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HAI News reports on developments in national and international campaigns on health for all. This newsletter highlights activities of network contacts involved in improving access to medicines, rational drug use and poverty eradication.

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WTO/TRIPS – generating much debate for discussion

The Asian Regional Workshop on WTO/TRIPS Agreement was organized by the Third World Network (TWN) and Health Action International Asia Pacific (HAIAP) with the cooperation of the United Nations Development Program (UNDP), World Health Organization (WHO), Medecins Sans Frontieres (MSF) and Consumer Project on Technology (CPTech)

Approximately ninety participants attended the workshop, among many of whom were policy makers and regulators, representatives and experts from health movements, NGOs and UN agencies (the WHO and UNDP) representing South and South East Asia, Africa, Europe and Australia.

The workshop was a follow-up to the successful Asia-Pacific regional workshop held in Colombo, Sri Lanka in April 2003 co-organized by TWN and HAIAP and the Ministry of Health, Sri Lanka to bring policy makers from the Asian region to deepen the discussion on the implications of trade policies and intellectual property laws on public health; update and analyze the developments at the WTO and other relevant fora since the first regional workshop in April 2003; to share pro-public health national experiences in laws, policies and practices; and to develop appropriate national and regional policy responses and practices. The workshop also intended to strengthen the role of NGOs at the national level in implementing the Doha Declaration on TRIPS and Public Health and to build stronger cooperation among NGOs, and between NGOs and national governments in this regard. Excerpts of papers presented are given below.

Session 1 – Patents and access to medicines: an overview of the issues

Martin Khor, Executive Director of Third World Network presenting a paper on “Patents and access to Medicines: an overview of the issues,” noted that there were many steps to be taken in ensuring access to essential medicines such as drug regulation, drug procurement and financing, actual distribution of drugs and the issue of manufacturing. All of these are affected by the patent regulations as prescribed under Trade Related Aspects of Intellectual Property Rights (TRIPS).

However, many of us are ignorant about patent laws under TRIPS. In reality even though there are obligations under TRIPS there is also a degree of freedom for countries to choose their own policy options. Many developing countries do not understand the flexibilities and ambiguities provided by TRIPS for opportunities to formulate national policies that are less damaging for public health.

Many technical assistance provided by international bodies such as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) create confusion among developing countries. They do not provide the history of TRIPS negotiations or the interpretations. In effect, countries need to build knowledge on the ambiguities and options and flexibilities provided by TRIPS in order to choose a national policy option that promotes public health. TRIPS can indeed be damaging but adopting appropriate provisions in the national legislation can make it less damaging.

The next step is how to implement policy measures such as government use, parallel imports and compulsory licensing. In some cases governments have to negotiate technical aspects and compensation with patent holder. In that case, we must know our rights and must overcome any hurdles that obstruct the safeguarding of public health. Then there are also health problems faced by generic producers. The products that are made or brought into a country must be tested for quality, efficacy and safety. The regulatory bodies must control this. This process is in danger of being misused by big companies. Drug regulators are being pressured to reject registration for generic drugs

which are similar to those already being patented. Many Transnational Corporations demand data protection and data exclusivity when they submit a drug for registration. The generic manufacturers should have access to data of the originator in order to produce the generic version. However, National Drug Authorities are pressured to protect the test data of big companies. Although data has to be protected, it should not be given exclusivity. So generic producers may be given data of the big drug companies. This is not TRIPS illegal.

Next, governments need to know the situation and rules on procurement, whether through local companies, imports or through government owned companies. This ties up with the issue of distribution of drugs and access by patients. Two issues are involved here: government policy on drug distribution (whether free, subsidized, what criteria is used, budget priority,) and the practical problems of distribution – and finally patients know how to take drugs, combination of drugs, etc.

Philosophically, every country wants to produce its own drugs, at least essential drugs. There are barriers, of course, in the form of technological capabilities, market size etc. Finally, each country needs to ensure that it is producing drugs in a way that meets the criteria of safety and effective.

Germán Velásquez from the WHO Dept. of Essential Drugs and Medicines Policy speaking on “WHO work on globalization and access to medicines: recent developments - WHO perspectives” quoted a message from Kofi Annan at the WTO Ministerial Conference in Cancún in September 2003.

