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HAI AP News

Penang, Malaysia

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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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Message from the Coordinator

On 20 May 2014 at the *ASEAN plus Three Countries* WHA side meeting in Geneva, lessons Learned concerning Universal Health Coverage (UHC) for 2.1 Billion Populations were shared.

In her summing up, WHO's Dr Marie-Paul Kieny asserted that UHC is not a vague concept; it was clearly defined. ASEAN countries have shown that UHC is feasible and that all countries can make measurable progress (see next page). A full report has been prepared by the HAIAP Coordinator <http://tinyurl.com/k2jvany>.

On 24 May 2014, in the face of what is undoubtedly a global health emergency, the Antibiotic Resistance Coalition (ARC), a multi-sectoral collaboration among civil society organizations, called on WHO member states to pass a critical resolution on antimicrobial resistance at the 67th WHA. HAIAP belongs to this Coalition. The HAIAP Coordinator made the intervention on behalf of ARC during the discussion on Resolution EB 134.R13 on 'Combating antimicrobial resistance, including antibiotic resistance' by reading out the ARC statement. (See Page 6 for ARC Declaration on Antibiotic Resistance.)

According to a recent The Lancet editorial, 1603 people have had suspected or confirmed Ebola virus disease in

HAIAP Website questionnaire

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

We have developed a small survey to get HAIAP Members' ideas about the website. We would really appreciate your thoughts and suggestions so we can make the website reflect the philosophy and values of our group as well as possible. Find the questionnaire here: <http://www.haiasiapacific.org/wp-content/uploads/2014/08/HAIAPQuaire.docx>

the four affected countries (Guinea, Sierra Leone, Liberia, and Nigeria) and 887 died between March, 2014, and Aug 1, 2014. The West African outbreak has become the worst in history. Amongst the victims were 60 health workers who lost their lives while helping others. Médecins Sans Frontières (MSF) has described the 6-month outbreak as 'out of control'.

The Lancet's other editorial was unequivocal in stating that its position on any conflict is that it will not support any side whose actions lead to civilian casualties. 'The role of the doctor is to protect, serve, and speak up for life. That, too, is the role of a medical journal,' it stated. The conflict in Gaza has so far claimed 852 civilian lives. The UN's Office for the Coordination of Humanitarian Affairs reports that 252 Palestinian children and 181 Palestinian women have been killed since July 7. 1949 children and 1160 women have been injured. 23 Gazan hospitals or clinics have been damaged. 250 000 Gazans have been displaced from their homes. 1.8 million people have reduced or no access to safe water. Epidemics of lice and scabies have broken out in shelters.

And there you have it. Two major events in the space of the last several months – the first precipitated by a micro-organism, and 'out of human control', the other, completely 'man-made' and within human control. Both extracting an almost equal toll in terms of human casualties. In response to the Ebola outbreak, WHO and the international community launched a US\$100 million plan on August 1 to scale up efforts to stem the outbreak. On August 4, the World Bank announced \$200 million in emergency funding to help the affected countries contain the spread of Ebola, deal with the economic impact of the crisis, and strengthen health systems in west Africa.

The war in Gaza is having far-reaching effects on the survival, health, and wellbeing of Gaza's and Israel's civilian residents. Has there been a similar response by the international community to this conflict? The Gaza situation lies at the intersection between health and politics... and politics must not be allowed to override all else especially when lives are at stake.

While the response to the Ebola outbreak is clearly and urgently needed, the toll in terms of lives lost and lifelong disability in Gaza due to unresolved societal and political differences, also cannot be ignored any longer.

It is time again to reiterate the call for HEALTH FOR ALL NOW!

Shila Kaur, HAIAP Coordinator

Universal Health Coverage for 2.1 Billion Populations: Lessons Learned from ASEAN Plus Three Countries

Shila Kaur, Health Consultant, Third World Network (TWN)
67th World Health Assembly 19 – 24 May 2014, ASEAN plus Three Countries side meeting Tuesday 20 May 2014 Palais des Nations Geneva

Background

ASEAN Plus Three Countries, Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Viet Nam, China, Japan and South Korea are diverse with regard to population size, social and economic conditions as well as health systems. The countries span two regions of WHO ie South East Asia Region (SEAR) and West Pacific Region (WPR) and cover 2.1 billion populations, with vast Universal Health Care (UHC) experiences and different stages of UHC development.

At this side event, the listed panelists shared country experiences on UHC.

Dr Toomas Palu (World Bank) congratulated WHO for its strong leadership of UHC, adding that it had been a privilege to work with Asian countries who had shown a strong commitment to UHC. He indicated that there was clear momentum for international commitment on UHC.

Amongst the lessons learnt in the process were:

- Governments must take responsibility for the poor and near poor for UHC.
- UHC is not just about raising money for health. Expenditure is also important. Services that are provided must prove value for money, as was efficiency.
- Supply side readiness of delivery also mattered. Service delivery was the emerging bottleneck and it was important that this was addressed as it relates to NCD.
- Affordability was a consideration; the Thai and Philippine experiences had demonstrated that it is possible to get UHC and good quality health care at low cost.

In her summing up, WHO's Dr Marie-Paul Kieny reiterated that availability, affordability and good quality were the basis for UHC. She indicated that even the richer countries struggle to meet changing health needs and demands. For example Japan is taking action to provide more community based health care in view of its rapidly aging population.

She asserted that UHC is not a vague concept; it was clearly defined. ASEAN countries had shown that UHC

was feasible and that all countries can make measurable progress.

The full report is available <http://tinyurl.com/k2jvany>

Intellectual Property Issues and access to medicines – the TPPA

UNITAID report: *The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health*
www.unitaid.eu

In March 2014 UNITAID published a 120 page report called *The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health* that was prepared by Kajal Bhardwaj and Cecilia Oh, with support from UNITAID. The authors state that responsibility for the interpretation and use of the material lies with the reader. UNITAID commissioned this report to identify proposed TPPA provisions that are likely to have implications for public health and access to pharmaceutical products.

The report's expressed concerns are particularly pertinent with regard to the negotiation of a Trans-Pacific Partnership Agreement, which has been positioned as a 'model' for the 21st century—implying that the same or similar provisions are likely to appear in future trade agreements, including those involving developing countries. The analysis is largely based on the text of the proposals of the USA that were leaked and made available in the public domain in 2011 and 2012. In November 2013, a more recent text became available (through Wikileaks).

Download the whole report here: <http://tinyurl.com/lmfm52j>

Extracts follow:

Origin and development of the TPPA

The proposed Trans-Pacific Partnership Agreement (TPPA) has complex origins. It was originally a free trade agreement (FTA) between Chile, New Zealand and Singapore and, later, Brunei Darussalam, known as the 'Trans-Pacific Strategic Economic Partnership Agreement'. The negotiations were, however, later expanded to become the TPPA and included other negotiating partners—Australia, Malaysia, Peru, the United States of America (USA) and Viet Nam. More recently, Canada, Japan and Mexico joined. To date, there have been 19 formal rounds of negotiations, the most recent being held in Brunei in August 2013, as well as a number of inter-sessional meetings.

