Pills includes publications that appeared during the following 10 years that provide a picture of the essential medicines journey and the challenges faced by those attempting to implement essential medicines programs. A comprehensive picture is provided in *Drugs Policy in Developing Countries* by Najmi Kanji, Anita Hardon, Jan Willem Harnmeijer, Masuma Mamdani, and Gill Walt (Zed Press 1992).

#### Reviewer David Stevenson describes how

'the authors, with practical experience in developing countries, give an account of the development of and changes in the policies of WHO, UNICEF and other agencies, and of the actions of drug manufacturing companies and of the governments of individual countries, in relation to the supply of medicines. In many developing countries one can see expensive and inappropriate medicines on sale to the public while health units do not have enough basic supplies to treat common illnesses. Parents may be persuaded to

spend scarce money on ineffective proprietary 'tonics' when it would be better to buy good food for their undernourished children. Dye-containing pills have been advertised to cure nearly every ill - one can see the poisons leaving the body with the coloured urine which results!'

#### Conference on National Medicines Policies Sydney 1995

The 1995 conference led by WHO in Sydney, Australia, was a major landmark. It brought together 300 people from almost 50 countries and focused on four key themes of national medicines policies: equity of access to medicines, rational use, the quality of medicines, and the role of the pharmaceutical industry.

That conference produced recommendations based on the four key themes which along the proceedings of the conference, were reported in a supplement to Australian Prescriber (Aust Prescr 1997;20 Suppl 1).

Many HAI and HAIAP members and partners participated and took the opportunity to plan further activities.

The conference provided a great impetus for policy work in the region. As an outcome of a networking meeting at the conference Dr Bala initiated the planning for the HAIAP sponsored first regional consultation of pharmaceutical sector and consumer groups for 14 Pacific Island Nations in Nadi, Fiji, in 1996. We believe it was that initiative that put the Pacific Island Nations on the map. Since 1996 WHO has convened very fruitful regional consultations among Pacific Island Nations' pharmaceutical sector leaders almost every year, resulting in the sort of regional cooperation that might be just a dream in other regions. The Sydney conference also led to educational interventions in rational drug use and ethical promotion, and underpinned discussions on rational drug use that continued at the International Conference on Improving Use of Medicines held in Thailand in 1997.

It was 17 years after the 1995 conference that 233 delegates from 46 countries participated in the follow-up Asia Pacific Conference on National Medicines Policies in Sydney, Australia on 26–29 May 2012. It provided the opportunity to share achievements and challenges. The impetus for this conference was the recognition that while many countries in the Asia Pacific region reported having a national medicines policy, progress on the implementation of these policies had been inconsistent. In addition, it was reaffirmed that robust and effective national medicines policies are an important tool in achieving the objectives of universal access to needed medicines and their rational use. It was also recognised that a

policy, no matter how carefully formulated, has no value if it is not implemented. Therefore, a detailed strategic plan is needed to link with National Medicinal Policy and it must include short- medium- and long-term strategies for policy implementation.

The Conference Report was published by <u>Australian</u> Prescriber.

In keeping with the conference theme of promoting and supporting further implementation of national medicines policies, there is particular emphasis in this report on identifying the key barriers and key enablers to policy implementation, steps to address these barriers and enablers, and how to monitor progress. important outcome of the conference was continuing commitment to further implement national medicines policies within the Asia Pacific region. There is enthusiasm for ongoing discussion between countries and the development of regional collaborations, groups and networks to support this important policy work.

#### **Current challenges**

Arguably the most challenging battles continue to be associated with Intellectual Property Rights.