“... instead of global rules negotiated by all, in the interest of all, and adhered to by all, there is too much closed-door decision-making, too much protection of special interests ... and the victims can be counted in the billions.”

It has now been established that there is tension between the TRIPS agreement and public health. Two issues of concern to WHO are:

- * HIV epidemic – pricing of Antiretrovirals (ARVs)
- * Bilateral trade agreements/intellectual property restrictions

Since 1999, four World Health Assembly resolutions have given WHO the mandate to:

- Assist Member States to develop medicines and health policies when faced with international trade agreements
- Monitor, analyze, study and report on health implications of international trade agreements
- Produce an analysis of Intellectual Property Rights (IPR), innovation and public health, including appropriate funding and incentive mechanisms for the creation of new medicines and,
- Encourage bilateral trade agreements take into account the flexibilities of the TRIPS Agreement

The WHO programme of work on pharmaceuticals and trade include:

- Guidance on cost-containment mechanisms for essential medicines, including ARVs
- Training and briefings on TRIPS safeguards
- Advice on the revision of national pharmaceutical legislation, e.g. in Brazil, Cambodia, P.R. China, Colombia, Indonesia, Kenya, Thailand
- Organization of interministerial meetings (health, trade, patent office) on globalization, IPRs and access to medicines, e.g. national meetings, ASEAN, SADC and WHO regional meetings.

WHO policy perspectives on access to medicines are:

- Access to medicines is part of the human right to health

- Essential medicines cannot be regarded as simply another commodity
- New ways and incentives for Research & Development are needed
- Promotion of the use of TRIPS flexibilities

On the last point, i.e. TRIPS flexibilities, a recent study of IPR legislation in 11 Latin American countries found that most countries had not adequately incorporated the full range of TRIPS flexibilities. Also the Doha Declaration and August 30, 2003 Decision have not been used. There are several reasons for this, among others:

- * Lack of knowledge/technical expertise
- * Need for amendment of national laws
- * External pressures or barriers such as obligations under Free Trade Agreements (FTAs)

However, recent developments also show positive signs which are as follows:

2002 - Zimbabwe declaration of emergency to allow Compulsory Licensing
 2003 - Malaysia Government use provision to import ARVs
 2004 - Mozambique and Zambia issued Compulsory Licensing for ARVs
 2004 - Canada and Norway amended national laws - EU, Switzerland and India under way (on para. 6 implementation)

Yet there is a recent development that may spell a negative sign for public health, i.e. Bilateral and trade agreements (FTAs). Some common provisions of FTAs affecting health are:

- Extension of patent terms ... compensation for delays
- Restriction on use of compulsory Licences
- Mandatory 5-year data exclusivity (Article 39) patent-DRA "linkage" requirement
- Restrictions on the use of INN for medicines
- Limitations on parallel imports
- Expanded definition of patentable matter

In the light of the above situation, post-2005 production of generics will depend on several factors:

- Effective use of public health TRIPS safeguards, including 30 August, 2003 Decision
- Economic incentives for production under Compulsory Licensing
- Full use of the transitional periods
- New ways and incentives for R&D of new medicines

The future of the debate about TRIPS and public health must consider the issues of the ethical aspects of the problem: essential drugs as a public good, access to essential drugs as a human right and the need for alternatives to Research & Development based on the real health problems.

He concluded his address with a statement from Paul Farmer, "The more effective the medicine, the greater the injustice against those that have no access to treatment".

Ellen 't Hoen from Médecines Sans Frontières' Access to Essential Medicines Campaign began her intervention on "Patents and Access to Essential Medicines", by saying that 30 to 50 per cent of the population in developing countries do not have access to essential medicines. This is especially so in India and in African countries. Access to essential medicines depends on many factors. Patent is not the only factor. For instance, there are the regulatory, quality, production, supply and rational use factors. At the end of the day all of these factors must be addressed.

The WHO defines essential medicines as “those that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts in appropriate dosage forms and at a price the individual and the community can afford”.

Thus, access to medicines is much broader than access to antiretroviral treatment. However, many talk about access to antiretroviral treatment for HIV/AIDS as it is a disease that deals with new medicines. Therefore, she stated “we can learn a lot from taking into consideration access to ARVs”.