The proposed TPPA goes well beyond traditional trade concerns and includes, among other elements, extensive obligations related to intellectual property and investor protection. The intellectual property obligations proposed for the TPPA exceed the minimum standards

of the multilateral World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Public interest and public health groups, as well as a number of United Nations agencies, have voiced concern over such 'TRIPS-plus' provisions. A dramatic illustration of the direct impact of TRIPS-plus rules captured global attention when, in 2007 and 2008, shipments of generic medicines from India to other developing countries were detained at European ports on allegations of intellectual property infringement.

Aside from the proposed scope and potential impact, the secrecy under which the TPPA negotiations have been conducted has attracted criticism. Negotiating texts that have been leaked to the public domain have caused disquiet regarding the scope and content of the provisions under negotiation.

In addition to TRIPS-plus intellectual property provisions being negotiated as part of the TPPA, there are also serious concerns that proposed provisions related to financing and/or reimbursement of medicines, as well as to investment, will have adverse implications for access to medicines and the protection of public health in general.

Patents

Overall, the USA's TPPA proposal appears to weigh heavily in favour of patent applicants by requiring lower levels of disclosure, lower standards of patentability, no pre-grant opposition proceedings, and multiple opportunities to amend patent applications. The overall impact of these measures is likely to be the granting of a greater number of patents on medicines and medical technologies, including a greater number of weak or 'poor-quality' patents.

Evergreening

By explicitly requiring that new uses, new forms and new methods of use – 'evergreening' –are patentable, the proposal of the USA removes the option for TPPA parties to adopt patentability standards similar to those adopted by Argentina and India. 'Evergreening' effectively allows patent holders, through successive and overlapping patents on new forms of old medicines, to enjoy longer periods of exclusivity on a medicine than the 20-year minimum period prescribed by TRIPS.

Scope of what can be patented (limiting exclusions from patenting)

The USA's TPPA proposal also requires TPPA parties to grant patents on plants and animals. The USA's proposal also requires that patents be granted on surgical and diagnostic methods—which could seriously hamper the provision of treatment by health-care providers and could lead to a situation where doctors

may be prevented from using a method of diagnosing a disease or where payment of a royalty is required for use of a surgical or diagnostic method. The TRIPS Agreement explicitly allows countries to make these exclusions from patenting, but the TPPA proposal of the USA would remove this flexibility.

The report also examines the sections of the TPPA that lower and weaken disclosure standards and tilt patent examination procedures in favour of Patent term extensions which is a straightforward way of delaying generic entry.

Bolar provision are weakened so generic manufacturers' provisional regulatory marketing approval or 'registration' in order to be ready to enter the market will no longer exist; thus creating significant barriers to the rapid entry of generic medicines into export market.

Data exclusivity

Data exclusivity as demanded in the USA's TPPA proposal would require generic manufacturers to conduct their own clinical trials to obtain marketing approval or to wait until a specified exclusivity period is over (five years plus any relevant three-year extension for small-molecule chemical medicines) before a generic product could be approved.

In many respects the USA's TPPA proposals on data exclusivity are not only TRIPS-plus but they also require data exclusivity in excess of previous FTAs concluded by the USA by substantially restricting the ability of governments to limit the anticipated negative impacts of data exclusivity. From a public health perspective, the recommendations of United Nations agencies and human rights institutions have been unanimous in warning developing countries against adopting data exclusivity in the first place.

Patent linkage

Patent linkage is of particular concern in developing countries. Through the system of patent linkage, pharmaceutical companies effectively have another avenue for preventing the launch of generic medicines.

Broad-ranging trademark protection

As well as increasing the term of trademark protection, the USA's proposals appear to expand significantly the scope of trademark protection and may require TPPA countries to provide protection that includes colours *per se*, in addition to sounds, scent and other non-visual marks. Current jurisprudence suggests that trademarks for tablet colour or shape are not registrable since the colour and/or shape of a tablet has an important function because patients often rely on the colour, size and shape of medication for reassurance that they are taking the right pill.

The overall effect of the proposed copyright provisions would be an extension of international obligations relating to the length and scope of copyright protection.

Restrictions on parallel importation

The proposed TPPA provisions on copyright seek to create a new international legal requirement that would limit the ability of countries to apply their chosen regime of exhaustion of intellectual property rights. This is in contrast to Article 6 of the TRIPS Agreement which preserves the freedom of countries to choose their regime of exhaustion in order to allow for parallel importation.

Access to scientific publications and journals

In the public health context, the expansive copyright protection sought under the TPPA could also have an effect on the research and development process in developing countries. Research on new medicines and other innovations in health care may be hampered if access to scientific publications and journals is restricted or curtailed.

Presumptions of validity increase the difficulty in challenging patents and increase the likelihood of poor-quality patents remaining in force .

Several developing countries are attempting through legislation or patent examination guidelines to improve the quality of patents granted, particularly in the field of pharmaceuticals. These measures, coupled with expanded patent opposition provisions, have resulted in low-quality patents on several key medicines being denied or revoked in countries such as India.

Chilling effect on generic producers

Several of the provisions proposed by the USA are likely to have a chilling effect on generic producers. The proposals would empower patent-holding companies to seek information in infringement proceedings regarding the entire supply and distribution chain of a generic company. This information could then be used to harass or intimidate other players in the supply and distribution chain—such as transporters, distributors etc. In addition, the USA is proposing harsh enforcement measures, high damages for infringement and criminal penalties for trademark cases in excess of what is required in the TRIPS Agreement.

Border measures

There is concern that customs officials may not be in the best position to judge whether a trademark is infringed in the context of import, export or transit. Under the USA's TPPA proposal, the application of border

measures for the import, export and transit means that seizures of generic medicines are likely to continue.

Pharmaceutical pricing, financing and reimbursement of medicines

One of the leaked TPPA texts is the annex on 'Transparency and procedural fairness for healthcare technologies'. The text proposed by the USA in the annex would require TPPA signatories to comply with obligations relating to pharmaceutical pricing and reimbursement schemes. The probable effect of these proposals would be to limit countries' policy space to adopt and enforce therapeutic formularies, reimbursement policies and other price-moderating mechanisms within public health systems.

Conclusion and recommendations

The analysis in this report indicates that the TPPA, if adopted, will have major implications for public health and access to medicines. The primary concern is that the implementation of the provisions proposed in the USA's proposals, as they currently stand, will restrict the adoption of policy options for developing countries to ensure that trade or commercial interests do not hinder the protection of health and human development.