#### **TRIPS**

For 10 years after introduction of the Essential Drugs Concepts and recommendation for use of generic drugs the pharmaceutical industry negotiated quietly behind the scenes and came up with TRIPS – Trade Related Aspects of Intellectual Property Rights. WHO and others were advocating for 'essential drugs', and that movement was seen as a possible threat to multinational pharmaceutical company sales. TRIPS (Trade Related Aspects of Intellectual Property Rights) (WTO 1995) aimed at

- 'Harmonisation' by 2005 all countries to join the World Trade Organisation (WTO) except for Least Developed Countries who could wait until 2016
- 20 year patent that would apply for all new products in WTO member countries
- · 'Reducing impediments to trade'
- 'Promoting technological innovation and transfer to the mutual advantage of producers'

Pre-TRIPS, 50 countries did not respect pharmaceutical patents at all.

Articles 30/31 of the TRIPS Agreement spell out flexibilities that allow compulsory licensing to manufacture without permission of 'rightful owner' in a national emergency so that it is possible to access medicines that are still under patent at reduced costs. Other articles cover more flexibilities eg public health need and government use.

However, to use these flexibilities, governments have to adapt their own national laws.

The TRIPS flexibilities allow countries to rightfully determine how they will access cheaper versions of newer medicines.

#### The Doha Declaration

The 4th WTO Ministerial Conference in Doha (Oct 2001) provided a clear political statement that public health concerns must override commercial interests - 'a road map to key flexibilities in TRIPS'

- countries are free to determine what is a national emergency
- where patent medicines are beyond the reach of people who need them, governments can override patents without negotiations with companies and without threat of retribution
- countries can make own rules about parallel imports
- procedure for issuing a compulsory license becomes easier and faster
- least developed countries are granted a 10 year extension - TRIPS compliance at earliest by 2016 instead of 2006

In HAIAP we have been kept aware of the activities undertaken by our members to maintain the rights of countries to access to essential medicines in the face of enormous pressure from pharmaceutical companies such as Novartis in India, also reported here.

Companies often try to confuse governments with misinformation – causing doubt about their legal rights to use the TRIPS flexibilities.

It is clear that there is need for our activities to continue.

#### **Free Trade Agreements**

Other threats to access to affordable medicines can come in the form of Free Trade Agreements (FTAs) FTAs are negotiated in secret and agreements made can over-ride legislation. For example, even if legislation underpins the use of compulsory licenses to access generic copies of a medicine, the agreement can say that the country is obliged to import a particular branded version at higher cost. Vigilance is crucial to expose and counter potential agreements that can have a negative impact on public health and access to medicines.

### HAIAP has a very important role in advocacy associated with IP issues and with FTAs

#### Why is advocacy needed?

To support peoples' rights - solidarity

- To counter misinformation about what is possible / legal
- To clear up legal uncertainty of rights under TRIPS
- To counter efforts to weaken provisions of the Doha agreement - advocacy for delegates at regional meetings, 'ministerials'
- To counter pressure on countries from vested interests eg MNCs and US government
- To address poor coordination between ministries or lack of awareness of implications of actions eg participation in 'trade agreements'
- 'chill factor' to support governments who are scared to use their rights because of perceived threats
- To counter myths

The Lancet Commission's tasks are seen as

- Synthesising lessons learned from the first 30 years of essential medicines policies' development and implementation
- Developing an agenda for the next 20 years of institutional, regional, national and global policies on essential medicines and other health technologies
- Raising global awareness of the relevance of essential medicine policies in achieving global health and sustainable development goals, with special attention paid to universal health coverage
- Defining the current needs of operational research that contributes to increasing the effectiveness and efficiency of essential medicines policies and programs.

#### **Conclusions**

During the last 30 years HAIAP members have stood against the might and wealth of people in power and have worked unselfishly for peoples' health and justice. HAIAP members also recognise that to achieve equity of access to essential medicines it is necessary to work with governments to strengthen components of essential medicines systems by developing and implementing comprehensive national medicines policies. Our groups would be happy to collaborate with the Lancet Commission to share experience from within our networks, given our 30 year history of championing the cause of access to essential medicines and rational use of those medicines.

More details about the Commission have been provided by the <u>Boston University Centre for Global</u> Health.

