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HAI AP News

Penang, Malaysia

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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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New HAIAP Website launched

Go to <http://www.haiasiapacific.org>

Your comments can be included at the bottom of each page or email beverleyfsnell@gmail.com with material and links for including on the site and any other suggestions and feedback.

Message from the Coordinator

HAIAP has relaunched its website!

We are now online again!

As you would know HAIAP lost its website around the time of relocation to Penang. Complicated communications with the previous Sri Lankan based website and domain administrators to retrieve the template and archival material were attempted without success.

We have done away with the idea of external administrators. Dr Ken Harvey began the work on a new website and trained Beverley Snell. Now we have a new entity: <http://www.haiasiapacific.org/>

Thank you Ken and Bev!

At the last planning meeting it was agreed that HAIAP would focus on Antimicrobial Resistance, the Trans Pacific Partnership Agreement and the State of Pharmaceutical Policies in the Asia Pacific region. These will be issues that we flag on the HAIAP website; news items, related work activities and latest developments on these issues will be regularly posted for partner information and action. We invite your feedback and contributions. Issue-related discussions can be undertaken through the website.

Bev and I want you to understand that the website is always evolving. We have launched what has been

done so far so we can work on it as we go along. Please provide ideas, input and feedback so that the website can become truly representative of the network. We want to make it a participatory effort.

All back issues of the HAIAP News are already available on the website and the website search function can lead you to material inside the issues.

This and all subsequent issues of HAIAP News will be available and searchable on the HAIAP website.

We want you to continue to contribute news items – major features or short partner updates, research articles and personal opinions – to HAIAP News. More than that we urge you to think about how we can make the website truly vibrant and inclusive.

Let's begin to PLAY again!

Shila Kaur



Awards

Prescrire Awards

2013_Prescrire_drug_awards.pdf
(From Bruno Toussaint, Publishing Director, Prescrire, with thanks.)



The independent French medical journal *Prescrire* held its annual awards in Paris on 30 January.

Prescrire's Annual Drug Awards recognise new drugs, or new indications for drugs already on the market, representing tangible progress for patients. Chosen in complete independence by the Editorial Staff of the non-profit French journal *Prescrire*, the Awards reflect the analysis of the available data on new products published in the journal over the past year.

For 2013, for the third year in a row, there was no '**Pilule d'Or**' ('**Golden Pill**'). This award recognises drugs that provide a major therapeutic advance for patients and healthcare professionals in a field in which no treatment was previously available.

Nor were any drugs added to *Prescrire's* '**Honours List**' of drugs that provide a clear advantage for some patients in comparison to existing therapeutic options. Just one drug was deemed to have made a positive, if modest, contribution to patient care.

Prescrire announced its Packaging Awards for 2013. Three winners for the **Packaging Award** demonstrate that quality drug packaging is indeed within reach for pharmaceutical companies. But a flurry of '**Yellow Cards**' and '**Red Cards**' point to a multitude of dangers from poor packaging and incomplete leaflets.

Information Awards for 2013 were announced: a handful of companies were honoured, but too many lag behind. Pharmaceutical companies' transparency, essential to their credibility, is a critical component in the choice of a drug, ranking just behind efficacy, adverse effects, ease of use and price. *Prescrire's* annual Information Awards reveal which companies practice transparency and which fall short.

©Prescrire 1 February 2014

See The 2013 *Prescrire* Awards: Drugs, Packaging, Information : <http://english.prescrire.org>

Here is the pdf with all the details

http://english.prescrire.org/Docu/Archive/docus/2013_PrescrireAwards.pdf

Katerva Awards: HealthPhone

"If the Nobel Society had an award for sustainability, it would resemble the Katerva Awards, a new international prize for the most promising ideas and efforts to advance the planet toward sustainability." Reuters 2011

'Katerva is not just interested in 'good' ideas; the ideas we are after will create big changes in how we live on this planet,' says Katerva's founder, innovation expert Terry Waghorn. Founded in 2010, 'Katerva's approach places emphasis squarely on action for a sustainable future - creating and implementing solutions to sustainability-related concerns' he says. 'Katerva uses the power of technology to engage a global network of experts who help us find the most interesting innovations on the planet - the best ideas you have never heard of.'

Healthphone won the 2013 Katerva Peoples' Choice Award. The *HealthPhone* which was nominated in the Gender Equality category, is a mobile-phone-based personal video reference library and guide to better health and nutrition practices, for families and communities. The videos have been created specifically with the illiterate in mind, and in their language. This gives them direct access to knowledge, in rich multimedia, to learn, share, educate others and use at the time when they need to deal with a health problem, where they are, and as they are, without a connection or cost. Videos are currently available in 63 languages.

"To be nominated as one of the most game-changing projects in development worldwide was truly exciting. To be selected as a finalist was a great honour. And, now, to be selected as the People's Choice, we're over the moon!"

"For us, the award serves as encouragement and we are energized to continue our work to provide women and communities life-saving health and nutrition knowledge to better look after themselves and their

families.” – Nand Wadhvani, Innovator and Creator of the HealthPhone.

HealthPhone was recently recognized by Healthcare Information For All (HIFA), a campaign and knowledge network with more than 7,000 members representing 2,500 organisations in 171 countries worldwide. Katerva also allows the public to help choose from the finalists the innovation they feel has the most to offer the world.

Intellectual Property Issues and access to medicines

From the TWN Info Service on Health Issues

MSF slams Bayer for saving drugs for those who can pay

TWN Info Service on Health Issues reported the Médecins Sans Frontières (MSF) response to the Bayer CEO Marijn Dekkers' statement that new drugs were being saved for those who can pay.

<http://au.news.yahoo.com/thewest/business/world/a/21019269/msf-slams-bayer-for-saving-drugs-for-those-who-can-pay/>

India's controller general of patents had angered Bayer in March 2012 when he authorised a local drugmaker to produce a generic copy of Nexavar, (sorafenib) saying the German company charged a price that was too costly for most Indians.

‘We did not develop this medicine (Nexavar) for Indians,’ Bayer CEO Marijn Dekkers said, according to the January 21st edition of Businessweek. ‘We developed it for Western patients who can afford it.’ Dekkers called the Indian regulator's action ‘essentially theft’.

Dekkers added in written comments that he had been ‘particularly frustrated’ by the Indian regulator's decision, which marked the first time a so-called compulsory licence of a patented drug had been awarded in India.

MSF said that the Bayer chief's remarks summed up ‘everything that is wrong’ with the multinational pharmaceutical industry. Manica Balasegaram, executive director of MSF's Access Campaign, said ‘Those who can't afford to pay are basically cut out of the system.’

The Indian government gave local pharmaceutical house **Natco Pharma** a licence to produce a copy of Nexavar, used to treat liver and kidney cancer, at a 97 percent discount on the original selling price of the Bayer product in India.

Global drug-makers say India's powerhouse generics industry and strict patent filtering reduce commercial incentives to produce cutting-edge medicines.

Doing the right thing

No government should be intimidated for doing the ‘Right Thing’ In Public Health: Dr Margaret Chan

<http://www.ip-watch.org/2014/01/24/who-director-general-no-government-should-be-intimidated-by-interested-parties/>

Discussions on access to essential medicines at the World Health Organization in January were in some ways overshadowed by the leak of a global pharmaceutical campaign aimed at derailing efforts by the South African government to revise its intellectual property policy. WHO Director General Dr Margaret Chan strongly supported South Africa, as did several developing countries, while developed countries remained silent on the subject.

Discussion covered the recent effort by some pharmaceutical companies to undermine efforts of the South African government to amend its IP laws, revealed through a leaked document bluntly titled, ‘Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa,’ (*IPW, Public Health, 22 January 2014*).

Mrs Precious Matsoso, Director-general of the South African Ministry of Health, and former head of the WHO program on Public Health, Innovation and Intellectual Property, explained that one of the objectives of the new South African IP policy is to contribute towards the protection and promotion of public health, and access to medicines in particular.