With financing threatened by funding cuts, the need for the widest range of options to reduce costs is paramount. Without effective approaches to reduce costs, medicine prices will stand in the way of access not only to HIV and AIDS medicines, but also to medicines for other diseases.

A positive agenda for intellectual property and access to medicines

As an alternative to signing the TPPA and adopting TRIPS-plus provisions that can threaten treatment access for many in developing countries, the negotiating parties may wish to consider the types of measures that would strengthen and further expand the gains made in the effort to increase treatment access. Governments may wish to adopt coherent approaches in which trade and intellectual property policies are formulated in a manner that preserves the ability to provide long-term, affordable and sustainable access to medicines. As an interested stakeholder, UNITAID supports the adoption of a 'positive agenda', wherein governments actively identify and implement policies that can help achieve the goals of trade and economic growth alongside the objectives of ensuring access to needed medicines and the protection of public health. Such a positive agenda might include some of the approaches outlined below.

Public health impact assessments of FTAs

Given the increasing numbers of bilateral and regional trade agreements, there should be a corresponding level of analysis of such FTAs from the economic and public health perspectives. There has been limited analysis aimed at measuring the costs and benefits of introducing intellectual property rights in developing countries, and even less analysis of the impact of specific changes in intellectual property policy in each country. Since some FTAs have been in force for several years, it may now be possible to examine and assess the public health impact of those FTAs that incorporate a number of TRIPS-plus provisions, including measuring the effects of data exclusivity or patent term extensions on access to affordable medicines. First and foremost, credible empirical information provides a basis of evidence to inform policy-makers and strengthen their position in trade negotiations. It can help to identify those areas in which greater flexibility in the negotiation of new intellectual property protection standards may be warranted, or can make the case that new standards may not be desirable at all. Further, in countries that have already adopted TRIPS-plus standards, the evidence can provide an important basis from which to identify complementary policies that can remedy or alleviate the negative impacts of implementation.

Balancing intellectual property rights and competition for public health outcomes

The introduction of generic HIV medicines into the global market created the competition that led to massive price reductions in HIV medicines. Generic competition, particularly from India, persists in reducing prices today, with the prices of first-generation HIV medicines at less than 1% of their 2001 prices. The policy objective is to achieve a balance between intellectual property rights and competition that is appropriate to the domestic context.

Examination of pharmaceutical patents

There is increasing evidence that low standards of patentability and shortcomings in patent examination can lead to the grant of poor-quality patents. Although a small number of new chemical entities are approved annually, the number of pharmaceutical patents applied for and granted is disproportionately large. There is a need to monitor and analyse trends in pharmaceutical patenting in order to respond to growing concerns about the increase in patents that protect relatively minor variants of existing drugs or processes while the number of new molecular entities is small. In these circumstances, the criteria applied to examine and grant pharmaceutical patents are a matter of concern.

A paper by WHO, the International Centre for Trade and Sustainable Development, and the United Nations Conference on Trade and Development reviews the various categories of patent claims for pharmaceutical products from a public health perspective. It proposes a set of general guidelines for the assessment of some common pharmaceutical patent claims, and suggests elements for the development of public-health-sensitive guidelines for the evaluation and review of pharmaceutical patents at national level in developing countries. The use of such guidelines should be encouraged, particularly in developing countries, to prevent the grant of poor-quality patents on pharmaceutical products.



The most recent officials' meeting was held in Ottawa in July 2014. No ministerial meeting occurred on the margin of the meeting in Ottawa and to this time, dates and location for the next officials' meeting have not been confirmed. A Ministerial meeting has not been scheduled at this time.

In New Zealand a national day of action against the TPPA is planned for November 8. It is reported that Barack Obama wants to put something in the public arena in November, and the political leaders of the 12 countries are expected to have a summit around 10-12 November. Other countries are looking to mobilise on that weekend too.¹

Declaration: New Antibiotic Resistance Coalition urges immediate action

In a declaration launched May 22, during the 67th World Health Assembly in Geneva, ReAct and partners in the new Antibiotic Resistance Coalition (ARC), a group of civil society organisations working in human, environmental and agricultural health, urges immediate global action to tackle the rapidly accelerating threat of

¹ <http://tinyurl.com/ku2bjow>

antibiotic resistance. Press release from the Antibiotic Resistance Coalition.

http://www.haiasiapacific.org/?page_id=528 (4th item down)
<http://tinyurl.com/ll4mhqj>

News

Novartis data falsified: Former Novartis employee arrested over valsartan data

Justin McCurry
www.thelancet.com Vol 383 June 21, 2014

A former employee of Novartis Pharma KK, the Japanese subsidiary of Novartis, has been arrested (June 11) on suspicion of falsifying clinical data to overstate the benefits of the Swiss drug manufacturer's hypertension drug valsartan.

Nobuo Shirahashi, aged 63, is accused of passing on falsified data to researchers that suggested that the drug, a popular treatment for high blood pressure in Japan, where it is marketed as Diovan, had secondary medical benefits. The research was later used in advertising campaigns for Diovan in Japan.

Based on data for 3000 patients provided by Shirahashi, researchers at Kyoto concluded that Diovan was the most effective of all the drugs analysed at preventing stroke and angina. Shirahashi, who left the company in May, 2013, allegedly altered charts comparing the frequency of stroke in trial participants who were given Diovan and other hypertension drugs, before submitting the falsified data to the Kyoto researchers.

Novartis Pharma is unlikely to escape scrutiny over its part in the alleged malpractice, with prosecutors expected to seek legal action against the firm for failing to prevent misconduct by its employees. Diovan has enjoyed impressive sales in Japan since it was made available there in 2000. Sales were worth more than JPY 100 billion in 2012, while cumulative sales have reached JPY 1.2 trillion.

Novartis Pharma is still reeling from allegations that it had not disclosed all of the possible side-effects of its leukaemia treatment nilotinib, marketed as Tasigna. The company's troubles deepened when a third-party commission it had set up found that employees might have broken Japan's strict privacy laws by illegally acquiring information about patients involved in clinical trials for Tasigna.

According to Kyodo news sources, Novartis Pharma KK was initially suspected of failing to report 33 cases of side-effects involving Tasigna, including 10 that were deemed severe, to Japan's health and welfare ministry following a clinical study led by Tokyo University. That revelation prompted an investigation into alleged violation of the pharmaceutical affairs law. The firm has

since acknowledged that at least 10 000 cases involving 10 different medicines might have been involved in a safety cover-up dating as far back as 2002.

