



August 2015

# HAI AP News

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

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Partners continue to be busy with activities at home and abroad - for instance, Prof Niyada Kiatying-Angsulee, participated at this year's World Health Assembly, at her own expense, mainly to witness the roll out of the Global Action Plan on Antimicrobial Resistance as well as to support the Thai delegation there. Niyada will also attend the Union of International Associations (UIA) Roundtable later this month as principal HAIAP representative. Dr Delen de la Paz and Dr Mira Shiva continue to blaze health activism trails in their respective countries of Philippines and India as civil society representatives at various national forums, supported by solid professional credentials, catalyzed by strong passions. Delen will be speaking at a symposium of the Philippine Society of Hospital Pharmacists in mid September on the topic 'Pharmacists and Antimicrobial Stewardship'. Dr Gopal Dabade continues to write to the mainstream media, putting forward cases of pharmaceutical company misdeeds and misconduct. Prof Azmi Hassali and his team at USM continue to publish in scholarly journals; Azmi regularly writes on matters of public health import as Letters to the Editor in local news dailies. Dr Ken Harvey has, among other things, been busy since September 2014, documenting consumer complaints on misleading chiropractic claims for specific conditions that could deter patients from seeking evidence-based health services - with potentially serious health consequences. In a very

## ***Message from the Coordinator***

My last message was a sharing on the outcome of a satellite meeting of HAIAP partners in KL, Malaysia. One of the things we agreed upon during that meeting was that since finances did not permit us to organise face-to-face meetings, we would continue to exist virtually and to meet whenever any opportunity presented itself. I must say that for a network that works mainly through virtual correspondence, responding to partners' needs based on demand and urgency, we have much to be proud of.

recent letter (30 August 2015), Ken and a colleague, Mr Mal Vickers, wrote to the Australian Health Practitioner Regulation Agency documenting their concerns about chiropractic claims, urging action against chiropractors who have breached the Chiropractic Board's Code of Conduct (read more in this issue of HAIAP News). My article on 'Challenges of Ageing and Good Health in the context of Universal Health Care: views from Malaysia' was published in the Commonwealth Health Ministers Report 2015; but I missed the side meeting organized by the Commonwealth Foundation on the topic, which took place just prior to this year's WHA 2015 in Geneva.

I am sure many of you continue to be busy with various activities and it would be really nice if you could share these through short reports which we could publish either in HAIAP News or on the HAIAP website. I would love to share your work with the HAIAP family, I can only do this, if you send me this information. So for those of you who have been busy attending meetings, addressing health rallies, publishing in journals and in mainstream media, and generally carrying the cross of health activism, you have our support, well done and carry on!

My very best wishes,

Shila Kaur

Coordinator



### **New drug pricing: does it make any sense?**

[New drug pricing: does it make any sense?](#)  
[Prescrire Int 2015; 24 \(162\): 192-195. \(Pdf, free\).](#)

Marc-André Gagnon of Carleton University asks 'Why are drugs so expensive?'. His analysis exposes the dangers that a business model gone adrift poses to healthcare systems and ultimately, to patients.

#### **Excerpts from the English version of a presentation delivered at Prescrire's 2015 'Pilule d'Or' (Golden Pill) ceremony:**

Specialty drugs, also referred to as niche drugs because they usually target narrow markets, are generally very expensive. What is new, however, is the general trend for these specialty drugs to become the main driving factor for escalating costs in national health systems.

A recent example is sofosbuvir (Sovaldi<sup>®</sup>, or combined with ledipasvir in Harvoni<sup>®</sup>), which would more than double the total cost of prescription drugs in the United

States if every patient infected with hepatitis C virus were treated with these drugs.

Although only about 1% of prescriptions are for specialty drugs, they can account for more than one-quarter of total expenditure on prescription medications. And spending on specialty drugs is anticipated to quadruple by 2020. Unlike sofosbuvir, most new niche drugs often provide only marginal therapeutic benefits. In oncology for example, they sometimes prolong survival by only a few weeks, but provoke serious adverse effects and can cost more than US\$100 000 per patient per year.

The significant and growing disparity between the therapeutic value of many new niche drugs and their price explains why these drugs are at the heart of the pharmaceutical industry's new business model.

With rare diseases as the focus of a new gold rush for the pharmaceutical industry, a pricing policy on niche drugs that amounts to a blank cheque is a threat to the sustainability of health systems.

It is important to remember that, from the patient's perspective, an unaffordable treatment is no more effective than a non-existent treatment.

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### **Prescrire devotes its special summer edition to 'Therapeutic advances that benefit patients'**



Genuine therapeutic advances are few and far between, and they can be difficult to spot. The independent journal Prescrire helps to single them out.