When the essential medicines concept is considered there are certain obligations in it that the TRIPS Agreement undermines. For instance, according to the TRIPS Agreement 20 years of patent protection is given to pharmaceuticals which can be a matter of life and death. TRIPS can also be considered as anti free trade because it creates a monopoly and keeps the drug prices high.

Based on the field work carried out by MSF, access to medicine is hindered because of reasons like high prices, and drugs not being produced due to lack of competition.

MSF sees IPR as a social policy tool. Primary justification for granting intellectual property rights is the benefit to society as a whole by promoting innovation in exchange for a limited monopoly. If it does not provide benefit, then the laws should be improved. TRIPS does not seem to benefit society. Therefore, an attempt was made to reform it so as to ensure access to medicines.

This was done through the Doha Declaration of which paragraph 4 says: “we affirm that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all”.

The Doha declaration also deals with the problem of production and exports to countries that have insufficient manufacturing capacity through paragraph 6, which was then translated into the August 30 decision. In reality, the solution is provided by Article 30 of TRIPS which says that countries have the right “to grant Compulsory Licences and the freedom to determine the grounds upon which such licenses are granted”. Under Article 30 of the TRIPS agreement, members may provide an exception to the exclusive rights conferred by a relevant patent to permit all acts associated with the production for export to a third country of a patented product or a product produced by a patented process; where the export addresses health needs in the third country; and the product and/or process is either (a) not patented; or (b) a Compulsory License has been granted or government use made of the relevant patent in the third country.

In effect, the TRIPS agreement is based on a ‘make believe’ solution to the problem of access to medicines, i.e. that patents are essential to ensure the development of new drugs. However, the world is facing a decline in drug innovation. For tropical diseases only a very few new drugs have been developed recently. This is not only an issue for developing countries anymore. Research and Development expenditure and new drug output is declining. When the situation in France is analyzed (France is considered as a country where drugs are registered first) most of the drugs that have been registered do not add to the therapeutic value over other existing drugs. There appears to be an Research & Development crisis.

The future holds both concerns and opportunities. The concerns include:

- * Erosion of Doha Declaration through bilateral and regional ‘free’ trade agreements
- * Lack of implementation of Doha
- * Propaganda instead of real measures – August 30 decision
- * Post 2005 – no generic versions of new medicines

* Changes in India generic pharmaceutical industry

* Concentration of industries

Without alternative financing mechanisms no health needs driven R&D

An example for the post 2005 concern is about HIV/AIDS treatment. HIV/AIDS patients now require second line ARV treatment, which is very costly. There are no generic equivalents for these drugs as yet. India, a potential generic producer, is hesitant to invest in second line ARVs as now they are unsure about selling them, due to the implications of TRIPS and product patents which were granted from January 2005. Thus, the generic source of new medicines may dry up.

The opportunities for the future are:

- Growing drug prices in the north no longer sustainable and therefore the concerns about access to medicines has become increasingly a global issue rather than just a third world issue.

- Growing public concern (antibiotic resistance, flu vaccine shortage, ACT shortage)

- Stagnation in innovation.

Therefore flexibilities that exist should be used now.

Dr K Balasubramaniam of Health Action International Asia – Pacific basing his delivery on “Patents and Access to Medicines” explained that access to medicines must be considered as a human rights issue. However, health as a human right is not enshrined in the constitutions of countries like Indonesia, Malaysia and Sri Lanka but they have ratified several multilateral Human Right Treaties that ensure the right to health. These include the following:

1. The United Nations Charter

2. Universal Declaration of Human Rights (UDHR)

3. International Covenant on Civil and Political Rights (ICCPR) and

4. International Covenant on Economic, Social and Cultural Rights (ICESCR)

These four are collectively known as the “International Bill of Human Rights”.

While the national policy issue is not resolved yet, there are other impediments, at the international level, to access to medicines. Two examples illustrate this. First the pharmaceutical industry attempted to block the enactment of TRIPS compatible national law in South Africa. Second, the US initiated a complaint against Brazil in the WTO dispute settlement system over Brazil’s national law on Compulsory Licensing. Multinational companies want total control of drug production through TRIPS.