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#### Feature: Tobacco Control - in brief

#### From Simon Chapman: Up in smoke

Monday, 24 November, 2014 MJA Insight

Read complete story

https://www.mja.com.au/insight/2014/44/simon-chapman-smoke

AUSTRALIA'S pioneering plain tobacco packaging legislation, which was fully implemented 2 years ago, is the single most important piece of tobacco legislation ever introduced.

Experienced tobacco control advocates have long spoken of the 'scream test' of policy impact — if a new policy gets no reaction from the tobacco industry it rarely has an impact, but if the industry screams blue murder the impact will be large. With plain packs, the screams are still being heard.

The Alliance of Australian Retailers (bankrolled by the tobacco industry) ran a multimedia campaign asserting that plain packs 'would not work', meaning they wouldn't reduce sales. This refrain was megaphoned at every opportunity. However, it created a small problem for another central plank of the industry's case because the British American Tobacco-funded Institute of Public Affairs (IPA) was warning that plain packaging would reduce sales by up to an unprecedented 30% in the first year and by further 30% tranches in every year after that.

Nothing in the history of tobacco control has ever had such an impact. A back-of-an-envelope calculation shows that starting with an annual consumption of 24 032 million cigarettes and cigarette equivalents in 2010–2011, and reducing this by 30% every year, by 2020 consumption would have fallen to just 969.4 million sticks — just 4% of the starting point.

The industry put all its efforts into three main arguments. They were that (1) the packs were *not* causing any reduction in sales; but (2) they were driving smokers down-market to buy cheaper brands with lower profit margins for manufacturers and retailers; and (3) the illicit market was booming, all because of plain packaging. Laughable figures were strewn about by a panicked industry.

In July 2014, the Australian Institute of Health and Welfare released the results of its latest national survey of tobacco use. These surveys have been conducted every 3 years since 1991, when 24.3% of Australians aged 14 years and over smoked on a daily basis. In November 2013, just 12.8% of adults smoked daily. With another 3% smoking less than daily, Australia now

has the lowest smoking rate in the world at just 15.8%. The percentage fall in Australia between 2010 and 2013 was a record 15.5%. The average percentage decline across the nine triennial surveys since 1991 had been 7.6%, with the previous biggest fall being 11%.

### Pascal Diethelm: tireless opponent of the tobacco industry

From Geoff Watts Profile www.thelancet.com Vol 384 December 6, 2014 Read the complete article

http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673614623266.pdf?id=caa9Xv9HTRk9EbqiCHTOu

If global tobacco industry executives ever choose to compile a list of people who've caused them trouble over the years, one name on it—and quite likely high up—would be that of an unassuming Swiss econometrician called Pascal Diethelm.

The exploit for which Diethelm is best known is one of the court cases in which he'd become involved. In the early 1990s, at WHO, he developed a database on the international prevalence of smoking. Diethelm began close to home with the University of Geneva. 'There was one person from the University who was publishing papers in which the harmfulness of second-hand cigarette smoke was minimised if not denied, and these studies looked strange.'

The man in question, a Swedish researcher called Ragnar Rylander, had also organised a number of symposia suggesting that passive smoking was inconsequential. Diethelm and a colleague searched Philip Morris documents and turned up a staggering 16,000 of them with Rylander's name; some detailed regular payments to him dating back to the 1970s. 'We accused the whole scheme of being a scientific fraud', says Diethelm. 'We revealed that Professor Rylander was secretly employed by Philip Morris as a highly paid scientific consultant.'

Rylander sued them. 'Everything we said was backed by documents, but we had a hard time convincing the court', Diethelm recalls. The case went to supreme court level before they got a final judgment in their favour.

Now 70, Diethelm shows no sign of abandoning his commitment to the various anti-tobacco organisations and other health charities he supports and works for.