‘This is not the first time that South Africa has been under such an attack, even in the face of the most devastating HIV and TB co-morbidities,’ she said. ‘In 2000, we saw this attack whereby Nelson Mandela was the first respondent.’ [At that time 39 drug companies attempted to sue the South African government over their legislation allowing compulsory licences and access to affordable medicines. After an international outcry and petitions with millions of signatures the companies were thrown out of court. Ed.]¹

The cost of combination antiretroviral therapy per person per annum was brought down from US\$ 10,000 to US\$ 1,000 since 2000. Mrs Matsoso explained, ‘This would not have been possible without generic competition.’ She added that South Africa has been able to provide treatment to 2.4 million people. However, only 4 percent of South Africans are on second line antiretroviral therapy and that number must be increased to 14 percent. This increase will not be possible at current costs for South Africa.

Dr Chan supported South Africa and reminded delegates of the *WHO 12th General Programme of*

¹<http://news.bbc.co.uk/2/hi/africa/1285097.stm>

Work, approved by member states, increasing access to essential, high-quality, effective and affordable medical products.

'I have been following the events in South Africa and I was very struck by what is happening and I have said so in other contexts and I will repeat again: no government should be intimidated by interested parties for doing the right thing in public health,' she said.

According to MSF '.. it remains a challenge for WHO member states, especially developing countries, to use the TRIPS flexibilities when drafting intellectual property policies that aim to promote access to affordable essential medicines.'

A group of NGOs published a draft resolution on access to essential medicines and Dr Chan noted the points made by the NGO community. She told member states, 'If these works are so important to you why are they left unfunded? This is a question you need to reflect on.'

US leads the world in use of compulsory licenses: Knowledge Ecology International

www.twn.my/title2/intellectual_property/info.service/.../ip140305.htm

The United States 'is leading the world in the use of compulsory licenses,' and is hypocritical in voicing indignation when developing countries issue compulsory licenses for essential drugs, a leading international civil society organisation, Knowledge Ecology International (KEI), has said in testimony before the United States International Trade Commission (USITC).

KEI's testimony was before a public hearing in February as part of the USITC's investigation titled 'Trade, Investment and Industrial Policies in India: Effects on the US Economy.'

The USITC investigation has been backed by several US industry associations including the Pharmaceutical Research and Manufacturers of America (PhRMA).

A number of other civil society groups had also testified before the USITC, rebutting the arguments of PhRMA and the other industry associations, and expressing strong support for India's use of compulsory licensing.

KEI had included an appendix to its written statement that provided numerous examples whereby the US government had issued compulsory licenses in several areas of intellectual property such as copyright, defence technology, information technology, energy patents, medicines, and health testing.

KEI focused its testimony on the manufacture and sale of generic drugs from India, the recent compulsory license issued by India on Bayer's patents for the cancer drug Nexavar (sorafenib), the decision by the Indian

Patent Office to reject the patent for Novartis' cancer drug Gleevec (imatinib), and the consequences of trade pressure in curbing India's role in supplying affordable medicines.

KEI noted that from 1970 until 2005, India did not grant patents on pharmaceutical products, and like many other developing countries, limited or eliminated patent protection for pharmaceutical drugs. When the World Trade Organisation (WTO) was created, its TRIPS agreement included flexibilities so that India and other countries could grant compulsory licenses that would allow affordable access to new drugs.

'If the USITC brings pressure on India to curb the manufacture and sale of generic cancer drugs, the actions will be directly responsible for the death of cancer patients living in developing countries, and this should be on everyone's mind', KEI added and explained 'For all the corporate propaganda about concern for global health, the fact is that nearly all companies manufacturing and selling cancer drugs have been indifferent to the inequalities of access, and only introduce measures to mitigate concerns over access when faced with compulsory licensing of patents or other actions against the patent monopolies'.

'When United States government officials become indignant over developing countries' issuance of compulsory licenses over cancer drugs, the degree of hypocrisy expressed by some parties is worth noting. The United States is leading the world in the use of compulsory licenses:

- in 2001, the US Department of Health and Human Services (DHHS) used the threat of a compulsory license for the patents on Bayer's ciprofloxacin, to successfully obtain a 50 percent price reduction for the drug.
- in a 2004 case involving patents on ritonavir, a drug used in the treatment of HIV infection, the concession by the patent holder was significant - Abbott Laboratories agreed to reduce the price of ritonavir approximately 80 percent for HIV patients on federally supported programs.
- in 2006, the Centers for Disease Control may have threatened to use the government's royalty free license to expand access to patented technologies used to manufacture vaccines for avian flu. KEI has an outstanding Freedom of Information Application for the details of this case.
- in 2010, a shortage in the US supply of Fabrazyme, (agalsidase beta) an expensive treatment for Fabry's disease, was caused by manufacturing failures by Genzyme Corporation, a firm now owned by Sanofi. The patents were invented on an NIH grant, and were owned by Mount Sinai School of Medicines.

Several Fabry's disease patients asked the NIH to grant a compulsory license for the patents on Fabrazyme. At the time, Fabrazyme was severely rationed in the United States, and patients were getting sicker. The NIH rejected the petition, in part because the NIH found other IPR barriers to entry, such as the FDA monopoly on test data. However, the Director of the NIH reported that 'Mount Sinai has assured us that it will not pursue an injunction against the marketing and sale of Replegal (agalsidase alfa) during any period of an existing or future shortage of Fabrazyme.'

(The full KEI written statement including the appendix can be found at <http://keionline.org/node/1967>)

Access to Hepatitis C treatment:

Professor Tariq Bhutta

On February 15, 2014, Professor Tariq Bhutta wrote to Medicines Patent Pool as follows:

Dear Mr Greg Perry

Recently Medicines Patent Pool (MPP) www.medicinespatentpool.org/ signed a licensing agreement with Bristol-Mayer Squibb to increase access to atazanavir in 110 countries representing 88.5 percent of people living with HIV. This initiative will go a long way to improve this second line treatment to people living with HIV who have developed resistance to first line regimens.

It is a great news for such patients who could not afford this drug at present due to high cost.

I want to bring your attention to another disease which is Hepatitis C - affecting almost 184 million people, 90 percent of which live in low income and middle income countries. One recent medicine which has transformed the treatment landscape is sofosbuvir. But the cost is prohibitive. A 12 weeks course will cost US\$84,000 even though the scientist involved in formulating sofosbuvir - Raymond Schinazi - estimates costs at just US\$1400. An even lower price was indicated by Andrew Hill and colleagues in a recent study showing that the minimum cost to manufacture was US\$100-250 per 12 weeks treatment course.² At this lower price the drug can be accessible to the majority of people suffering from Hepatitis C.

I would request you to take up this important issue with its manufacturer who should also be involved, to ensure this medicine reaches those in most need.

²<http://hepatitisnewdrugs.blogspot.com.au/2013/11/aasld-sofosbuvirsimeprevir-what-is.html>

Medicines Patent Pool replied as follows:

Dear Prof Bhutta,

Thank you for your comments on our recent agreement with Bristol-Mayer Squibb. We agree that the new licences could significantly extend second-line treatment options for people living with HIV.

At the moment, MPP's mandate is focused on negotiating access agreements for key WHO priority HIV medicines. However, we recognise that there is a growing interest among international public health organisations to explore how the MPP could be adapted to address access issues around other diseases such as Hepatitis C and Tuberculosis. We are currently assessing internally how we could respond to public health needs.

We appreciate your interest in our work and invite you to visit our website to stay informed about our future activities.

Best regards
Greg Perry
Medicines Patent Pool

Post scripts

No sofosbuvir patent in Egypt, but Gilead deal still expensive

Cairo, 8 April (Heba Wanis*) – Preliminary examination of the patent application on sofosbuvir, a major hepatitis C medicine, at the Egyptian Patent Office showed that it is unlikely to be patented.