In April, Novartis Pharma KK responded to the Diovan and Tasigna revelations by replacing its president and two other senior executives. It is also reviewing all doctor-led studies involving the firm since 2011. Several other employees implicated in professional misconduct have been sacked, while funding for collaborative research with universities and other research bodies has been suspended. Two studies on valsartan were retracted last year. The Kyoto Heart Study published in the European Heart Journal in 2009 was retracted in February, 2013. The Jikei Heart Study published in The Lancet in 2007 was retracted in September, 2013

<http://tinyurl.com/ohezrcg>

AIDS 2014, Melbourne

Press release: HIV Cure, HIV Co-Infection and HIV Laws Feature on Day 2 of AIDS 2014

www.aids2014.org

July 21, Melbourne, Australia - AIDS 2014, the 20th International AIDS Conference, officially began Sunday 20 July in Melbourne, Australia, with moving tributes to the six delegates who lost their lives aboard flight MH17.

Representatives of the organisations that lost colleagues – the World Health Organisation, AIDS Fonds, Stop AIDS Now, The Female Health Company, and the Amsterdam Institute for Global Health and Development – joined 11 former, present and future presidents of the International AIDS Society (IAS) and members of the Dutch HIV community on the main stage in front of more than 5,000 delegates from around the world for a moment of remembrance.

'I strongly believe that all of us being here for the next week to discuss, to debate and to learn is indeed what our colleagues who are no longer with us would have wanted,' Prof. Françoise Barré-Sinoussi, International Conference Chair of AIDS 2014 and President of the International AIDS Society told the gathering. 'We will remember their legacy and forever keep them in our hearts.'

Prof. Barré-Sinoussi went on to say: 'The tremendous scale up of HIV programmes has begun to reverse the spread of HIV. According to the new UNAIDS report released a few days ago, nearly 14 million people living with HIV in low and middle-income countries are now being treated. Millions of lives are saved. But this is far from being enough and we still have plenty to do. Let's

show the world that neither brutality nor hatred can stop us. Let's join our forces to build a better future for all.'

In welcoming the gathering to host-country Australia, the local Co-chair of AIDS 2014, Prof. Sharon Lewin, said: 'I am delighted that this week we will hear about some truly ground-breaking advances in new treatments of hepatitis C and tuberculosis, two of the most significant co-infections in people living with HIV. As a scientist, I remain passionate that the search for a vaccine and cure must continue. I sincerely hope that what you learn and see in Melbourne rapidly translates to action, action that contributes to our collaborative and escalating efforts to see the end of HIV.'

At a press conference, Prof. Lewin said the focus of efforts for an HIV cure was currently on developing treatments leading to remission. She said the latest research and findings were significant in that 'they have shown us that we can wake up the virus reservoir and make enough of the virus to leave the cell, making it visible to an immune response.'

Conference activities (Monday 21 July) began with plenary presentations about the latest advances for an HIV cure (Jintanat Ananworanich of Thailand), latest trends in HIV epidemiology (Salim Abdool Karim of South Africa), and how people with HIV are participating in the contemporary global response to HIV (Lydia Mungherera of Uganda).

Also, were two key symposiums: one addressing hepatitis co-infection among people living with HIV; and another looking at the barriers to effective HIV prevention created by the discrimination against key affected populations and criminalisation of HIV transmission, exposure and non-disclosure in some parts of the world.

A joint press conference on the role police are playing in HIV prevention was held by senior representatives of police and law enforcement agencies from Seattle Police Department, Vietnam, Ghana and the UN.

AIDS 2014 Global Village, is an international showcase of community related HIV programmes and activities.

Special sessions included symposiums on viral latency and reservoirs, tuberculosis co-infection among people living with HIV, the future of science in the global HIV response and galvanizing a movement for ending the AIDS epidemic by 2030.



STEPPING UP THE PACE

Feature: Tobacco Control in the region

Australia: Treasury figures show fall in tobacco sales despite counter industry claims

Mon 23 Jun 2014 – Australian Broadcasting Corporation (ABC) <http://tinyurl.com/o8bqh2z>

In June 2014, *The Australian* [newspaper] said tobacco industry statistics showed the compulsory plain packaging of tobacco products for sale in Australia had backfired and tobacco consumption has actually grown during the first full year of the new laws. But the Federal Treasury has released figures that contradict that. The Department of Treasury keeps records on the sales of cigarettes for taxation purposes, but has never before made the information publicly available.

The tobacco industry cited research from the data analysis firm *Infoview*. But the data behind the *Infoview* research has not been released, and the company will not reveal who commissioned it.

The Treasury data reveals that 3.4 per cent fewer cigarettes were sold last year than 2012.

Professor Simon Chapman, from the School of Public Health, University of Sydney, says the Government decided to introduce plain packaging because it was very obvious from internal documents of the tobacco industry and from lots of literature in the tobacco trade press that the industry regarded packaging as a leading form of tobacco advertising. There was no ambiguity about this. And because tobacco advertising is banned in Australia and has been since 1992, the Government was really just trying to finish the job.

It is reported that the Treasury data is consistent with national data from the Australian Bureau of Statistics. It shows total consumption of tobacco and cigarettes for the March quarter of 2014 at the lowest level since records began in 1959. Simon Chapman explained that sales fell in the year after the introduction of plain packaging by 5 per cent, and if adjusted for population increase, it is really a remarkable fall.

Any amount of denial of that really needs to be seen for what it is. It's just motivated talk by the tobacco industry who are very, very distressed about it all, and do not want to see it happen in other countries.

Anne Jones, who is the technical advisor on tobacco control for the International Union Against Tuberculosis and Lung Disease, says the fact that the data from *Infoview* has not been released for public scrutiny speaks for itself: 'It's really outrageous. This is really a tobacco industry inspired tactic to repeat these sorts of false claims in overseas media in the countries that are directly considering whether to go along the Australian route and introduce plain packaging for their own populations.'



WHO: countries across the Pacific are considering following in Australia's footsteps and introducing plain packaging of cigarettes.

Mon 30 Jun 2014
<http://tinyurl.com/pqvomcu>

The WHO is set to join governments across the region in a major drive to make the Pacific tobacco free within 10 years. The WHO Pacific coordinator of non-communicable diseases, Dr Temo Waqanivalu, says the project will be launched in Honiara in two weeks and plain packaging is among the tactics being considered.

'They've done the graphic warnings on the packets so the next step after that is to actually move towards plain packaging.'

Dr Waqanivalu says increasing the tax on cigarettes and cracking down on the tobacco black market are the keys to reduce smoking. 'If those two happen, well then especially the young smokers, the youth, they're the first ones who actually going to begin to quit,' he said.

'Economic ministers should really think seriously about assisting... part of that is facilitating increased taxation on tobacco cigarettes.'

The WHO says Cook Islands has been a leader on reducing smoking, having significantly increased the price of cigarettes with plans for further rises.

'Cook Islands is really exemplary of what we are trying to promote across the Pacific and they've done exceptionally well.'