### A step change for tobacco control in China?

From Editorial - www.thelancet.com Vol 384 December 6, 2014 Read complete article

http://download.thelancet.com/pdfs/journals/lancet/PIIS01406736 14623199.pdf?id=caa9Xv9HTRk9EbqiCHTOu

China's people are at grave risk of tobacco-related diseases. The prevalence of smoking in China is 52.9% among men and 2.4% among women, equating to more than 300 million smokers aged 15 years and older.

On Nov 24, a long-awaited draft national tobacco control guideline was released by China's State Council, aiming to reduce the harms of tobacco smoke and protect public health. This is the first time that the Chinese Government has considered state-level legislation on tobacco control. According to the proposed regulations, smoking is to be prohibited in all

indoor and some outdoor public places, including schools and hospitals for women and children. All tobacco advertising, promotion, and sponsorship will be banned, and health warnings are to cover 50% of all tobacco packages. There are to be strict controls on selling tobacco to minors, and smoke-free families will be promoted. Fines will be imposed for violation of the regulations, and the Administrative Department for Health and Family Planning is to oversee smoking control in public places; governments at all levels should guarantee funding for smoking control measures.

Enforcement is key for smoking bans—how thoroughly will smoking prohibition be observed and enforced throughout China? Taxes on tobacco products need to be raised substantially to discourage smoking, and effective smoking cessation treatments will be needed to help China's large population of smokers to quit.

#### **News from the Region**

### India 'too reliant' on Chinese drug imports, worries Delhi

By Shilpa Kannan BBC News, Delhi 5 December 2014
The complete story can be read at
http://www.bbc.com/news/business30330898#story\_continues\_3

This is not something you'd expect between Indian and Chinese traders - who traditionally view each other with suspicion.

India produces a third of the world's medicines, mostly in the form of generic drugs. But more than 80% of the raw materials for these drugs are imported from China. That gives its neighbour and rival a virtual monopoly over pricing and supply - so much so that there are no domestic producers left for many essential medicines in India.

India has more than doubled the import of antibiotic drugs from China in recent years, and the trade is now worth billions of dollars. There are now no domestic producers left for penicillin and its derivative, for example, leading to fears of a public health crisis if China were to ever stop its supply.

Drug companies in India blame the government, saying that low-cost imports have driven many manufacturers to close down.

'Bureaucracy and lack of environmental clearances in India have made it uneconomical to produce raw materials anymore,' says chief executive Ketan Shah. But switching back to mass production of raw materials is not difficult, he adds. 'China became so much more competitive artificially. Indian companies had no incentive to continue production - so we are out of it. But

it is not too late at all. If the government acts quickly things can turn around in less than 10 years.'

#### **Promoting investment**

Now the Indian government has decided to step in. Ajit Doval, India's National Security Adviser, recently warned that India should take immediate steps to create adequate infrastructure to become self-sufficient in manufacturing essential medicines.

Delhi wants Chinese manufacturers to shift production to India, and to help them, the government is setting up large-scale pharmaceuticals and chemical industry clusters.

One such cluster is the Mangalore Special Economic Zone (SEZ). Here businessman Ravinder Sethi is using it to sell the idea of a large industrial park to the Chinese.

'One of the major constraints so far stopping Chinese pharmaceutical companies from investing here is infrastructure,' he says.

So in the SEZ he is promoting, they are providing a central effluent treatment plant hoping to attract producers. And the potential to invest and grow is huge in India.

Policymakers do not just want Chinese investment in India, but are also negotiating better access for India's pharmaceutical industry in China. This will not just secure India's drug supply, but also help compensate for the widening trade deficit between the two neighbours.

# Generic Medicines and prescribers – Malaysia, Australia

#### Generic Medicines in Malaysia

Assoc Prof Mohamed Azmi Ahmad Hassali School of Pharmaceutical Sciences, Universiti Sains Malaysia

http://www.thestar.com.my/Opinion/Letters/2014/11/12/Generics-A-necessary-option/orhttp://fw.to/0OQlelg

In modern healthcare interventions, medicines will always be the mainstay of therapy. Many healthcare policy makers across the world have mandated the use of generic medicines as a measure to reduce medicine costs and increase consumer access.