The examination revealed that the 'invention' does not satisfy the novelty and inventiveness criteria to be granted a patent. The final decision of Egyptian Patent Office has not been issued yet; however, it is clear that sofosbuvir will not be patented in Egypt. In the meantime, the Ministry of Health agreed with Gilead Sciences Inc., the US-based multinational pharmaceutical company, to pay US\$300 per bottle per month to purchase sofosbuvir for its national HCV treatment programme.

- Heba Wanis is a Researcher on Access to Medicines with the Egyptian Initiative for Personal Rights www.twinside.org.sg/title2/intellectual_property/info.../ip140408.htm

WHO Guidelines on Hepatitis C treatment:

MSF Statement April 9: 'We welcome the release of these guidelines as they provide guidance on how to start treatment in resource-limited settings; but equally important is the registration of new oral drugs in middle-income countries like India', said Dr Simon Janes, Medical Coordinator of MSF in India. 'The critical aspect now is implementing them, and this hinges on ensuring that access to new drugs and diagnostics is not hampered by patent barriers that undermine low-cost generic supply.'

Sofosbuvir has been released in the US at US\$84,000 for 12 weeks' treatment, which equates to US\$1,000 per pill and it could be priced as much as US\$5,000 in Thailand. The price Gilead says it will charge for sofosbuvir in developing countries is still far too high for people to afford.

Sofosbuvir and related drugs can however be produced generically in India and marketed at very affordable prices, just like antiretrovirals used in the treatment of HIV. A study by researchers at Liverpool University has found that a 12 week course of sofosbuvir could cost as low as US\$68-\$136. It is possible that diagnosis and treatment together could cost as little as US\$500. Leena Menghaney, India Manager for MSF's Access Campaign explained that bringing the price down will be critical to scaling up treatment, so if the costs of drugs are unaffordable, countries should use all the legal means available to ensure affordable access. Already, civil society groups have filed patent oppositions in India to ensure affordability and generic production; with 12 million people estimated to be infected with chronic hepatitis C in India, there is a lot at stake.

http://www.msfacecess.org/about-us/media-room/press-releases/global-response-hepatitis-c-hangs-access-new-oral-drugs#overlay-context=home_page

News

Smallpox: WHO Executive Board passes the buck to the World Health Assembly

Austin, Texas, 28 Jan (Edward Hammond) ...The World Health Assembly (WHA) will undertake a substantive consideration of destruction of smallpox virus stocks when it meets in May 2014. At the meeting of the WHA's Executive Board on 20-25 January 2014, a preliminary exchange of views revealed significant disagreement among Member States on the issue.

Read the details at TWN Info Service

www.twinside.org.sg/title2/health.info/2014/hi140104.htm

Measles: Four Western Pacific countries and areas are the first in that region to be measles-free

From WHO WPRO News Release SEOUL, 20 March 2014

www.wpro.who.int/mediacentre/releases/2014/20140320/en/

The World Health Organization Western Pacific Region celebrates a milestone today with the announcement of measles elimination by Australia, Macao (China), Mongolia and the Republic of Korea. They are the first countries or areas in the Region to receive this distinction. Measles kills approximately 330 people

worldwide every day, mostly children under the age of five years, making this a truly significant achievement as WHO Member States in the Western Pacific Region work towards the elimination of measles.

This welcome news occurs against a backdrop of measles outbreaks during 2013 and early 2014 in China, the Philippines and Viet Nam, highlighting the challenge in ensuring high and consistent coverage of immunization programs across a diverse range of countries.

Despite these outbreaks, steady progress has been apparent with measles incidence at historically low levels by the end of 2012. Measles deaths in the region have dropped by an estimated 84%, from 12,100 in 2000 to just 2000 in 2012. This drop is largely attributable to an increase in high coverage with two doses of measles vaccine provided either during routine immunization services or mass vaccination campaigns.

'All countries must now intensify their efforts to immunize all children against measles and indeed other vaccine-preventable diseases, particularly those in harder-to-reach communities and remote areas', urged Dr Shin Young-soo, WHO Regional Director for the Western Pacific. 'We must reach every community, no matter where they are. This is the heart of equity. We have made significant progress in recent years. Let us not be complacent but strive even harder to help ensure the well-being of generations to come.'

UK DVD of 'Fire in the Blood' is available

This DVD can be found in shops wherever quality DVDs are sold but also available for download or rental in high- and standard definition on [*iTunes*](#) in the UK.

Since releasing in the UK, '*Fire in the Blood*' has screened at some 60 international film festivals, in cinemas and on television in numerous countries, winning a number of major awards (including *Best Debut Film* at the Mumbai International Film Festival just last month) and becoming the longest-running non-fiction film in the history of Indian cinema!

'All of us who have worked so hard on '*Fire in the Blood*' for the past half-dozen years are extremely proud of this, our very first DVD release, and gratified that so much of the material which couldn't be included in the theatrical version of the film can be seen as extra features on this disc.' - **Team Sparkwater**

on behalf of everyone involved in *Fire in the Blood*

www.fireintheblood.com

World Health Day 2014: Preventing vector-borne diseases

Slogan: 'Small bite, big threat'

Source: WHO Press Release 2 APRIL 2014 | GENEVA

<http://www.who.int/mediacentre/news/releases/2014/small-bite-big-threat/en/>

More than half the world's population is at risk from diseases such as malaria, dengue, leishmaniasis, Lyme disease, schistosomiasis, and yellow fever, carried by mosquitoes, flies, ticks, water snails and other vectors. Every year, more than one billion people are infected and more than one million die from vector-borne diseases.

The Organization also emphasizes that these diseases are entirely preventable. Newly published *A global brief on vector-borne diseases* outlines steps that governments, community groups and families can all take to protect people from infection.

'A global health agenda that gives higher priority to vector control could save many lives and avert much suffering. Simple, cost-effective interventions like insecticide-treated bed nets and indoor spraying have already saved millions of lives,' says Dr Margaret Chan, WHO Director-General. 'No one in the 21st century should die from the bite of a mosquito, a sandfly, a blackfly or a tick.'

Vector-borne diseases affect the poorest populations, particularly where there is a lack of access to adequate housing, safe drinking water and sanitation. Malnourished people and those with weakened immunity are especially susceptible.

Schistosomiasis, transmitted by water snails, is the most widespread of all vector-borne diseases, affecting almost 240 million people worldwide. Children living and playing near infested water are particularly vulnerable to this disease which causes anaemia and a reduced ability to learn. Schistosomiasis can be controlled through regular mass treatment of at-risk groups with a

safe, effective medicine, as well as improving access to safe drinking water and sanitation.

Within the past two decades, many important vector-borne diseases have also re-emerged or spread to new parts of the world. Environmental changes, a massive increase in international travel and trade, changes in agricultural practices and rapid unplanned urbanization are causing an increase in the number and spread of many vectors worldwide and making new groups of people, notably tourists and business travellers, vulnerable.

Mosquito-borne dengue, for example, is now found in 100 countries, putting more than 2.5 billion people - over 40% of the world's population - at risk. Dengue has recently been reported in China, Portugal and the US state of Florida.

Reports from Greece say that malaria has returned there for the first time in 40 years.

'Vector control remains the most important tool in preventing outbreaks of vector-borne diseases,' says Dr Lorenzo Savioli, Director of WHO's Department of Control of Neglected Tropical Diseases.

'Increased funds and political commitment are needed to sustain existing vector-control tools, as well as medicines and diagnostic tools - and to conduct

urgently needed research.'

On World Health Day 2014, WHO called for a renewed focus on vector control and better provision of safe water, sanitation and hygiene - key strategies outlined in WHO's 2011 Roadmap for the control, elimination and eradication of neglected tropical diseases, which sets targets for the period 2012-2020.