Month after month for the past 35 years, the French non-profit journal Prescrire has helped tens of thousands of healthcare professionals to make the best choices from amongst the available therapeutic options.

The August 2015 special issue of Prescrire's French edition explores just what constitutes decisive progress for the benefit of patients.

Genuine therapeutic advances are in the minority, and can be difficult to spot. Certain advances seem 'obvious', when they increase survival time without a disproportionate decrease in quality of life, or when they reduce suffering, or allow complications or serious adverse effects to be avoided. This was the case for the first antiretroviral drugs, and then the first 'triple therapy' combinations to treat patients infected with HIV. These advances were the result of significant public investment in research. The advances which have benefited patients suffering from certain rare diseases are also the result of strong public will, and of regulation favourable to progress.

Other advances are less obvious, but useful, for example when they aim to better protect people: adding a child-proof cap to the packaging of a dangerous drug to decrease the risk of accidental ingestion by a child; safety devices to reduce the risk of needle-stick injuries in healthcare professionals. These advances are the result of teamwork at drug and device companies or at regulatory agencies who give thought to improving the way medicines are used.

Still other advances, involving older drugs that are no longer protected by a patent, are almost never highlighted, with a few exceptions. Evaluating these drugs, optimising their dosages, looking for new forms that are better tolerated, inventing better-adapted packaging, can also be sources of genuine progress for patients.

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["Des progrès décisifs au profit des patients"](#)

[Rev Prescrire 2015; 35 \(382\).](#)

[View the table of contents \(Free, in French\)](#)

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## **TPPA negotiations as at August 2015**

### **The TPP Agreement and implications for access to essential medicines**

*In this edition of the Journal of the American Medical Association (JAMA), Jing Luo, MD and Aaron S. Kesselheim, present their point of view on the TPPA. It is reassuring to see a critical analysis of the TPPA in an American publication.*

*This 'Viewpoint' in JAMA August 20, 2015 discusses the importance of US intellectual property law to the goals of rewarding innovation and increasing global access to drugs within the context of the Trans-Pacific Partnership (TPP) Agreement.*

<http://jama.jamanetwork.com/article.aspx?articleid=2430590>

After a difficult legislative battle, President Obama signed into law Trade Promotion Authority on June 29, 2015. This legislation allows for an up-or-down vote with no amendments in Congress for international trade agreements such as the Trans-Pacific Partnership (TPP) Agreement.

Thus, in its current form, the TPP could lower the bar for the patenting of pharmaceutical innovations and make it substantially more difficult for generic manufacturers to enter the market in TPP member countries.

The TPP Agreement is still being negotiated. Recently, in a meeting of trade ministers in Maui, Hawaii, negotiators failed to finalize the text of the Agreement due in large part to disagreement regarding intellectual property protections for pharmaceutical products.<sup>1</sup>

Intellectual property rights, including patents, are central to the business model of brand-name pharmaceutical manufacturers. Manufacturers can charge high prices during patent-protected periods without fear of

competition, earning profits that are intended to provide incentives for investment in drug innovation. However, low-income patients frequently lack access to expensive drugs, and excessive spending on pharmaceuticals can strain government budgets, leading to reductions in other health services. In addition to addressing barriers to trade, the TPP will affect the pharmaceutical market in member countries due to its intellectual property provisions.

It is critical to ensure that patents protect only innovative pharmaceutical products and for governments to balance grants of market exclusivity with other competing interests, such as the widespread availability and affordability of certain drugs. In the United States, for example, patents are supposed to be issued only to novel products that are an innovative step beyond what already exists, and patents along with a variety of regulatory and other exclusivities permit conventional drugs to receive an average time of about 13 years of market exclusivity before competing generic versions are approved.

The 1994 Trade Related Aspects of Intellectual Property (TRIPS) Agreement, which countries must agree to as a criterion for membership into the World Trade Organization, standardized basic intellectual property protections for pharmaceutical products around the world. Before TRIPS many lower-income countries had chosen not to grant patents for pharmaceutical products, emphasizing low-cost access over contributing to incentivizing innovation; however, the TRIPS Agreement required all signatory countries to change their policies and grant pharmaceutical patents.

In the years since, countries have implemented this requirement in different ways. Indian law, for example, required new forms of existing drugs to show significant improvements in efficacy before they can be granted a patent. This controversial provision was recently upheld in an Indian Supreme Court decision related to a new formulation of imatinib (Gleevec), a tyrosine-kinase inhibitor used to treat chronic myelogenous leukemia.<sup>3</sup> In that decision, the Indian Supreme Court stated that the beta crystalline form of imatinib was not patentable in part because it was too similar to an older formulation discovered prior to India's enforcement of patents for pharmaceutical products under TRIPS.