In Malaysia the existence of good quality generic manufacturers has helped the healthcare consumer to alleviate issues related to high cost of medications. Furthermore, developing the local pharmaceutical industry has become a national agenda under the 12 National Key Economic Areas (NKEAs).

In this regard, the Malaysian Government via it National Medicine Policy encourages the use of generic medicines in both the public and private sector and thus provides an opportunity for the generic industry to increase its market share. With a growing incidence of non-communicable diseases such as diabetes, hypertension and an increasing ageing population, there is an ever-increasing need to contain the increase in healthcare cost, which can be achieved by switching to generic drugs.

At present, generic prescribing and the practice of generic substitution are relatively low and hence there is still room to increase the generic market share and create opportunities for the generic drug manufacturers to increase their sales. Having conducted research on the quality use of generic medicines in the Malaysian healthcare system among healthcare stakeholders (consumers, practitioners and health policy makers), there is still scope for further promotion of generic medicines.

The following studies have been undertaken to explore views about the us of generic medicines in Malaysia.

### 1. Malaysian generic pharmaceutical industries: perspective from healthcare stakeholders

Journal of Pharmaceutical Health Services Research 2014; Zhi Yen Wonga, Mohamed Azmi Hassalib, Alian A. Alrasheedy, Fahad Saleemb, Abdul Haniff Mohamad Yahayaa and Hisham Aljadhey Pharmacy Department, Hospital Teluk Intan, Teluk Intan, Perak, Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Penang, Malaysia and College of Pharmacy, King Saud University, Riyadh, Saudi Arabia

**Objective:** to document the published literature related to healthcare stakeholders' knowledge, attitudes, views and perceptions towards generic medicines or generic substitution in Malaysia and to suggest recommendations to improve generic medicines utilization in Malaysia according to different healthcare stakeholders' need.

**Methods:** A systematic search of articles published in peer-reviewed journals from January 2001 to November 2013 was performed. The search used 11 electronic databases. The search strategy involved using Boolean operators for combinations of the following keywords: generic AND Malaysia, Malaysia AND pharmaceutical, Malaysia AND Medicine Policy, Malaysia AND Economic Transformation.

Key findings: Twelve articles were included in this review. Two studies were conducted with generic manufacturers, one study with medical practitioners, six studies with community pharmacists and three studies with medicine consumers. Generic manufacturers expressed concerns about the generic medicines policy and drug approval system in Malaysia. In addition, medical practitioners, pharmacists and medicine consumers still have misconceptions about safety, quality, efficacy and bioequivalence of generic medicines. Furthermore, despite the availability of some pro-generic policies, there is a lack of implementation of these policies in the country.

Conclusion: Different healthcare stakeholders have different concerns and views towards generic medicines as well as different levels of knowledge about them. The existing generic medicines policy and Economic Transformation Program should be implemented as planned. Educational and promotional campaigns should be carried out to improve utilization of generic medicines among all healthcare stakeholders in Malaysia.

# 2. Does educational intervention improve doctors' knowledge and perceptions of generic medicines and their generic prescribing rate? A study from Malaysia

Mohamed Azmi Hassali, Zhi Yen Wong, Alian A. Alrasheedy, Fahad Saleem, Abdul Haniff Mohamad Yahaya and Hisham Aljadhey smo.sagepub.com at Universiti Sains Malaysia on November 6, 2014

**Objectives:** To investigate the impact of an educational intervention on doctors' knowledge and perceptions towards generic medicines and their generic (international non-proprietary name) prescribing practice.