World Health Organization

VECTOR-BORNE DISEASES

VECTORS MAY BE A THREAT TO YOU, AT HOME AND WHEN TRAVELLING

VECTORS ARE SMALL ORGANISMS THAT CARRY SERIOUS DISEASES

MOSQUITOES

SANDFLIES

TICKS

COMMON VECTORS

WITH JUST 1 BITE they can transmit diseases such as:

Malaria

Leishmaniasis

Yellow fever

Dengue

Lyme disease

Japanese encephalitis

Diseases spread by vectors kill a million people every year and more than half of the world's population is at risk

TAKE SIMPLE MEASURES TO PROTECT YOURSELF AND YOUR FAMILY

Get vaccinated against yellow fever and Japanese encephalitis

Install window screens

Use insect repellent

Wear light-coloured, long-sleeved shirts and trousers

Sleep under an insecticide-treated bed net

Get rid of stagnant water from places where mosquitoes breed, such as in old containers, flower pots and used tyres

For more information, contact your health-care professional
www.who.int/world-health-day

Feature: Antibiotic use and antibiotic resistance in food animals in Malaysia - A threat to human and animal health

Prepared by Health Action International Asia Pacific (HAIAP) and Third World Network (TWN) Penang
in association with Consumers' Association of Penang 10 October 2013

HAIAP is particularly concerned with the threat that antimicrobial resistance (AMR) poses to human health. At the first joint DSAP/USM-ReACT-HAIAP³ seminar in September 2010, Dr Ken Harvey and Dr Mary Murray spoke on the matter and stressed the need for cross-sector collaboration. In April 2013 HAIAP-ReACT-International Federation of Medical Students' Associations (IFMSA) Workshop on International Health and AMR for Undergraduate medical students was held at the Monash University-Sunway campus in Kuala Lumpur.

In the second half of 2013, HAIAP (Shila Kaur) and TWN (Evelyne Hong) jointly began working on a document/brief looking at the status of antibiotic use and antimicrobial resistance in food animals in Malaysia. This study was eventually completed in late 2013 and became the basis of a Memo that went public under the auspices of the Consumers Association of Penang (CAP) during a press conference in January 2014.

From 28 April – 1 May 2014, ReACT, the South Centre and What Next Forum will convene a follow up Workshop on Civil Society collaboration for a Survival Plan for AMR. This second meeting will follow an earlier meeting held in October 2013 in Berlin where participants agreed that a broader network of Civil Service Organisations engagement was crucial for a Survival Plan.

HAIAP will present HAIAP/TWN report on the status of AMR in food animals in the Asia Pacific region at this second meeting.

The complete document provides background and sets the issues in context. It can be found at:

<http://www.haiasiapacific.org/wp-content/uploads/2014/04/Memo-on-Antibiotics-in-animal-feeds-the-case-for-Malaysia-21-Nov-2013-V1.pdf>

Here we focus on the use of antimicrobials in livestock in Malaysia.

Overview

Two tragic events took place recently in Malaysia. The first was reported in the *Borneo Post*, a regional newspaper which revealed that up until August 2013,

ten people had died in Sibu Hospital from carbapenem-resistant Enterobacteriaceae.

The second tragedy occurred in the first week of October when four people died and 60 others were hospitalised after eating contaminated chicken at a wedding feast in Yan, Kedah. The Health Department said it was most likely due to Salmonella contamination.

Many more cases are occurring throughout the country, which do not come to public notice. Antimicrobial or antibiotic (both terms will be used interchangeably) resistance (AMR/ABR) is one of the most serious health threats Malaysia faces. Infections from resistant bacteria are now common and some pathogens have even become resistant to multiple types or classes of antibiotics. With the increasing ineffectiveness of 'drugs of last resort', we are on the brink of a public health crisis. It needs to be taken seriously and urgently dealt with.

Antibiotics in food animals in Malaysia

Antibiotic resistance and its spread in veterinary medicine is a worldwide problem. Resistant bacteria carried by food-producing animals can spread to people, mainly via the consumption of inadequately cooked food; handling of raw food or cross-contamination with other foods; but also through the environment (eg animal manure and contaminated water-animal sewage) and through direct animal contact.

The main difference between antibiotic use in humans and animals is that in the latter case, there is mass administration of antibiotics to many animals at the same time for the purposes of disease prevention and growth promotion. A therapeutic dose may be up to 10 – 100 times greater than a dose used in growth promotion. Treatment is directed against a particular infecting microorganism and the goal is to eradicate or control it as quickly as possible. Contagious spread of disease can be fast in large herds.

In the case of growth promotion, smaller doses are administered for longer periods of time, for weeks to months. The net result is that as much as 80% of the total amount of antibiotics given yearly to many food animals goes for growth promotion.

Such practices provide favourable conditions for the emergence, spread and persistence of antibiotic-resistant bacteria capable of causing infections not only

³Discipline of Social and Administrative Pharmacy/Universiti Sains Malaysia/Action on Antibiotic Resistance

in animals but also in humans. Furthermore a lack of diagnostic services means that most therapeutic antibiotic use in animals is empiric, rather than being based on laboratory-proven disease.

For animals and birds farmed in large herds or flocks, a few ill individuals generally result in the entire herd or flock being treated to avoid rapid contagion and stock losses.

The antibiotics used for food-producing animals are frequently the same or belong to the same classes as those used in human medicine. Antibiotics are used in greater quantities in healthy food-producing animals than in the treatment of disease in human patients. According to the World Health Organization (WHO), there is no clear evidence of the need for or benefit from the use of antibiotics in animal husbandry.

Antibiotics as growth promoters

The largest quantities of antibiotics are used as regular supplements for prophylaxis or growth promotion in the feed of animal herds and poultry flocks. This results in the exposure of a large number of animals, irrespective of their health, to frequently sub-therapeutic concentrations of antibiotics.

Further, antibiotics that are used as growth promoters are generally not even considered as drugs and are either not licensed or licensed solely as feed additives. Marketing practices of antibiotics for therapeutic, prophylactic or growth promoter uses in animals by industry influence the prescribing patterns and behaviour of veterinarians, feed producers and farmers.

The lack of laws and regulatory mechanisms and poor enforcement regarding the promotion and use of antibiotics in animals and birds are a major contributor to the rampant and indiscriminate use of antibiotics.

Some antimicrobials, especially those that target gram-positive bacteria, are associated with an increase in the rate of animal growth when they are given in sub-therapeutic amounts in stock feed to food-producing animals. However these drugs also alter the gut flora of exposed animals so bacteria are present that are resistant to the antibiotic used.

Scientific data strongly suggest that avoparcin use as a growth promoter in animals contributes to an increased pool of vancomycin-resistant enterococci (VRE). VRE cause serious infections mostly among immunocompromised patients in hospitals. There are also concerns that the genes that cause resistance to vancomycin may spread from *enterococci* to other bacteria such as *Staphylococcus aureus*, for which vancomycin is one of the drugs of last resort, leaving few or no treatment options.

Antibiotic-resistant bacteria in food animals

Bacteria and resistance to critically important antibiotics associated with food animals include *Escherichia coli* and *Salmonella spp* resistant to 3rd and 4th generation cephalosporins and to fluoroquinolones; *Campylobacter spp* resistant to macrolides and fluoroquinolones; *Staphylococcus aureus* resistant to all beta-lactam-type drugs (ie MRSA); *enterococci* resistant to vancomycin (VRE).

The use of fluoroquinolones (egenrofloxacin) in food animals resulted in the development of ciprofloxacin-resistant *Salmonella*, *Campylobacter* and *E.coli*.

An increasing number of studies indicate that a major proportion of resistant *E.coli* that cause extra-bowel infections in humans may have originated in food animals especially poultry.

Since 2003, a new variant of MRSA has emerged and spread among food animals, primarily in pigs, in many countries. This is already a problem for the control of MRSA in some countries and the prevalence appears to be increasing.

According to WHO, inadequate understanding about and training on appropriate usage guidelines and the effects of inappropriate antibiotic use on resistance are common among farmers, veterinary prescribers and dispensers.

Antimicrobial use in livestock in Malaysia

According to the National Pharmaceutical Control Bureau (NPCB) of the Ministry of Health, Malaysia, there are currently 97 different antimicrobials registered for use. Most of these registered drugs are used in poultry and pig farms, less in cattle and goat farms.