The TPP may end such flexible approaches to granting patents and add a number of new requirements related to intellectual property in addition to the TRIPS measures.

In the case of pharmaceuticals, the text of the draft seeks to bring international intellectual property law into closer alignment with current US standards regarding the scope of what may be patented. For example, US negotiators favor allowing patents to cover inventions in all fields of technology (including inventions derived from

plants and microorganisms), despite legal systems in other countries that include a more limited scope of patentable subject matter. The TPP also could allow new uses of a known product to be granted additional monopoly protection. This may reduce TPP countries' abilities to create patent laws that seek, as India's does, to ensure that only truly innovative and clinically important pharmaceutical products are patentable. Seeking patents for the new methods of using existing drugs is a common tactic that pharmaceutical manufacturers in the United States use to delay the generic competition.

The TPP also contains provisions that could make it more difficult to successfully challenge patents after they have been issued by shifting the burden of proof onto the challengers. This would ensure that potential generic market entrants must expend substantial resources to clear the numerous interrelated patents that innovator companies obtain on their products, increasing the cost and time of generic entry. The TPP draft could also impose substantial civil and criminal penalties on potential generic manufacturers found to have infringed patents, increasing the business risk for these companies. Moreover, language requiring the seizure and destruction of in-transit goods for 'confusingly similar' products may expand the geographic scope of the TPP to affect countries not part of the direct agreement, such as India or Brazil, which may find it more complicated to ship generic medicines that are legal under their patent regimes through TPP member states.

Thus, in its current form, the TPP could lower the bar for the patenting of pharmaceutical innovations and make it substantially more difficult for generic manufacturers to enter the market in TPP member countries. In addition, legal generic products could become seized during international transit. The overall effect of the TPP could be to extend the effective patent life of drugs and to decrease the availability of generic drugs or biosimilar medicines available to patients around the world.

Some economists have suggested that the intellectual property chapter of the TPP should be abandoned, because it could result in higher drug prices for patients.<sup>8</sup> By contrast, industry representatives suggest that strong intellectual property protections are necessary for costly research and development, although this assertion has been disputed.<sup>9</sup>

It is likely that a balance between these competing objectives has not been struck by the TPP agreement in its most current form. The recent breakdown in negotiations suggest that some countries are taking a hard-liner on pharmaceutical-related provisions, so there remains hope that an agreement could be negotiated. If the United States continues down the path exposed in the leaked draft and expects other TPP

countries to accept new standards for pharmaceutical intellectual property protections, it should also allow concessions that would encourage low-cost and high-quality generic drugs competition once market exclusivity ends.

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## Countering counterfeit medicines

### **INTERPOL-coordinated operation strikes at internet with seizure of 20 million illicit medicines**

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

Interpol operations – Storm (Southeast Asia), Mamba (Eastern Africa) and Pangea (targeting the Internet) – continue to go from strength to strength. Successive raids on licit and illicit markets have shown improved results in terms of seizures, arrests, convictions and the closure of illicit websites.

Operation Storm was featured in HAIAP News in December 2012. [HAIAPNews4Dec2012.pdf](#)

### **18 June 2015 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 VIII**

Dates: 9-16 June 2015, Participating countries: 115, Participating agencies: 236



#### **Results:**

A record 20.7 million fake and illicit medicines seized, including blood pressure medication, erectile dysfunction pills, cancer medication and nutritional supplements. Estimated value: USD 81 million; 156 arrests; 429 investigations launched; 550 adverts for illicit pharmaceuticals removed from the Internet; More than 2,410 websites taken offline;

Two websites linked to the sale of the potentially lethal and illicit diet drug DNP (2,4-dinitrophenol used for weight loss) shut down.

Operation Pangea VIII was the largest ever Internet-based operation focusing on the illicit sale of medicines and medical devices via the Internet, with the participation of 236 agencies from police, customs and health regulatory authorities. Private partners from the Internet and payment industries also supported the operation, which saw a record number of 20.7 million illicit and counterfeit medicines seized – more than twice the amount confiscated during the 2013 operation.

The action resulted in the launch of 429 investigations, the suspension of 550 online advertisements for illicit pharmaceuticals and 2,414 websites taken offline.

In addition to interventions on the ground, which included the discovery of an illicit warehouse full of counterfeit and expired medicines in Indonesia, the operation also targeted the main areas exploited by organized crime in the illegal online medicine trade: rogue domain name registrars, electronic payment systems and delivery services.

In the case from Indonesia, authorities uncovered an operation where criminals were altering the expiry date or the amount of the active ingredient on packages of counterfeit, expired and unregistered medicines at the warehouse and returning them to a pharmacy for sale.