**Methods:** This is a single-cohort pre-/post-intervention pilot study. The study was conducted in a tertiary care hospital in Perak, Malaysia. All doctors from the internal medicine department were invited to participate in the educational intervention. The intervention consisted of

an interactive lecture, an educational booklet and a drug list. Doctors' knowledge and perceptions were assessed by using a validated questionnaire, while the international non-proprietary name prescribing practice was assessed by screening the prescription before and after the intervention.

**Results:** The intervention was effective in improving doctors' knowledge towards bioequivalence, similarity of generic medicines and safety standards required for generic medicine registration (p = 0.034, p = 0.034 and p = 0.022, respectively). In terms of perceptions towards generic medicines, no significant changes were noted (p > 0.05). Similarly, no impact on international non-proprietary name prescribing practice was observed after the intervention (p > 0.05).

**Conclusion:** Doctors had inadequate knowledge and misconceptions about generic medicines before the intervention. Moreover, international non-proprietary name prescribing was not a common practice. However, the educational intervention was only effective in improving doctors' knowledge of generic medicines. Keywords Education, generic medicine, generic prescribing, doctor,

#### Australia

#### **Doctors Under the influence**

Zoe Stewart: Monday, 25 August, 2014 MJAInsight https://www.mja.com.au/insight/2014/31/zoe-stewart-under-influence

A recent <u>research article</u> found that medical students and junior doctors exposed to information from pharmaceutical companies were more likely to refer to drugs using their brand names.

The authors used a survey to show that for each 10% increase in exposure to pharmaceutical promotion there was an associated 15% lower adherence to published prescribing guidelines.

While doctors often seem to think they are immune to <u>pharmaceutical industry marketing</u>, the reality is that none of us are. The influence of marketing on prescribing habits is well established, but it is not the only influence.

External influences add to a range of factors that impact on our decisions about which medications to prescribe in different contexts. Ideally, as clinicians, we are primarily influenced by evidence-based guidelines and consideration of efficacy, mechanism and side effect profiles. In reality, influences that are less sound often win out.

In fact, external influences begin shaping our medical decision making from the start of our time at medical school.

A number of US medical schools came under public scrutiny after students from <u>Harvard Medical School</u> found that some of their lecturers were being funded by pharmaceutical companies and that the material they were teaching was influenced as a result.

While the relationships between Australian medical schools and pharmaceutical companies may be less obvious, I distinctly remember learning suturing and 'best practice' wound care from a company representative using only brand names and being told by the representative that there were no appropriate alternatives to their wound care products.

It seems grossly unethical to teach biased information, particularly to junior students who are less equipped than their senior colleagues to critically appraise that information. This has the potential to influence the way junior doctors prescribe and practise throughout their entire careers. Indeed, medical students from universities with less stringent regulations on the influence of pharmaceutical companies have been found to be more likely to prescribe high-cost, low-value medications.

Of course, it is not only industry that can exert undue influence on the prescribing habits of doctors and certainly not only junior doctors who are affected. One-off events like high profile media stories or journal articles can also alter patient and doctor perception of the evidence for or against certain medications and thus influence prescribing.

So, what should we be doing about all of this?

First we must recognise that these and other factors are major influences on the way we prescribe and practise medicine. Our prescribing will always be influenced by external factors, but we should try to ensure they are the right external factors.

Regulations restricting pharmaceutical advertising are useful and it is admirable that many individual health professionals try to limit pharmaceutical industry influences by, for example, not meeting with drug representatives or attending pharmaceutical industry-sponsored conferences. However, there are clearly other factors which are less immediately apparent yet perhaps just as important.

To promote change, we could start by following the lead of the observant Harvard students and critically examine and prioritise the influence of various external factors on our prescribing habits.

Dr Zoe Stewart is an Australian junior doctor and a clinical research fellow in metabolic medicine at the University of Cambridge. She has an interest in medical research and its translation into policy and clinical practice and is supported by the <u>Gates Cambridge Trust</u> and <u>Jean Hailes for Women's Health</u>