But Dr Waqanivalu says the tobacco industry is fighting back. He said. 'We see them influencing ministries of

health.' He also said the WHO's plans also involve setting up services to help people quit.

Fiji: public smoking ban comes into force

<http://tinyurl.com/ngs535g>

Wed 3 Jul 2013

Fiji's ban on smoking in public places came into force in July.

The revisions to the previous year's Tobacco Control Regulation Act see major public areas like nightclubs, restaurants and retail outlets designated as smoke-free zones.

Smokers face a fine of up to \$US105 if they light a cigarette in a public place, and owners face a fine of up to \$525 if they allow smoking at their business. Enforcement officers have the power to give on the spot fines.

Fiji's health ministry says concerns about the impacts of smoking led to the country's revised tobacco regulations. The new regulations were preceded by a public awareness program over the past three months.

Head of the Tobacco Control Unit at the Health Ministry of Fiji, Aminiasi Tavui, has told Radio Australia's Pacific Beat program the public for the most part supports the new regulations. 'We've been receiving positive feedback from the public,' he said.

Solomon Islands to crack down on tobacco sales

<http://tinyurl.com/qgtoosn>

Thu 18 Apr 2013

Under changes being considered by Cabinet, it would be illegal to sell tobacco products within 200 metres of schools and restaurants. Smoking in some public places, including schools, restaurants and government offices, will be also be banned.

Dr Lester Ross, Permanent Secretary for the Ministry of Health, told Radio Australia there'll also be big warnings on cigarette packets. 'I understand that some countries in the Pacific have 30 per cent of the packet on the front and 70 per cent on the back,' he said. 'I think our taskforce at the moment are aiming to go for the largest percentage of the packet in the Pacific.'

Chinese traders in Honiara (Solomon Islands capital) fear they'll be unfairly targeted because a lot of their shops are located in the restaurant precinct in the city's Chinatown. 'It seems that if anyone's going to be prosecuted or caught for doing the wrong thing, it will most likely be from those shops because they're not going to be going anywhere, therefore they're an easy target for the enforcement.'

China

Thu 9 Jan 2014

<http://tinyurl.com/pb26ox6>

China, home to some 300 million smokers, is the world's largest consumer of tobacco, and smoking is a ubiquitous part of social life, particularly for men.

Tougher regulation of smoking is a priority this year, officials from the National Health and Family Planning Commission said, adding that the agency was pushing lawmakers to toughen laws on tobacco use. The drumbeat to reduce tobacco use has grown steadily louder in the past few years, but experts say China's powerful tobacco industry, which has resisted raising cigarette prices and use of health warnings on cigarette packs, has been a tough opponent.

'Compared to the damage to health that smoking causes, tobacco's economic benefits are trivial,' Mao Qun'an, a spokesman for the commission, told a news conference in January.

Several cities have banned smoking in public places, but enforcement has been lax. Beijing pledged in 2008 to prohibit smoking in most public venues, including government offices, but no-smoking signs are frequently ignored.

Steps recommended by the commission range from intensifying education on the dangers of tobacco to banning smoking in schools and hospitals.

An official in the tobacco control office of the Chinese Centre for Disease Control and Prevention said in December that lawmakers would consider the nationwide ban on smoking in public places this year. The commission's statement follows a government circular urging Communist Party cadres and government officials not to light up in schools, workplaces, stadiums, and on public transport, among other places, so as to set a positive example.

Indonesia

Fri 27 Jun 2014

<http://tinyurl.com/ovstlod>

Indonesia will continue its attempts to implement new health warning regulations for cigarette packaging, despite most tobacco companies failing to comply. A law requiring manufacturers to display graphic health warnings on cigarette packs came into force in June 2014. Despite being given 18 months notice, only a handful of brands were ready. Indonesia's Health Minister Nafsiah Mboi says the tobacco industry has always tried to delay government regulation.

A government survey last year showed that 36 per cent of the population aged above 15 years smoke, with average consumption of 12 cigarettes a day.

'The aim is to provide the community with honest and accurate information in the form of pictures so they can decide (whether or not to smoke),' Health Minister Nafsiah Mboi said.

An anti-tobacco group however said compliance has been low so far. The National Commission on Tobacco Control said only six out of more than 3,800 cigarette products have the graphic warnings displayed. 'The government should enforce the law, there should be no tolerance even for the richest businessmen who violated the law,' commission member Hakim Sorimuda Pohan said.

Some of the richest businessmen in South East Asia's biggest economy are owners of tobacco firms and Indonesia has not ratified the framework convention on tobacco control.

A pack of cigarettes in Indonesia costs much less than in many other countries, at a little more than \$1.

Sri Lanka: Pictorial warnings on cigarette packets from Jan. 31, 2015

The Island July 14 2014

By Chitra Weeraratne

Old stocks of packets of cigarettes without pictorial warnings on 50-60% of their display area will not be available after January 31, 2015. The aforesaid agreement was arrived at before the Supreme Court by the petitioner, the Ceylon Tobacco Company and the respondents, the Minister of Health, the National Authority on Tobacco and Alcohol and the Attorney General.

The CTC agreed that it would not pursue, before any forum in Sri Lanka or overseas, any petitions of that nature challenging the ministerial regulations in respect of pictorial health warnings. In view of the aforesaid agreement between the parties, the fundamental rights violation application and the Appeal filed by the CTC were withdrawn and dismissed.

The CTC has complained to the Supreme Court that the ministerial regulation which called for pictorial health warnings does not give the CTC adequate time to dispose of the old stocks of cigarette worth about Rs. 1.9 billion. The Court of Appeal on May 27, 2014 ordered that packets of tobacco should carry pictorial health warnings covering 50 to 60% of their display area. A ministerial regulation issued soon after said that the order should be implemented by July 1, 2014. Later, the CTC filed a fundamental rights violation application in the Supreme Court and had the time extended to December 31, 2014.

Fighting the myths spread by the tobacco industry*

The tobacco industry tries stalling discussions over tax increases in many countries by using arguments that are untrue or by exaggerating the expected impact. It is time to break down those myths to shed light on the real impact of tobacco tax increases.

Myth: Tobacco tax increases will reduce tax revenue (because consumption goes down).

NO

Tax revenue actually increases (because reduction in sales is less than proportionate to the price increase). As demonstrated in Egypt and the Philippines, an increase in tobacco taxes does increase government revenues.

Myth: Tobacco taxes will reduce economic activity.

NO

Spending on tobacco will be replaced by spending on other consumer products and services.

Myth: Taxes create a financial burden on poor smokers since they spend a larger share of their income on tobacco products.

NOT EXACTLY

Because people on lower incomes are more sensitive to price increases, they will alter their consumption behaviour by either quitting or reducing the level of tobacco consumption more than higher-income consumers. Consequently, higher taxes will help reduce their own personal spending on tobacco as well as improve their health.