INTERPOL's Executive Director of Police Services Tim Morris said: 'More and more people are using the Internet to purchase everyday items, and criminals are taking advantage of this trend to deceive customers into buying fake and even dangerous medicines and medical products online, with no concern to the health risks this poses.'

'Through strong collaboration between law enforcement, health agencies and Internet and payment companies, INTERPOL's Operation Pangea VIII has made significant progress in protecting innocent consumers by shutting down illegitimate online pharmacies and seizing illegal and counterfeit pharmaceutical products,' added Mr Morris.

He highlighted a case in the UK where authorities discovered an illegal online pharmacy selling unlicensed medicines obtained from another country. Police and the MHRA raided a premises connected to the website – which was arranged to look like a legal pharmacy – and seized 60,000 units of potentially dangerous medicines worth an estimated USD 2.4 million.

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### ***Examining evidence: the private for-profit healthcare sector and Universal Health Coverage (UHC)***

<http://www.globalhealthcheck.org/?p=1800>

*Posted on Global Health Check by Mohga Kamal-Yanni on Aug 18th, 2015*

On 2nd July 2015 at the International Conference on Public Policy (ICPP), Oxfam, together with Dr. Anuj Kapilashrami of the Global Public Health Unit, University of Edinburgh, convened a session entitled '**Private sector and Universal Health Coverage: Examining evidence and deconstructing rhetoric**'.

The session aimed to look at new and existing evidence on the role of the private for-profit sector in health, and to critically evaluate this in the context of achieving UHC in low- and middle-income countries. The five papers presented looked at a wide range of private sector actors in health care delivery but raised a number of common themes and challenges.

#### **Cost**

High costs, and continued challenges around out-of-pocket spending (OOPS), was a common theme across the papers. Difficulties faced in controlling the level of fees charged by private providers were also highlighted.

## Equity and access for the poorest

Challenges in controlling out of pocket payments and the overall costs of private healthcare present significant obstacles to achieving UHC, and especially to ensuring access to healthcare for the poorest. Another recurring barrier to equitable access highlighted is the location of private services. A paper mapping India's private healthcare provision by Mukhopadhyay et al highlighted that urban, metropolitan areas benefit from the majority of private hospitals, while in rural areas, disproportionately populated by poorer people, the private sector is largely comprised of individual practitioners.

## Poor quality and regulatory challenges

Usar's paper investigating perceptions of shops selling medicines in Nigeria highlighted major concerns around their 'pervasive regulatory infringements' – and especially the selling of drugs beyond the scope of the licenses – as well as the lack of training of staff. The same paper pointed to the challenges of regulating medicine vendors in Nigeria in order to improve their quality.

The study also found that that there is almost no regulation that guards against anti-competitive behaviour. Furthermore, 'there is little monitoring by governments of quality and health outcomes, or attention to how the private health sector supports national health objectives'.

## Impact on the public system

Doherty concluded that 'legislative gaps and enforcement problems, together with the fact that prices are not contained in any meaningful way, either through price controls or active reimbursement mechanisms, mean that for-profit private care in the region is likely to become increasingly unaffordable for any but the wealthiest'. Yet, if the for-profit private sector is poorly regulated and potentially growing, what impact could this have on the public health system left for the majority of the population?

The final paper by Jisha C. J., examining a state health insurance scheme in India (Kerala), highlights an additional worrying trend, where some private hospitals register in the state insurance scheme, only to de-register themselves once they have attracted some new patients to their facility. It can be assumed this trend will waste public resources spent on administration, as well as raising serious concerns about both equitable access and the behaviour of private providers.

**Conclusion:** The evidence presented at the Oxfam-University of Edinburgh session makes a further contribution to the debates over the role of the private sector in achieving UHC. While the papers can only shed light on the specific areas they analyse, it is clear

that the wider themes they highlight chime with the findings of broader studies on the comparative roles of the public and private sectors.

Oxfam hopes to continue these discussions further, and will be hosting additional blogs on Global Health Check from the contributing authors and discussants exploring the details of the evidence presented in the coming months.

**Third World Resurgence #298/299 Focus on WHO: Resisting Corporate Influence.** David Legge: WHO may be compromised as a result of corporate influence. Judith Richter: Greater collaboration between WHO and big business – is it justified? See complete edition here: <http://www.twn.my/title2/resurgence/2015/298-299.htm>

## **Australia: Chiropractors' claims to treat a wide range of conditions challenged**

See the complete letter from Ken Harvey and Mal Vickers and references [here](#).

The Australian Health Practitioner Regulation Agency (AHPRA) supports 14 National Boards (including the Chiropractic Board) that are responsible for regulating the health professions. The primary role of the National Boards is to protect the public by setting standards and policies that all registered health practitioners must meet.