According to the National Pharmaceutical Control Bureau (NPCB) of the Ministry of Health, Malaysia, there are currently 97 different antimicrobials registered for use - mostly in poultry and pig farms, less in cattle and goat farms.

Some of the drugs fall under WHO's criteria of Critically Important Antimicrobials for human health; their use needs to be restricted in the veterinary sector. More than half of the antibiotics registered with the Ministry of Health for food animals are not recommended for veterinary use by the WHO.

According to the Department of Veterinary Services (DVS), in Malaysia monitoring of veterinary drug residues/antimicrobials in food of animal origin is based on EEC Directive 1990 and on the capability of the laboratory to conduct the required tests. The Department also states that monitoring of veterinary drug residues in animal feed in Malaysia would be

implemented in 2013, in keeping with requirements of the Animal Feed Act 2009.

It appears that the Government of Malaysia has either not kept up with the times or is unaware of the fact that the European Union had instituted a ban on the use of antibiotics as growth promoters in animal feeds in January 2006.

The certification scheme of the Department of Veterinary Services

The DVS is a gazetted agency under the Ministry of Agriculture Malaysia. The DVS oversees certification programs, inspections, accreditation and implementation of legislation to support the food safety and quality management system in the country. In 2003, the DVS introduced the Livestock Farm Practices Scheme (SALT) on Good Animal Husbandry Practices (GAHP). SALT aims to ensure that farms practising GAHP produce safe and wholesome food of good quality, in sustainable and environmentally friendly conditions. SALT-compliant farms receive a certificate and logo. SALT certification is awarded to farms that meet the criteria of GAHP, animal health management, bio-security, good infrastructure and prudent use of drugs. The certification scheme covers all types of livestock: beef cattle, dairy cattle, broiler chicken, layer chicken, breeder chicken, deer, goat, sheep and pig.

In 2012, the DVS carried out a preliminary study of antimicrobial resistance in food-producing animals and foods.

Livestock (chicken): Thirty-eight isolates of different species of *Salmonella* were taken from chicken cloacal swabs for antimicrobial susceptibility testing. These cloacal swabs were from a SALT supervised and certified farm located in central Malaysia. The study found 13.5% tetracycline-resistant *Salmonella*, 5.4% Polymixin B and Erythromycin-resistant *Salmonella* and 2.7% Chloramphenicol, Penicillin G and Trimethoprim-resistant *Salmonella*.

Food samples: Forty-three isolates of different species of *Salmonella* was tested from food samples such as beef, mutton and chicken. About 62.8% of *Salmonella* was isolated from imported products (44.2% beef and 18.6% chicken).

It is clear from this preliminary DVS study that there are problems with the SALT certification scheme. More than half of the domestic chickens harvested from the SALT certified farm in this study were found to be resistant to ampicillin, sulphonamide and tetracycline. The situation was even worse with imported chicken: the study found that 87.5% of bacteria were ampicillin-resistant, 75% were nalidixic acid-resistant and 50% were streptomycin/sulphonamide-resistant.

Effects on human health of antibiotics use in food animals

In Malaysia multidrug-resistant strains of *Listeria monocytogenes* were found in frozen burger patties taken from supermarkets and other retail shops; *L. monocytogenes* commonly found in raw foods, can cause listeriosis, common symptoms of which range from gastrointestinal upset to headaches, fever and in severe cases, brain infection and/or blood poisoning.

The study examined the susceptibility of *L. monocytogenes* isolated from raw beef, chicken and vegetarian patties to 11 different antibiotics. Thirteen out of 41 bacteria samples or isolates were not resistant to any of the antibiotics, while 28 were resistant to at least one and 19 were resistant to at least two antibiotics. Tetracycline followed by erythromycin resistance were the most common forms of resistance.

Antibiotic resistance in Malaysian hospitals

The Institute for Medical Research (IMR) data collected from 37 hospitals throughout Malaysia for the National Surveillance of Antibiotic Resistance for 2012 found significant increase in resistance of *Escheria coli* to 3rd and 4th generation cephalosporins, ciprofloxacin, ampicillin and ampicillin/sulbactam, gentamicin and piperacillin/tazobactam.

Salmonella showed a slight increase in resistance rates towards cephalosporins, ie ceftazidime and ceftriaxone. In the gram-positive cocci category the overall rate of MRSA was 17.3% although the rate in hospitals varied from 2.3% to 25.8%.

Clearly the increase in antibiotic resistant infections in Malaysian hospitals has multiple causes such as in inappropriate use of antimicrobial medicines, including animal husbandry, poor infection prevention and control practices, and insufficient diagnostic, prevention and therapeutic tools. Underlying factors that accelerate the emergence and spread of antimicrobial resistance include the lack of a comprehensive and coordinated response as well as weak or absent resistance surveillance and monitoring systems.

European regulations on antibiotics in animal feeds

On January 1, 2006 an EU-wide ban on the use of antibiotics as growth promoters took effect. The ban was the final step in the phasing out of antibiotics used for non-medicinal purposes.

After 2013, medical substances in animal feeds in the EC will be limited to therapeutic use by veterinary prescription only.

Why the EU banned antibiotics as growth promoters in animal feeds

The goal of the EU and country-specific bans on non-essential antibiotic use in food animal production is to reduce the pool of resistance genes in farm animals and other non-human settings. Although a resistance monitoring system was not in place in 1986 when the first European ban took effect in Sweden, efforts to educate farmers and a system for monitoring antimicrobial use were in place. After the ban, antimicrobial consumption fell without a loss in meat production.

In Denmark, DANMAP data demonstrate that the same ban on non-essential antibiotic use in food animal production is working without major consequences for animal health.

Dutch efforts on establishing a monitoring system differ. Dutch officials promulgated regulations to limit antibiotic usage in animal production but without a plan to implement or enforce them. When the Netherlands experienced high levels of antibiotic resistance in food animals following massive use of these agents, the government intervened by mandating a 50% reduction in antibiotic usage in the next three years through defined daily dosages and transparency in prescriptions.

The EU ban on antimicrobials as growth promoters was based on direct evidence from several studies that established three important principles:

- Low-dose, nontherapeutic use of antibiotics selects for resistance to those antibiotics
- Resistance to antibiotics used in humans is determined by the same mechanism as those used in animals.
- Resistance genes disseminate via the food chain into the intestinal flora of humans.

Effects of the ban

The EC's main reason for instituting a ban on the use of antibiotics as growth promoters was to deflect the risk of transferring antibiotic resistance genes to humans.

Available data suggest that the growth-promoter ban has driven an increase in infections and therefore a substantial increase in the use of therapeutic antibiotics for food animals in Europe, but the ban also has reduced overall antibiotic use in animals. Reports show that in Sweden, as a result of the ban and a focus on disease prevention and correct use of antimicrobials,

the total use of antibacterial drugs to animals decreased by approximately 55% in the period 1986 - 1999, and a relatively low prevalence of antimicrobial resistance has been maintained.

According to WHO, under good production conditions, it is possible to reach good and competitive production results for the rearing of poultry without the continuous use of antibiotics in feeds.

The ban on antibiotics in animal feeds will have consequences in the international trade of poultry meat because the EU only imports foods obtained from animals that were not fed with antibiotics in application of the precautionary principle allowed by the World Trade Organization.

Conclusion

It is established that antimicrobial resistance is influenced by both human and non-human antimicrobial usage. It is also acknowledged that antimicrobial resistance is a global public health problem; the global health community is already beginning to speak of a post-antibiotic era. The Ontario Medical Association in Canada report recommends the setting up of a system to track who is buying antibiotics in the farming industry and how much is being bought; the setting up of an independent body to develop and maintain best antibiotic use guidelines that Ontario doctors can use to guide their practice when confronted with resistant bacteria and less familiar antibiotics; instituting a veterinary prescription-only standard of antibiotic access for livestock and closing the loop which allows farmers to import antibiotics for own use, and amending the Food and Drugs Act.

The state of antimicrobial resistance in Malaysia is not known and results of existing research in this area have not been made public.