Myth: Tobacco tax and price differences between countries create an incentive for illicit trade in tobacco products.

NOT EXACTLY

There are other more important factors that encourage illicit trade, such as weak governance/lack of high-level commitment, weak customs and excise administration, corruption and complicity of cigarette manufacturers.

CONSEQUENTLY

Tax increases should be introduced together with actions to strengthen tax administration (such as simplifying taxation, monitoring the tobacco products market and strengthening customs and police) to reduce incentives for tax evasion by manufacturers and criminal organizations

*http://apps.who.int/iris/bitstream/10665/112841/1/WHO_NM_H_PND_14.2_eng.pdf?ua=1

News from the Region

Malaysia: No end to tug-of-war between doctors and pharmacists

Doctors are still dispensing in Malaysia

by Jaqueline P'ng, June 7, 2014

<http://tinyurl.com/qg7oy4s>

The debate on whether our doctors should hand over their power to dispense medicine has moved in 'endless circles', said Lim Heng Moh, a former vice-president of the Malaysian Pharmaceutical Society (MPS).

'These issues of consumers' convenience, doctors complaining of revenue loss and why should they give up their right to continue as it is, have been discussed. And it has moved in endless circles,' he said.

On hindsight, said Lim, the problems of irrational usage of drugs, wrongful dispensing, polypharmacy and distribution abuses of controlled items are rampant in the current healthcare system, in which doctors are both the prescribers and dispensers of medicine. 'Why, at this juncture, when there are enough pharmacists and pharmacies, do we allow ourselves to fall into this trap?' he asked. He noted that the Malaysia's prevailing practice of dispensing by doctors is a legacy of the British Colonial Administration. Doctors were allowed to dispense on the basis that it is a 'service only'.

The argument was already settled back in 1980s when the former Deputy Health Minister Datuk K Pathmanaban favoured dispensing separation

'Retiring medical specialists are better off concentrating on their rightful role of consultation, without the burden that comes with a dispensing role,' Dr Lim said and added that doctors who have been pushing products to patients and wholesaling would also be at the losing end when stripped of their dispensing right while doctors who concentrate on healing patients will gain because patients will see more benefits in their services and appreciate them more.

The importance of teamwork

Gan Ber Zin, a former chief pharmacist at a government hospital, said doctors and pharmacists in public hospitals work as a team to weed out errors during the dispensing process. 'Such teamwork had worked very well in government healthcare facilities. Why should those who choose to seek treatment from private facilities, be denied the maximum benefits which can be derived with more comprehensive teamwork by all the healthcare providers?' he said.

Gan also pointed out that 'Doctors are giving the public the impression that pharmacists are not allowed to prescribe. However, many medications including the

various cough and cold remedies, creams and ointments, eye drops, medicines for diabetes, asthma and painkillers are under Group C classifications, and not permitted for sale by general retailers, but may be supplied by pharmacists - without doctors' prescriptions', said Gan.

Discriminatory pricing

Drug companies are selling their products at cheaper rates to doctors than to pharmacies, which is a form of inducement to encourage private clinics to sell their products. Such a price discrimination policy is depriving pharmacists from doing business in an open market, as well as the public from more competitive medicine prices. [See HAIAP News HAIAPNews4Dec2012.pdf 'Challenges for Community Pharmacy' Page 9.]

'Self-paying private patients without medical coverage prefer to get a prescription and buy the dispensed drugs from the pharmacy, as they have a choice to hop from shop to shop in an open market for the best price,' said Gan.

Gan suggested that a public forum be held to create awareness on what people can stand to gain from DS.

Consumer Association of Penang Viewpoint: Separation of dispensing rights

Start in regional towns first

<http://tinyurl.com/jw5brok>

Previously, when doctors were accorded the legal right to dispense, there were very few pharmacists and pharmacies in the country. However, this is no longer the case.

There are already more than 6,000 pharmacists registered with Malaysian Pharmacy Board. More than 500 new pharmacy graduates are added to the nation each year. The issue of a shortage of pharmacists does not arise.

A pilot scheme on dispensing separation can be started in the bigger towns such as Kuala Lumpur, Penang and Johor Bahru. Following this initial exercise, pharmacists will be encouraged to set up even more pharmacies in major towns as well as expand their services to the rural areas in anticipation of the expansion of dispensing rights out of the major towns. Exemptions can always be given to the remote areas that have none or very limited access to pharmacies until the situation improves.

Some have pointed out that pharmacies are not open 24 hours a day, unlike clinics. However, there are very few of these 24-hour clinics, so many patients are seen going to the emergency departments of hospitals instead. The Malaysian Pharmaceutical Society immediate past president, Mr John Chang has already indicated that if a clinic can open 24 hours, so can a

pharmacy, and that this is merely an administrative issue driven by the current doctor-dispensing market.

One doctor had previously indicated that leaving dispensing with the doctors is economical and entails a lower risk of mistakes. CAP begs to differ. Our surveys have shown that the prices of drugs sold at pharmacies are reasonable. In addition, as pharmacists are trained in the area of dispensing and can monitor for prescription errors and drug interactions, there will be a lesser chance of mistakes and adverse outcomes of medication. Doctors do not have this training.

Doctors do not, or at least should not, make exorbitant profits on medicines. As far as monetary benefits go, the doctors should not feel too much of a loss. The doctor would make more savings now as he will not have to employ and train dispensing staff, thus reducing staffing costs. The rooms or the areas previously used for storing medicines and dispensing will be cut down, and can be converted into more treatment rooms or even better waiting areas for patients. The doctor will not have to worry about dispensing errors which can be a nightmare.

Pharmacists as prescription monitors

One key role that pharmacists can and should play in the private sector is to screen for prescription errors. This role is part of their training and is currently carried out very effectively by pharmacists in hospitals. This is attested by a letter from a pharmacist in a Government hospital, which appeared in the press last year: The writer states,

'If any error is noted, the pharmacist calls the doctor, informs him about it and corrections are made to the prescription. This is what we call an intervention and it will be recorded. Interventions are made every day on prescriptions from doctors and trainee doctors. If the public were privy to the types of interventions the pharmacists make every day, the public would be more supportive of the proposal to separate the dispensing function from the prescribing function'.

Errors in prescribing do happen – under- or overdosing, writing a wrong dosage regime or prescribing drugs that adversely interact with each other, or are not suited for the patient's age - among others. These errors, which might give rise to serious health risks to patients, can be spotted by a pharmacist in advance. Doctors in private clinics are dispensing without this added benefit to patients.