In August, 2010 the Chiropractic Board asked all chiropractors to review their advertising, including their websites, as a priority to ensure that the content meets the advertising requirements of the Health Practitioner Regulation National Law Act 2009 (National Law) and the provisions of the Guidelines on Advertising.

Section 133 of the National Law prohibits advertising that is false, misleading or deceptive or is likely to be so; creates an unreasonable expectation of beneficial treatment, and encourages the indiscriminate or unnecessary use of health services.

Subsequently, there has been ongoing concern that a number of chiropractors continue to breach s.133 of the National Law (and also the Chiropractic Board Code of Conduct). For example, in December, 2011 the author of an article in 'The Conversation' was 'disturbed' that chiropractors were offering 'adjustments' for a wide range of childhood problems (for which there was no evidence of efficacy). In July 2014, CHOICE was concerned some chiropractors were promoting themselves as alternatives to GPs for the care of babies and children.

On September 4, 2014 Dr Ken Harvey and Mr Mal Vickers met with Mr Scott Gregson, Executive General Manager, Consumer Enforcement, Australian Competition & Consumer Commission (ACCC) and presented a two page document containing examples of misleading chiropractic claims for specific conditions

they believed could deter patients from seeking evidence-based health services with potentially serious health consequences. They were concerned that the chiropractic businesses identified were in breach of the Competition and Consumer Act 2010, Schedule 2, s.18 which prohibits a person, in trade or commerce, from engaging in misleading or deceptive conduct.

Following this meeting, Mr Gregson said he had passed the concerns to two representatives of AHPRA in October 2014. He felt that this initial discussion was positive. In May, 2015 Mr Gregson noted that the ACCC continued to engage with AHPRA about these matters. However, given the ongoing concern, he had no objection to the matters being raised directly with AHPRA.

In a July 2015 [communique](#), the Chiropractic Board expressed ongoing concern that advertising by their profession may be seen as misleading and deceptive. The Board noted that practitioners may lack understanding of evidence and evidence-based practice; a matter they proposed to address in their next newsletter.

However, five years had elapsed since the Chiropractic Board asked all practitioners to review their advertising, including their websites as a priority, to ensure that the content meets the advertising requirements of the National Law and the provisions of the Guidelines on Advertising.

Dr Harvey and colleagues believe they should now be held accountable for their breaches of the law. They wrote to the CEO of APHRA and included ten representative complaints. They alleged that these complaints identified conduct that is likely to harm consumers and breached Section 133 of the National Law and the Chiropractic Board Code of Conduct.

For example, a number of Australian chiropractors continue to advertise on their web sites that they are proficient in treating a variety of non-musculoskeletal conditions: sinusitis, influenza, pneumonia, hypertension, dysmenorrhoea (painful menstrual cramps of uterine origin), asthma, allergies, tinnitus, bad hearing, colic, hiatus hernia, irritable bowel, diarrhoea, constipation, hormone imbalance, thyroid issues, cancer, heart disease, diabetes (and every other life threatening condition), forgetfulness and even learning difficulties and behavioural problems.

Some chiropractor web sites assert that everybody, from a newborn baby to the very elderly, can benefit from having their spine checked and adjusted to ensure their body functions at its best; that intensive chiropractic care (more than 7 visits per year for more than one year) increases resistance to winter bugs and common childhood diseases by 'boosting' the immune system, and that people who participate in a regular

program of chiropractic care will suffer less from reoccurring symptoms like indigestion, sinus problems and stress.

Others state that the benefits of regular chiropractic care in pregnancy include preventing caesarean delivery, a reduction in labour time by up to 5 hours and a 50% decrease in the need for painkillers during delivery. In addition, some chiropractors advertise Naturopathic services (including natural allergy testing) and other non-evidenced based services such as Biomesotherapy, Homeopathy, Total Body Modification, NAET (Energy Balancing Procedure) and Hair Tissue Mineral Analysis (HTMA) for which they appear to have neither appropriate training nor recognised credentials.

However, these complaints raise an important question about the ability of the Chiropractic Board to make timely, non-biased and transparent determinations as to whether the claims in these ten complaints are in breach of the s.133 of the National Law.

The recent [Independent Review of the National Registration and Accreditation Scheme for health professions](#) noted widespread concern about delays in assessing and finalising complaints and notifications, poor communication with complainants and inadequate explanations of outcomes. In addition, Harvey and Vickers understand that the Chiropractic Board has used just one 'independent peer reviewer' to determine if similar complaints have breached relevant advertising standards. Given the clear [division](#) within the Chiropractic profession about the subject matter of these complaints they submitted that this would be a completely inappropriate procedure to assess our complaints.