There are clear indications that some SALT certified farms are unable to meet Good Animal Husbandry Practices. The fact that imported meat products have shown higher percentages of resistant strains of *Salmonella* points to lapses in monitoring and enforcement.

Proposals

In response to the serious global and national AMR problem, the Consumers' Association of Penang (CAP) developed a series of proposals covering development of legislation and monitoring and activities for the Ministries of Health and Agriculture.

Feature: Vanuatu - The costs and affordability of drug treatments for type 2 diabetes and hypertension

Ian Anderson, Amanda Sanburg, Howard Aru, Len Tarivonda, Susan Ivatts, Rufina Latu, Jacob Kool.

The complete article including references is available here:

http://www.haiasiapacific.org/?page_id=176

The costs and affordability of drug treatments for type 2 diabetes and hypertension in Vanuatu

The setting

Vanuatu is an island nation located in the South Pacific Ocean. The archipelago, of volcanic origin, is some 1,750 kilometres east of northern Australia. With a land mass of 12,190 square kilometers, the population of Vanuatu was recorded as 234,023 at the November 2009 census. There was a 2.3% population growth rate over the 10 years between census counts. The population is dispersed across 6 island provinces with 80 islands: the majority of the population is geographically isolated. Although the urban population is increasing, 75% of people live in rural areas. However, urban migration is increasing at an alarming rate, particularly from rural islands as people seek employment or education. Most of the population are employed in subsistence agriculture, the rest being in government departments, private companies and other employment sectors.

Disease patterns in Vanuatu are changing. In the past the main causes of illness and death were preventable or treatable conditions resulting from poor access to health services. The pattern included problems such as: acute respiratory infection, pneumonia, gastrointestinal diseases, skin infections, parasitic infestation, and complications associated with pregnancy and birth. Increasingly, health issues now are related to lifestyle. Rural to urban migration is causing overcrowding in urban areas, especially Port Vila, and housing is often of poor quality. Water and sanitation are inadequate in some urban settlements. Urban living is too often associated with poor nutrition, increased consumption of alcohol, drug abuse and unprotected sexual activity and there are increases in non-communicable diseases including diabetes, hypertension and heart disease as well as STIs. Since 2005, NCDs have been among the leading causes of mortality.⁴

Abstract

Non-communicable diseases (NCDs), including diabetes and hypertension, pose increasingly significant health, policy and financing challenges in Vanuatu, a lower middle income Pacific Island country. Pharmaceutical costs to Government are becoming unsustainable. We show how pharmaceutical cost to

Government rise in large, step-wise, patterns as diabetes or hypertension progressively become more severe.

For diabetes, pharmaceutical costs to Government increased more than four-fold from US\$5.59 per patient per year (pppy) to US\$24.55 pppy in Vanuatu in late 2012 as a person moves from regular testing of blood glucose levels to first stage oral medication. Pharmaceutical costs increased again to US\$367 pppy when insulin and other associated drugs are required. For hypertension, pharmaceutical costs to Government increased more than twelve times as the patient advances from first line drugs to additional drug therapy (US\$1.38 pppy to US\$17.58 pppy), eventually rising to US\$75 pppy if additional drugs are required.

Progression of diabetes and hypertension to more advanced stages squeezes an already tight Government health budget. One patient requiring insulin absorbs the equivalent drug allocation of 76.4 other citizens. Only 1.31% of the total population could be treated with insulin, or 5.3% treated with the full regime of anti-hypertensive drugs, before the total Government drug budget for the country would be fully spent. Yet the latest estimates suggest a diabetes prevalence of 22% of those aged 20 to 79 years in Vanuatu.

Primary and secondary prevention of diabetes and hypertension is therefore a particularly important policy priority. Every person who adopted a healthy lifestyle and was able to avoid diabetes or keep it under control would avert direct drug costs to Government of up to US\$367 per person per year. Those able to avoid or control hypertension through adopting healthy lifestyles would avert costs to Government for drugs of up to US\$75 per person per year: the equivalent of what the Government currently spends on average on 18 other citizens.

Introduction: diabetes and hypertension as development issues

Non-communicable diseases(NCDs), including diabetes and hypertension, are increasingly being recognised as development issues. The World Health Organization estimates that two thirds of global deaths in 2008 were caused by NCDs, more than all other causes combined. Around 80% of these deaths occurred in low and middle income countries. NCDs also account for half of all global disability.

⁴http://www.wpro.who.int/health_services/service_delivery_profile_vanuatu.pdf?ua=1

Vanuatu faces several health challenges

Vanuatu is a relatively small (population 249,528) lower-middle income (GNI per capita of \$US 2750) country ranked 125 out of 187 countries in the United Nations Human Development Index for 2011. Vanuatu faces a double burden of disease: NCDs now contribute to 70% of all deaths, while maternal, newborn and nutritional disorders contribute a further 25%. NCDs now contribute over half (56%) of years of life lost, whilst communicable diseases still contribute over one third (35%). Reports from UNICEF state that nearly 7 per cent of all children in Vanuatu are severely stunted and 20 per cent moderately stunted.

Diabetes and hypertension: growing health challenges in Vanuatu

Diabetes was reported as the sixth known cause of death in 2011 and the third highest NCD when 294 new cases of diabetes were reported. There is no formal diabetes register in Vanuatu at present. However, based on usage data from the Vanuatu Central Medical Store, approximately 62 people are currently being treated with insulin. Limited capacity for vigorous, nation-wide, screening for early detection of diabetes is a major cause for underestimation. Latest estimates suggest a prevalence rate for diabetes of 22% for those aged 20 – 79 in Vanuatu. Hypertension is also a challenge. A recent WHO supported NCD STEPS survey⁵ found that approximately 30.8% of males and 26.7% of females of the 4671 surveyed adults had raised blood pressure. Around 95% of males and females of that sample were found to have raised blood pressure but were not currently on medication.

WHO estimates that rates of mean fasting blood glucose for women rose from 4.6 mmol/l in 1980 to 5.3 mmol/l in 2008, and from 5.2 to 5.4 for males over the same period. The NCD STEPS survey found that almost one in five adults had impaired fasting blood glucose, a risk factor for Type 2 diabetes. More than one fifth (22 %) of adults of working age (25 – 64 years) have three or more risk factors for acquiring any NCD. Only around 10% of adult men (7.5% - 11.9%) and 5% of adult women (3.6%-8.5%) did not demonstrate signs of any of the major NCD risk factors.

Demographic pressures will add to these risks, and the cost burdens to Government. Vanuatu currently has a youthful age structure, with a median age of 20.5 years. However 35% of the population are also aged between 25 and 59 years. Ageing of the population will therefore see an increase in heart, vascular and diabetes related deaths and disability in future years unless strong preventive measures are taken. Importantly, the current relatively youthful demographic structure does not

necessarily translate into a capacity to finance public health care costs; only 23,584 people contributed to the National Provident Fund in 2010, which the Ministry of Finance sees as a proxy for the size of the formal workforce. Even if the size of the formal economy increases, there is no income tax in Vanuatu to generate revenue for Government, including an increasingly over-stretched public health system.

The study

We sought to estimate the pharmaceutical cost to Government of treating Type 2 diabetes and hypertensive patients in Vanuatu during late 2012. The objective of the study was to estimate how the financial cost to the Government's pharmaceutical budget increased as the disease progressed, and then place those estimates in the context of Government health expenditure and overall affordability.

The unit of analysis was the direct pharmaceutical drug cost to Government. Data limitations did not allow the analysis to extend to other direct medical costs, including doctors' and nurses' time, other medical equipment used including syringes and dressings, diagnostic tests including Xrays, patient referrals, surgery or other related treatment arising from medical complications or administrative overheads. Data and time limitations did not permit analysis of direct (out of pocket) or indirect (foregone income) costs to individuals or their carers.

We used Vanuatu Government Standard Treatment Guidelines for treating a patient with Type 2 diabetes or hypertension including recommended generic brand and dosage of drug throughout the progression of the disease.