Based on information that we have previously sought from the Ministry of Health, it is the clinic doctors themselves who must dispense the medication directly to their patients. [In other countries the law requires that a pharmacist must dispense the medication directly to the patients. Ed] Clinic assistants, who have no formal

training, are only supposed to help with the preparation, mixing and labeling of medication. Even these activities, according to the Ministry of Health, should be under the direct personal supervision of the doctor concerned. But how often is this case on the ground? [In other countries the law requires supervision by a qualified pharmacist. Ed]

Dispensing is a specialized area and the potential for error is very high when untrained staff take on the role of dispensing. Furthermore, patients might not receive proper instructions on how the medication is to be taken, the precautions that are necessary, and information on side-effects or drug interactions. Pharmacists are trained to perform all these roles. Patients should not be exposed to the risks arising from their medication being dispensed by unqualified personnel.

The pharmacy profession is highly regulated to guarantee quality standards in all aspects of their practices. The Pharmaceutical Division actively monitors Pharmacy practice according to regulation and enforcement of law.

Expansion from a pilot implementation

At the same time that the initial pilot project is being implemented in major towns, the Ministry of Health should initiate steps making it mandatory for doctors to give patients itemized billing as a routine procedure and to write their prescriptions using the generic names of drugs.

At the same time expansion from the pilot to general implementation should be planned.

Australia: Transparency hurdles

Ken Harvey

<http://tinyurl.com/l4tvj5t>

MEDICINES Australia has submitted edition 18 of its self-regulatory **Code of Conduct** to the Australian Competition and Consumer Commission for authorisation.

The outcome will be interesting.

In 2012, when **edition 17** of the Code was released, the ACCC limited its **authorisation** to 2 years rather than the 5 years sought to encourage Medicines Australia to improve transparency around payments to individual health care professionals.

This was in accord with international developments such as the **US Open Payments** (the Physician Payments Sunshine Act), which mandated full public disclosure of these relationships.

Medicines Australia responded by establishing a **Transparency Working Group**, with representatives from member companies, and from a diverse range of

health professional and consumer groups. By May 2013, the group had agreed on a set of **transparency principles** applicable to all therapeutic goods companies.

These included collecting details on all monetary transactions between a company and an individual health care professional, and reporting these transactions on a single, public website that is readily searchable.

As I wrote in MJA InSight last year, a transparency model consultation and discussion paper included various implementation options on which the group had failed to reach a consensus, including the levels of payment to be recorded and reported.

The revised Code, agreed solely by members of Medicines Australia, has two major flaws. First, it provides no assurance that information about transactions will be transparent for many individual health professionals as it allows them to **opt-out** of public disclosure while retaining the financial and related benefits of their interaction with member companies. This is Clayton's transparency.

Second, it fails to implement the concept of a single website for consolidating information about transactions provided by different companies. Without this, those interested will have to trawl the websites of all Medicines Australia member companies to collate their own list from those doctors who have consented to make this information available.

The main reason why the Code is so weak is because other therapeutic goods industry associations (eg, the **Generic Medicines Industry Association**) have not adopted any transparency provisions in their codes and have also opted out of ACCC code authorisation (and thus being subjected to ACCC persuasive powers).

There are also increasing numbers of non-members of therapeutic goods industry associations (especially generic companies based in India) not bound by any self-regulatory code.

It's therefore not surprising that many members of Medicines Australia were worried that attempting to force full disclosure would put them at a competitive disadvantage with other therapeutic goods companies, especially generic companies.

All of which highlights the problems of self-regulation raised in 2010 by the **Working Group on Promotion of Therapeutic Products**. This working group provided principles to harmonise the disparate therapeutic goods industry codes and addressed the need for non-members to adhere to codes as a condition of gaining marketing approval by the Therapeutic Goods Administration (TGA).

The federal government's response in 2013 was merely to set up a **Codes of Conduct Advisory Group** to assist industry to implement the recommendations of the working group. There is only one **report** from this group currently in the public domain and it is unclear what, if any, progress has been made.

Self-regulation is incapable of delivering the outcomes required, which has led the US, France, Portugal and Turkey to embrace **government regulation** of transparency. In Australia, it is time to revisit the **Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013**. A revised Bill should make transparency (and other ethical considerations) a condition of market authorisation by the TGA.

Meanwhile, the ACCC should not provide a fig leaf of respectability by authorising edition 18 of the Medicines Australia Code. Rather, they should defer authorisation and refer this mess back to where the responsibility lies — the **Regulatory Policy and Governance Division** of the Department of Health, the TGA and the government, all of whom have failed to address the limitations of self-regulation.

The ACCC has called for **submissions** about the code, which close this week (1 August). It is an opportunity to have your say on the proposed arrangements.

Dr Ken Harvey is adjunct associate professor in the School of Public Health and Preventive Medicine, Monash University. He represented the Consumer Health Forum on the government's Working Group on Promotion of Therapeutic Products and Medicines Australia's Transparency Working Group and Code Review Panel.

Bangladesh

Gonoshasthaya Kendra: Char Development Program

Geographically, Chars are detached lands in Bangladesh, which are surrounded by river water and detached from the main land. The riverine Chars in Bangladesh have not been in the focus of development of the public and private agencies. Char dwellers are living along with hunger, flood and river erosion. They have no Government / non government hospital facility, higher secondary school, even primary school. Electricity is not present in any char. After sunset or late in the evening darkness covers entire chars.

If anybody becomes sick, there is no doctor and hospital, and no transport. It is necessary to carry the patient with a small wooden bench and then walk Km after Km and cross the river by boat. Service ferry boat is the only means to cross the river and reach the main land.

There are around 350 chars raised in Jamuna, Brahmaputra, Tista and Dhorola Rivers in Gaibandha and Kurigram districts and 2.5 millions of families are living in these chars. Every year they are affected by natural disasters like flood and river erosion and thus lose their properties and become even poorer to the poorest. They fight back to find a place in newly accredited lands to re-begin their livelihood with courage. They are living under poverty and perpetual victims of natural hazards.

After the 2004 flood in Bangladesh, GK started post flood rehabilitation and development activities in chars of Gaibandha and Kurigram districts. And there after in 2006, GK started the Integrated Char development Program with the financial support of FSC (France Support Committee) and PKSF (Polly Karma Shohayak Foundation), CLP, Christian Aid and Bashati Trust Foundation. The Integrated Char development Program consists of Health, Education, Seasonal Loan and Cooperative Bank activities. Today this program is operating at 68 Chars in 29 Unions of 16 Upazilla under Gaibandha and Kurigram districts covering over 10,000 families.