The writers suggested that the procedure used by the [Therapeutic Goods Advertising Complaint Resolution Panel](#) would be more appropriate. While the Therapeutic Goods Advertising Code applies to the advertisement of therapeutic products, as distinct from practitioners, its aim is similar to that of s.133 of the National Law; that is to ensure promotional messages and general information to the public are truthful, valid and not misleading, such as by arousing unwarranted expectations or downplaying possible risks.

Alleged breaches of the Therapeutic Goods Advertising Code, 2007 are investigated by a Complaint Resolution Panel (CRP) comprised of nominated representatives of consumer, health professional and relevant industry groups. The CRP has an independent Chair elected by the Therapeutic Goods Advertising Code Council. The CRP decides whether or not the complaint is justified based on the materials each party has provided and the results of its own enquiries. To ensure fairness, each party to the complaint is given an opportunity to provide

a written submission to the Panel. This process is clearly set out in the CRP procedures.

In comparison, the Chiropractic Board's procedure to address advertising complaints appears extremely protracted, fails to address the potential bias of one 'independent peer practitioner' and appears to provide no transparency regarding the evidence provided to justify or deny the allegations, let alone publically disclosing whether or not a breach of s.133 of the National Law has occurred.

If the public and health professionals are to have confidence in the Chiropractic Board then Harvey and Vickers suggested that the complaints submitted must be investigated by a much better procedure than the current sole 'independent peer practitioner' process. At the very least, the writers asked that the investigation of their complaints by the Chiropractic Board be overseen by the AHPRA National Board.

Finally, if complaints fail to change aberrant chiropractor behaviour, a more radical solution would be to apply the provisions of the [Swedish Quackery Act](#) to the National Law. In Sweden, only a physician is allowed to treat specific diseases such as cancer, diabetes, epilepsy; pathological conditions associated with pregnancy or childbirth, or treat a child younger than eight years old. The violation of these restrictions is an offence and may be prosecuted.

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## **Australian Medicines Handbook for Pacific Island Countries (AMH)**

The AMH is an independent, evidence-based, national drug reference. It is an important clinical resource for health practitioners concerned with the quality use of medicines. The comparative drug information makes it unique among drug reference tools on the market, as it allows users to compare drugs and make informed treatment choices.



The AMH organisation generously donates multiple copies of this wonderful reference to the Chief Pharmacists in the Pacific Island Countries. Each copy weighs one kg so the cost of freight is a big issue.

Transport of the books cost more than AU\$1000 this year and that was made possible through the support of 'Remedy', the Victorian Pharmacy Students Association who raised the funds to cover the cost of freight. This initiative is a valuable support for our Pacific Island colleagues who are extremely grateful to AMH and 'Remedy'. It is intended that it will be an annual venture.

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## **Antibiotic Awareness Week 2015**

The global Antibiotic Awareness Week will take place from 16-22 November 2015. With the theme 'Antibiotics: Handle with care', the week will encourage everyone that they have a part to play, and that by using antibiotics responsibly now we can change the future.

The theme of the campaign reflects the overarching message that antibiotics are a precious resource and should be preserved. They should be used to treat bacterial infections, only when prescribed by a certified health professional. Antibiotics should never be shared and the full course of treatment should be completed – not saved for the future

In Australia, NPS MedicineWise will be working with a range of organisations to encourage the responsible use of antibiotics across the health sector, across agriculture and industry, and in the community.

Without antibiotics, infections that were once easily treated may once again kill. Together we can make a difference and change the future. Stand by to hear more about Antibiotic Awareness Week in the coming months.



<http://www.who.int/drugresistance/en>



## Feature: Antimicrobial Stewardship preparations

Information supplied by Crystal Yim, Jeremaia Mataika and Apolosi Vosanibola

In Fiji it is recognised that resistance to antimicrobials is an increasingly serious patient safety and public health problem. Resistance will threaten the treatment of infections that depend on antimicrobial therapy. There has been awareness that antimicrobials may not be used in the best way to maintain their efficacy so investigations are being undertaken to inform a campaign aimed at the best use of antimicrobials by health professionals in the community..

### **Fiji: Investigations to inform development of Antimicrobial Stewardship**

#### **1. Investigation of meropenem use at the Colonial War Memorial Hospital**

<http://tinyurl.com/ogeo3lb>

In 2014 it was noticed that the use of meropenem had increased significantly in Fiji Divisional Referral Hospitals. This development caused considerable concern to staff of the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) in the Ministry of Health and Medical Services (MHOMS).