We recognise that for many patients, diabetes and hypertension coexist as co-morbidities. However for ease of exposition we first show how pharmaceutical cost rises for diabetes as the disease worsens, and then separately show how costs increase for hypertension. We used current prices in October 2012 from the Government owned Central Medical Stores as the source of pricing and cost to Government for drugs.

Results

In the case of diabetes, pharmaceutical costs to Government are initially low, but then rise in a step wise fashion. Glucose testing strips cost the Government US\$5.59 per patient per year at the initial testing stage. If advice on lifestyle and diet changes are not successful, oral medication in the form of metformin tablets are prescribed. The cost to Government of one 500mg Metformin tablet to help control blood sugar levels is US\$0.01 per tablet. As blood glucose testing strips are still used on a monthly basis, total direct pharmaceutical costs rise to US\$24.55 per patient per year. If the diet

⁵www.who.int/chp/steps/Vanuatu_STEPS_Report_2013.pdf

and metformin are insufficient to control the diabetes, a second oral medicine is added, glibenclamide. Dosage commences at 5mg daily but can rise to a maximum of 10mg twice a day. Adding in the additional costs of US\$8.10 per patient per year for glibenclamide increases the total drug cost to the Government of US\$32.65 per patient per year. At this stage blood glucose testing may also increase with associated costs dependent on frequency of testing.

If the disease progresses further and insulin is required the costs rise dramatically. The drug cost of insulin alone adds a further US\$262 per patient per year at a conservative dose of 40 Units daily. Dosage of 1 g metformin twice daily would continue provided renal function remains adequate. Glibenclamide would be discontinued, but the frequency of testing for blood sugar levels would increase from monthly to weekly tests at a health facility. Ideally, blood sugar levels would be tested daily, but the vast majority of patients in Vanuatu cannot afford a glucometer and the testing strips and so rely entirely on public health facilities. In total, this would bring the net cost of drugs to US\$305.78 per patient per year: a more than twelve fold increase from the oral medication stage using metformin. Experience in Vanuatu and elsewhere suggests that when a patient's diabetes has progressed to the point of requiring insulin, there are usually other risk factors present, including high cholesterol and high blood pressure, or the diabetes has triggered medical complications affecting target organs which require additional drug treatment. Most commonly, aspirin, simvastatin and enalapril are added, incurring an additional US\$61.17 to treatment costs each year. This brings the total pharmaceutical drug cost to Government to US\$366.95 per patient per year: a 15 fold increase in costs from oral medication using metformin.

Discussion

The steep increase in costs as the diseases progress has the potential to quickly exhaust the government's pharmaceutical budget. The notional budget allocation for drugs from the Government's Central Medical Store is the equivalent of US\$4 per person per year in Vanuatu. Total expenditure on the pharmaceuticals line item in the budget was US\$1.37 million in 2012, making it the fourth largest item of expenditure within the budget for health that Government appropriated from its own resources. That budget line covered vaccines, laboratory consumables, dental supplies and X rays.

Provision of additional essential drugs for those with diabetes and hypertension does come at a high 'opportunity cost' in terms of the number of people that could be treated with drugs for other diseases in Vanuatu. If an insulin regime is required, this absorbs the equivalent of 76.4 other person's notional drug

allocation rising to 91.7 persons' notional drug allocation if simvastatin and other drugs are employed. Even relatively low costs of drugs can become unaffordable in a low resource setting such as Vanuatu.

Conclusion

Vanuatu faces important health financing challenges. It has a health system heavily dependent on government financing and provision, but with low absolute levels of domestically generated health expenditure of around US\$64 per person per year in 2012. Just two NCDs – diabetes and hypertension – impose large and ultimately unsustainable pressures on the Government's pharmaceutical budget. The high level of current risk factors is a potentially ominous warning of future health and financing challenges – 30% of the adult population in the recent survey have raised blood pressure but 95% of those are not on medication. The chronic, long term nature of NCDs such as diabetes and hypertension carries implications for Vanuatu's health budget and, ultimately, the Government's longer term fiscal strategies.

While more funding is needed in the health sector, the prospects for substantial increases are limited in the immediate future, due to a combination of several factors including relatively modest economic growth in Vanuatu; a narrow tax base (and no income tax); vulnerability to economic and natural disaster shocks; competing Government priorities; and limits to already quite substantial aid funding from development partners.

Focusing the country's limited resources on effective primary and secondary prevention through health promotion, lifestyle change, screening, early detection and treatment and effective clinical management are therefore strategic interventions. These strategies would improve health outcomes for large segments of the population, whilst simultaneously averting - or at least postponing - additional expenditure pressures on an already tightly constrained public budget.

News from the Region

Vanuatu: Introduction to Clinical Pharmacy workshops

Amanda Sanburg, Principal Pharmacist

A four day clinical pharmacy program was developed covering topics relevant to the Pacific Island Countries and limiting drugs to those available on the Vanuatu National Essential Drugs List. The program consisted of some didactic practice-based presentations with extensive interaction, group work and discussions with feedback. Each participant presented a case study for discussion. Non-pharmaceutical topics included team

building discussions and exercises as well as an update on Excel spreadsheets and accessing clinical drug information.

Six of the seven ni-Vanuatu⁶ pharmacists attended the workshop together with two pharmacists from Solomon Islands. One ni-Vanuatu pharmacist works in private practice but felt the material would be useful for her daily practice.

Non-communicable diseases (NCD) and their treatments were the major topics discussed as pharmacists can make a significant positive impact on compliance amongst our NCD patients. Extra focus on subjects such as consideration of lab results and pain management were included.

The release of the updated standard treatment guidelines (Vanuatu Health Worker Manual 2013) helped to facilitate discussions and update everyone on local practices. Each participant received a hard copy of the Health Worker Manual and the presentations on a memory stick.

There was much similarity between practice in the Solomon Islands and Vanuatu. Patient medication records have recently been introduced in the Solomon Islands following a visit by Vanuatu staff in August and these are progressing well apparently. With both countries using the same computer system we can share resources for this program.

Feedback was very positive from both the participants and the facilitators and suggested a role for inclusion of other topics such as antibiotic treatment and cancer chemotherapy. All participants agreed/pledged to commence one small activity into their daily work that was new and related to clinical practice as soon as they returned to their workplaces. Then a second area could be introduced within a month.

Potential for future workshops: The facilitators and participants felt similar workshops could be conducted for other Pacific Island Country pharmacy staff as they are based on the current countries' practices and National Essential Medicines Lists. A workshop will be delivered in Solomon Islands in July 2014.

The Vanuatu Director General of Health and WHO representatives are keen for similar workshops to be held for the doctors and nurses as well so all health staff will be working collaboratively to improve the rational use of medicines.

Support from WHO and AusAID was acknowledged.

The program is available from Amanda Sanburg
<smjsanburg@hotmail.com>

⁶ ni-Vanuatu refers to people from Vanuatu – as in Malaysian from Malaysia.

Australia: We can't have it both ways on homeopathy

Dr Ken Harvey

<http://tinyurl.com/l74k4kg>

Australia's National Health and Medical Research Council (NHMRC) has released a draft information paper titled '*Evidence on the effectiveness of homeopathy for treating health conditions*'.

Homeopathy is a 200-year-old alternative medicine practice. It has two core beliefs that are impossible to reconcile with modern scientific knowledge. The first is that 'like cures like'; that is, substances that cause symptoms in healthy people have the ability to treat people with similar symptoms when administered in minute amounts. Thus, if a patient is complaining of difficulty sleeping, a homeopath might prescribe coffee prepared according to homeopathic principles. The second belief is that serial dilution and shaking the remedy (potentization or dynamization) releases 'immaterial and spiritual powers', thereby making the substance more active.

Homeopaths believe they can treat a broad range of acute and chronic conditions in patients of all ages, including pregnant women, mothers, fathers, babies, young children, teenagers, and the elderly.

However, based on all the evidence considered, the NHMRC concluded that there were no health conditions for which there was reliable evidence that homeopathy was effective.