Char Medical Camp in Char Fassion, Bhola

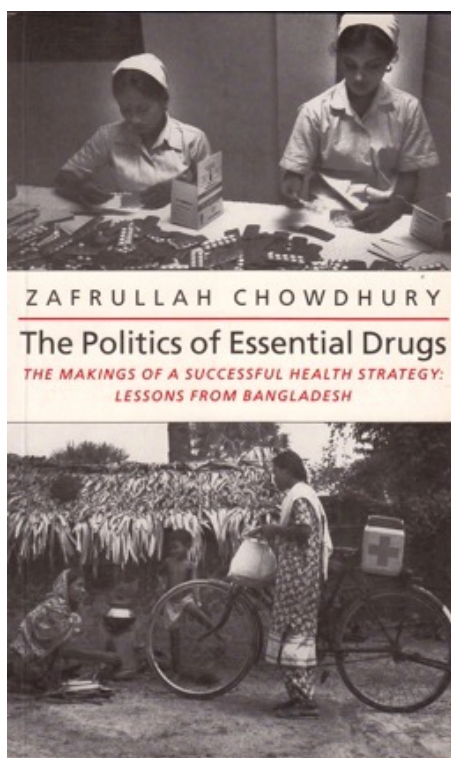
During 6-10 June 2014 GK conducted another medical camp in Char Fassion, Bhola (a coastal island) which was attended by 9 specialist doctors, 9 junior doctors and 10 technicians and pharmacists, 19 paramedics and one electrician. During the five day camp 1620 women, men and children received treatment and 70 surgical operations were done.

Zafrullah Chowdhury: The Politics of Essential Drugs – lessons from Bangladesh is now available as an e-book.

<http://bookdir.info/?p=533458>

The Politics of Essential Drugs: the makings of a successful health strategy – lessons from Bangladesh – Zafrullah Chowdhury –is now available as a pdf, epub, free download ebook and audiobook

When a country adopts an essential drugs list, bans ineffective and harmful pharmaceuticals and endeavours to boost local drugs production, it incites the wrath of the global drugs industry. This book tells the story of how Bangladesh, after introducing its National Drugs Policy in 1982, had to withstand a concerted



campaign by transnational companies, their governments, and large sections of the medical profession. It assesses the achievements and the limitations of the Bangladeshi experiment, describes reform attempts in other countries, and provides evidence of malpractice and corruption in the pharmaceutical industry.

See also HAIAP Newsletter - August 2012 - Bangladesh: A Long History of National Medicines Policy: where are we now? Dr Zafrullah Chowdhury, provided Lessons from Bangladesh National Drug Policy 1982 at the Asia Pacific Conference on National Medicines Policies, Sydney, May 2012.

HAIAPNews3August2012final.pdf

Pakistan: Drug Prices Issue

From Daily 'DAWN' Karachi by Afshan Subohi

<http://www.dawn.com/news/548043/review-of-drug-prices>

It is not always ignorance that draws the sick to soothsayers. Many a times access to scientific healthcare is an issue of affordability for the country's over 50 million poor. Letting medicine price hike by lifting the price control, as demanded by the pharmaceutical industry, could translate into a health catastrophe. While the private sector is pushing for deregulation of drug pricing, the government is unwilling to forego its control over the highly lucrative sector. It has, however, conceded to review prices in hardship cases.

Over 450 pharmaceutical companies sell Rs100 billion worth of drugs a year. The industry is targeting export of one billion dollars by 2013, if 'the right policy environment' is provided by the government. The industry's revenue grows by an average 12 per cent a year. The annual average growth rate of local companies is higher at 19 per cent as compared to 11 per cent in case of multinationals. Every year, at this rate, local companies are gaining from multinationals about two per cent of the domestic drug market.

Experts monitoring developments closely feel that it would be fairer if the profile of not only the products but the drug firms is reviewed by the price control committee to arrive at an informed and prudent decision.

'Why dissect only hardship cases and not the full range of medicines? If some products are not earning enough, others must be making huge profit to more than make up for the loss in some others. Drug firms themselves claim to be best performing segment of manufacturing in the country'.

There are many tablets and capsules selling at over 1,000% margins. People who can afford, complain persistently about high cost and low quality of drugs. The health component of family budgets has increased exponentially over the past 22 years despite price controls. For example, people over 70 years, with old age ailments may be spending as high as Rs10,000 per month on medication that normally include tablets for hypertension, tranquilisers and diabetes.

A course of antibiotic for a child is given, for one reason or the other every two months till he enters teenage, and costs at least Rs300. It is not hard to imagine what drug spending would be like for an average family particularly when doctors are generally inclined to go for over-drugging - often allegedly influenced by drug companies.

Pakistan will miss the Millennium Development Goals unless drastic measures are taken to improve healthcare access for its citizens. The Ministry of Health has confirmed to have received about two dozen hardship cases where the industry is seeking a price increase.

'The deregulation of drug pricing is not on the table. Yes, we have received some hardship cases that would be considered individually on merit by the drug pricing committee having representation of all relevant stakeholders. After due deliberations, a decision will be taken on case-to-case basis on each product separately', Khushnood Lashari, federal secretary, health told *Dawn* from Islamabad.

'We are willing to address their concerns but they cannot be allowed to fix drug prices at their whim. They need to appreciate that despite challenges, they have been offered opportunity to make it big, the kind of business that they have achieved', he argued.

'Managing the health matrix for public healthcare is the key responsibility of the government. No, we are not willing to forego our role of a watchdog of public interest', Lashari stressed.

The robust drug sector argue for deregulation - their case for price increase cites inflation, rupee depreciation and higher overhead costs. Imported chemicals used as raw material for drug manufacturing becomes dearer with the strengthening of dollar.

A representative of Pharma Bureau, a platform of multinational drug companies pleaded in favour of

deregulation. He did not approve of the idea of marketing medicines with generic names. 'If the situation is allowed to persist many multinational drug companies will pack up and go', he said.

'In Pakistan, 95 per cent of drug patents have expired. About 1500 basic molecules are used for some 60000 registered medicines described as generic branded drugs. There is no ban on generics but if at all produced they do not have mentionable market share', Dr Farid of Pharma Bureau told *Dawn*. He said the quality would be compromised if the government decides to promote generics to bring down price.

Zahid Saeed of Pakistan Pharmaceutical Manufacturers Association held that high performance of the sector is primarily the result of the quality of entrepreneurship. 'The companies are doing well despite a hostile environment because of corporate leadership. The lifting of price control will give a major boost to the industry that has all the ingredients of an innovative competitive sector in a phase of growth', he said over telephone.

In Pakistan 1500 basic medicines that cover over 95 per cent of all drugs in the market have been formulated to produce 60,000 products by about 520 local and multinational companies. It means excepting about five per cent, patented drugs are essentially the same chemicals produced by various companies in different shapes and colours and packaged differently with printed material that the majority of users cannot read or comprehend.

'Arch rivals in the market — local and multinationals — stand united on the issue of pricing of drugs. 'Fiercely divided they might be on a number of issues including the lingering subject of data exclusivity in Pakistan, they are brothers in arms when it comes down to pricing', commented a senior bureaucrat in the Ministry of Health.

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