Meropenem is a broad-spectrum antibacterial agent, with activity against the majority of Gram positive, Gram negative and anaerobic bacteria. Its use and misuse raises the potential for the development of significant bacterial resistance with profound clinical impact on the Fijian healthcare system. In addition, meropenem is very expensive with the current procurement cost of meropenem at \$8.82 for a 500 mg vial. Recently, bacterial resistance to meropenem has emerged in the Divisional Hospitals and use of the last line antibiotic colistin has become necessary. For these reasons, meropenem use at the three Divisional Hospitals including the Colonial War Memorial Hospital (CWMH) must be strictly limited.

According to the *Indications for Meropenem Use at Divisional Hospitals Policy*, meropenem is indicated for;

*Any individual patient where there is a clear clinical evidence of infection*

**PLUS**

*A culture of blood plus other relevant body fluids confirmed positive for an organism shown to be resistant to all other available (or appropriate) antibiotics.*

*A confirmed outbreak of an organism resistant to all other available (or appropriate) antibiotics in the Intensive Care Units only (NICU, PICU or adult ICU); as empirical therapy for patients with clinical evidence of infection, for a maximum of 72 hours pending results of microbiology specimens. If infection with a*

*multi-resistant organism is not microbiologically confirmed at this time, meropenem must be ceased and appropriate alternative antimicrobial therapy instituted. Once the outbreak is declared and controlled by the Infection Control Unit, empirical antibiotic therapy must revert to a non-meropenem containing regimen.*

*In both situations the duration of treatment should be the decision of the treatment Consultant.*

It was considered necessary to assess the use of meropenem at the CWMH compared to the *Indications for Meropenem use at Divisional Hospitals Policy* and provide recommendations to improve rational use of meropenem there and to reduce the development of further antibiotic resistance.

A retrospective study was undertaken at the CWMH between October 2014 and November 2014 to investigate the reasons for the 40-fold increase in meropenem consumption since 2008 in the Divisional Hospitals of Fiji. Data was gathered by an intern pharmacy student from Monash University and hospital pharmacy staff under the guidance of pharmacists from the FPBSC.

Data from the *Restricted Antimicrobial Request Form*, pharmacy dispensing program PatisPlus® and microbiology laboratory records were used to analyse the prescribing of meropenem compared to the *Indications for Meropenem use at Divisional Hospitals Policy* and treatment guidelines. Infection control unit nurses, Pharmacy Department staff and the Head of the Microbiology Department were interviewed, prescribers were surveyed and an infectious disease prescriber was consulted to provide prescriber related comments about the use of this drug.

It was found that meropenem use can be optimised in several areas including appropriate dosing, use of sensitivity data, infection control and prevention, and good stock management. A few of the critical interventions recommended to address these problems include: the updating of the *Indications for Meropenem use at Divisional Hospitals Policy*, development of the *Meropenem Treatment Guideline*, microbiology results be made available on PatisPlus®, development of stock management standard operating procedures and all cases of multi-resistant organisms to be treated as an outbreak.

**Findings:** The following elements would need to be in place to improve the use of meropenem:

1. Effective infection control and prevention measures

2. Availability and use of the hospital hygiene practices and facilities
3. Efficient microbiology laboratory and prompt dissemination of results
4. Appropriate prescribing of antibiotics in line with guidelines and protocols
5. Adherence to policies and procedures that were in place (such as the completion of the restricted antibiotic form)
6. Good stock management of essential medicines and consumables
7. Utilisation of PatisPlus® in Pharmacy and Microbiology departments

Maintenance of a reliable supply of correct antibiotics is crucial to avoid the use of restricted antibiotics in their absence.

Development of a strategic plan is recommended for each hospital department involved. The plan will include instructions for successful implementation and monitoring of the recommended interventions to reduce inappropriate meropenem usage and prevent development of antibiotic resistance.

## 2. Community perceptions of antimicrobial use in Fiji



There have been anecdotal reports received by FPBSC about patients asking doctors to prescribe antimicrobials and doctors prescribing antimicrobials too freely, patients buying antibiotics over-the-counter from community pharmacies and patients sharing antibiotics. Patient perceptions and knowledge about their need for antimicrobials required investigation. A nation wide representative survey of the Fijian community and focus groups including private health practitioners is currently being undertaken to answer questions related to attitudes and perceptions about antimicrobials.

Conducting a nation wide survey in a country made up of widely dispersed islands is logistically very difficult and very expensive and requires a large quantity of resources and a strong contingent of trained human resources.

However, to overcome budgetary and human resource constraints there was an alternative to conducting the survey within these communities. Each August the Hibiscus festival is held for one week in Fiji's capital, Suva, and 'Queens' compete from all over the country. Communities from all the islands come to support them. The annual Hibiscus Festival is supported by Vodafone telephone company; and the MoHMS customarily has an information tent.

So it was decided that the survey would be conducted at the Hibiscus festival during the second week in August

to capture people's knowledge and perspectives about antibiotics from all over the country.