So why did the NHMRC commission their own report? The NHMRC has been concerned about reports of non-evidence-based complementary or alternative medicine being used in place of evidence-based treatments for patients with serious but treatable conditions.

In addition, the NHMRC was asked to assist the Department of Health with a review of whether natural therapies should continue to receive an Australian Government Rebate on Private Health Insurance - to ensure that taxpayer funds paid through the rebate subsidise only natural therapies that are underpinned by a credible evidence base.

Homeopathy is one of a number of natural therapies for which many private health insurance funds provide ancillary (extras) cover and for which the government provides a 20 to 40 per cent rebate. The ancillary benefits provided by different funds take no account of clinical effectiveness and vary widely with respect to the services covered and the maximum money refunded per service per person per year.

A Natural Therapies Review Advisory Committee has been set up to review the findings of the NHMRC and provide advice to the Government as to which therapies

should continue to attract a rebate. Given the NHMRC report on homeopathy, it seems unlikely that homeopathy will continue to attract a rebate after April 1, 2015 - the date that changes are expected to be implemented.

The NHMRC report is also likely to have impact on other areas. A number of natural therapy colleges offer degrees and diplomas in homeopathy. For example, the Endeavour College of Natural Health notes that its Bachelor of Health Science (Homeopathy) is 'accredited through the Office of Higher Education' and as such, students are entitled to assistance under the Federal Government's schemes open to any Australian citizen undertaking a degree.

If one arm of government states that homeopathy lacks an evidence base, should another accredit homeopathy courses and assist with student fees?

Naturopaths may also have to reconsider their treatment methods, one of which is homeopathy. Indeed, a number of other diagnostic and treatment modalities used by naturopaths are in scope of the government review and are currently being evaluated by the NHMRC including iridology, reflexology and herbalism.

A survey of general practitioner referral and practices showed that nearly two-thirds of GPs reported that they would not refer a patient for homeopathy under any circumstances. In the UK, homeopathic prescriptions have undergone a steep decline over the past 15 years.

Pharmacists who sell homeopathic remedies may also need to have a rethink, especially as the Pharmacy Board Code of Conduct includes (S2.2 h), 'providing treatment options based on the best available information and not influenced by financial gain or incentives'. Companies that produce homeopathic remedies may also have to update their promotional/educational information.

Finally, recognising that patients often don't inform their doctors about the complementary medicines they are taking (and doctors often don't ask) the NHMRC has also produced another useful document, 'Talking with your patients about Complementary Medicine'. While intended as a resource for clinicians, it is equally valuable for patients and the general public.

New Zealand: March against the Trans Pacific Partnership Agreement

HAIAP news has been following progress of the TPPA and its impact on access to medicines. This is the first time that we share news from New Zealand.

Following the WikiLeaks publication of the intellectual property chapter of the proposed TPPA in November

2013, *The New Zealand Herald* reported on February 21 that the high price of the breast cancer drug Herceptin (trastuzumab) in New Zealand could stand unchallenged for up to an extra 12 years under proposals leaked from the Asia-Pacific free-trade talks. The leaked material revealed efforts to extend makers' monopoly rights over their drugs for eight to 12 years. It was interpreted in medical circles as a push to boost legal protections for the makers of original, patented drugs and to reduce access to lower-cost copies of post-patent medicines. New Zealand's state drug-funding system relies heavily on generics.

According to ***Kiwis concerned about the TPPA*** 'The New Zealand government is negotiating an international agreement that could have a huge effect on the lives of ordinary kiwis. It's called the Trans-Pacific Partnership Agreement (TPPA)⁷, and it involves eleven other Asian and Pacific-rim countries, including the United States. If it goes ahead, we risk damage to our innovative economy, our pristine environment, our health, and the ability to shape our own future.

'Because the negotiations are being conducted in secret, what we know about the TPPA comes from leaked documents and detective work. We live in a democracy, which means we have the right to know what is done in our name and to have a say.'

It's Our Future – Kiwis concerned about the TPPA

In Wellington, New Zealand, on 29 March 2014 over 300 people gathered as part of a nation-wide protest against the proposed TPPA and its potential impact on many aspects of life and sovereignty as well as on access to medicines.

Victoria University economist, Geoff Bertram explained

'Economists have put a lot of effort and time over the last century, into making the case that free trade can be a good idea from which all can benefit. And indeed, any of you can go down and buy a flat screen TV and computer and will be familiar with the benefits you can get from free trade. But this deal is not about that. It's being sold with two terms that you should not be taken in by. One is free trade. The other one is partnership. This is not really about partnership. It's not really about free trade.'

'The sort things that are central to the so-called trade part of the agenda are in the area of non-tariff barriers. That is to say, restrictions on the ability of certain companies or agents to gain access to markets on terms that are favourable to them. So things like copyright, intellectual property, regulatory arrangements, and so on are central to the negotiations agenda; and it's important to note that economic theory does not give the sort of support for removing non-tariff barriers.'

⁷<http://www.itsourfuture.org.nz/what-is-the-tppa/>

Eileen Brown, Policy and Program Organiser from the CTU (Council of Trade Unions) spoke to the people:

'The Trans Pacific Partnership contains threats to our health system; to our public services; to public enterprises; and our ability to use government purchasing to develop our economy and to our improve environment; the working conditions of New Zealanders, and our right to make laws and regulations that are in the interests of most New Zealanders.

'...This agreement could have governments preventing employers meeting conditions such as paying a living wage. It could prevent governments requiring suppliers to meet health and safety conditions that are currently being developed to improve our appalling health and safety statistics in New Zealand workplaces. Each of these is a major concern.

'So, too, is the absence of consultation - the secrecy in which negotiations are being held, and the fact that it is being adopted by governments without full public examination and opportunity for comment.'

See more at:

<http://thedailyblog.co.nz/2014/04/01/they-marched-against-the-tpa-and-the-threat-to-our-sovereignty-part-tahi/#sthash.2i8WJ0mX.dpuf>

Pakistan

Prescription Habits in Pakistan - and Vital Need for Qualified Pharmacists

Raza UA, Khurshed T, Irfan M, Abbas M, Irfan UM.
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A study published in the *Pakistan Journal of Medical Sciences* shows that most prescriptions in Pakistan do not meet the international standards. As per research, 90% of prescriptions have expensive brands although economical (less expensive) quality substitutes are available.

Abstract

Objectives: To find out prescription patterns of general practitioners in Peshawar.

Methods: Cross-sectional survey of drug prescriptions was done at six major hospitals and pharmacies of Peshawar between April and May 2011. A total of 1097 prescriptions that included 3640 drugs, were analyzed to assess completeness, average number of drugs, prescription frequency of various drug classes, and number of brands prescribed.

Results: No prescription contained all essential components of a prescription. Legibility was poor in 58.5% prescriptions. Physician's name and registration number were not mentioned in 89% and 98.2% prescriptions respectively. Over 78% prescriptions did not have diagnosis or indication mentioned. Dosage, duration of use, signature of physician and directions for taking drugs were not written in 63.8%, 55.4%, 18.5% and 10.9% of prescriptions respectively. On average each prescription included 3.32 drugs. Most frequently prescribed drug classes included analgesics (61.7%), anti-infective agents (57.2%), multi-vitamins (37.8%) and gastrointestinal drugs (34.4%). We found 206, 130, 105 and 101 different brands of anti-infective agents, gastrointestinal drugs, analgesics and multivitamins being prescribed.

Summary:

Percentage of Branded medicines - 90%
Average of medicines per prescription - 3.32
No duration of medicines use mentioned - 55.4%
Prescription writing unclear - 58.5%
No dose mentioning - 63.8%
No diagnosis mentioned - 78%
No prescriber name - 89%
No registration number of prescriber - 98.2%

Conclusion: We observed a high number of average drugs per prescription mostly using brand names, and over-prescription of analgesics, antimicrobials, multivitamins and anti-ulcer drugs. Quality of written prescriptions was poor in terms of completeness.

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