Images printed on T shirts.



The 'Hibiscus Festival' survey team

Preliminary analysis indicates that the survey (involving 5000 participants) covered the Fiji Islands population well and that education and age of participants reflected the Fiji profile.

## 3. Investigation of antimicrobial use to inform national development of AMS

In addition to the above investigations, a consultant from WHO Manila undertook a study that included key informant interviews, field visits to health-facilities, laboratories, health facilities and pharmacies, etc. to understand and analyse current strengths, weaknesses, bottlenecks and points of entry for actions to contain AMR, which will inform the development of a the national policy. Relevant national counterparts such as the Ministry of Agriculture, Rural and Maritime Development and National Disaster Management Ministry of Fisheries and Forests, Department of Environment were included in the study to assist in the formation of a multi-sectoral comprehensive response to the threat of AMR.

## Results to be analysed and presented

The results of the above community studies are yet to be analysed and presented. Targets identified in the community survey will inform the campaign that is to be undertaken in Fiji in November 2015 as part of WHO's International Antibiotic Awareness Week. The findings of all the surveys will inform the development of the Antimicrobial Stewardship program.

Results of the studies and the responses to the results will be shared in the next edition of HAIAP News.

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### **Malaysia: Public Perceptions towards Implementation of Dispensing Separation: Results from a Cross Sectional Analysis**

J Pharma Care Health Sys 2015, 2:4

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see <http://tinyurl.com/ntwtpta> for the complete article

In most developed countries, prescribing is the responsibility of physicians while dispensing of medications is the responsibility of pharmacists. This clear demarcation of roles avoid conflicts such as physicians encouraging demand for medicines or substituting more expensive medicines because of substantial profit margin on medication sales. Furthermore, the separation of roles enhances treatment, as pharmacists being the medicine specialists receive, review and deliver prescriptions and safeguard good dispensing practices and patient care. The Malaysian healthcare system has yet to introduce a legislature that implements separation of physicians and pharmacists roles. The convention has been that physicians dispense the medicines they prescribe and there has been strong resistance among the profession for separation of roles. Recently, a proposal was offered to seek the Malaysian population's point of view towards dispensing separation. Therefore, a study aimed to assess general public perceptions towards implementation of dispensing separation was undertaken in the State of Penang, Malaysia.

A cross-sectional study design was adopted to conduct the study. A pre-validated questionnaire was offered to 1000 residents in the state of Penang, Malaysia. Both descriptive and inferential statistics were used for data explanation. Sixty-three percent of the respondents were females with Malay being the prevailing ethnic group (n = 527, 52.7%).

Seven hundred and sixteen (71.6%) of the respondents reported pharmacists as a reliable source of medicine-related information when compared with physicians, when diagnosis has been made. Majority of the respondents (n = 876, 87.6%) assured their support towards implementation of dispensing separation in Malaysia. The respondents explained that dispensing separation will result in optimization of patient safety (n = 890, 89.0%), help in to reduce medication error (877, 87.7%) and will reduce the cost of medication (n = 777, 77.7%).

There was a significant support for future implementation of dispensing separation among all demographic variables. Results of the study presented strong evidence of public support and benefits of dispensing separation in Malaysia. These findings are of high relevance to the policy makers as they provides an overview of public choice for implementing dispensing separation in Malaysia.

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### **Malaysia: General practitioners' knowledge, attitudes and prescribing of antibiotics for upper respiratory tract infections in Selangor: findings and implications**

Expert Rev. Anti Infect. Ther. 13(4), 511–520 (2015)

Mohamed Azmi Hassali, et al

For the complete article and a full list of authors see

<http://tinyurl.com/porgqrw>

Background: Antibiotics are widely prescribed especially for upper respiratory tract infections (URTIs). Their irrational use can increase costs and resistance. Aim: Assess knowledge, attitude and prescribing of antibiotics for URTIs in Selangor, Malaysia, using a cross-sectional survey among general practitioners (GPs) working in private clinics in 2011. Results: One hundred and thirty-nine physicians completed the questionnaire (response rate = 34.8%). 49.6% (n = 69) agreed antibiotics are helpful in treating URTIs, with most GPs agreeing antibiotics may reduce URTI duration and complications. The majority of GPs reported they felt patients expected antibiotics, with 36.7% (n = 51) agreeing patients would change doctors if they did not prescribe antibiotics and 21.6% (n = 30) agreeing when requested they prescribe antibiotics even if they believe them to be unnecessary. When assessed against six criteria, most GPs had a moderate level of knowledge of prescribing for URTIs. However, antibiotic prescriptions could be appreciably reduced. Conclusion: Further programs are needed to educate GPs and patients about antibiotics.

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