Multinational Corporations (MNCs) argue that strong patent protection is an incentive for Research & Development (R&D). In reality, public funding for R&D is higher i.e 50 per cent in 1998 compared to MNC funding of only 48 per cent. Only 10 per cent of R&D is directed to health problems that account for 90 per cent of global disease. In such a situation, TRIPS create a monopoly with the patent holder being able to charge any price that he/she wants. In other words, the law of the jungle will prevail.

The situation might be worse in this year. Developing countries will have to wait for 20 years to produce generic drugs. But by then no generic company would want to produce it because by that time the drug will have no use or the sales will be very low as new drugs would have been developed by then.

Year 2005 has been anticipated as a “A national health disaster” by the Indian drug manufacturers Association. This is because previously it was possible to make generic versions before patent expiry, as patents were granted only to process patents and not

products. The implementation of the TRIPS Agreement in 2005 will remove this flexibility.

We are here today, in this workshop, to try and prevent this from happening. To make this dream a reality an alternative model incorporating Compulsory Licensing and Parallel Imports should be designed.

We hope the workshop will bring out ways and means of providing those two provisions in the national laws on patents in developing countries for the sake of public health.

Cecilia Oh from the Department of Essential Drugs and Medicines Policy, World Health Organization further discussed the Doha Declaration and the Paragraph 6 solution. The Doha Declaration on TRIPS and Public Health was agreed during the third WTO Ministerial Conference November 2001. Paragraph 4 is the pivotal provision for public health, which says: TRIPS “can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all” she said.

The Doha Declaration basically reaffirms the use of policy options to safeguard public health which are TRIPS-consistent. These options are:

- Government use, found in Article 31 of TRIPS
- Compulsory licences, also in Article 31
- Parallel importation, provided in Article 6
- Exceptions to patent rights (e.g., Bolar exception)

Article 31 of TRIPS provides for “public non-commercial use” and the discretion is with the government to define it as broadly as possible. It refers to the government’s right to use the patent without consent. This article also provides a fast-track approach to Compulsory Licensing in which the government has an option not to go into negotiations for voluntary licensing before they use the patent. It needs to be noted that even the US and the UK have very broad provisions allowing this option. The UNDP recommends that governments adopt these same standards of the US and the UK.

Article 6 refers to the import and resale of patented products without the consent of the patent holder. This can be done if there is a provision for the exhaustion of patent rights. States practising this provision includes South Africa and Malaysia which adopted the international principles of the exhaustion of rights. It is crucial to have explicit provisions in patent laws to make this provision effective. The TWN Manual shows how those provisions may be worded to achieve the desired objectives of the policy makers.

Exceptions to patent rights are provided in Article 30, one of which is the Bolar exception, which includes research and experimental production for export. The advantage of this option is that it is automatic without need for undergoing the process of application.

The provision on Compulsory Licensing is found in Article 31. It is a misconception that this provision can be used only during cases of emergencies; this option is available on broad grounds and the Doha Declaration says that countries have to determine what those grounds are. The conditions for the exercise of this option are as follows:

- prior negotiation with the patent holder
- compensation to patent holder
- appeal process.

The Doha Declaration is the first step in a process which starts to look at the flexibilities of the TRIPs Agreement that basically leaves the responsibility of supply to developing countries. It also gives additional affirmation that Governments should implement TRIPs in a way that supports public health.

There is however one problem, Paragraph 6 of the Doha Declaration. The problem is that countries with insufficient or no domestic manufacturing capacity cannot effectively exercise right to grant Compulsory Licences. While developing countries with manufacturing capacity are restricted by Article 31 (f) of TRIPs which says that production under a Compulsory License must be predominantly for the supply of the domestic market. The problem is how to provide for a Compulsory Licensing for imports so that developing countries with manufacturing capacity can help other developing countries with insufficient or no manufacturing capacity to have access to affordable drugs.

The Doha Declaration had mandated the TRIPs Council to find an "expeditious solution" for Paragraph 6, by December 2002. The TRIPs Council could not find a solution by December 2002. An interim solution was adopted through the General Council 30 August 2003, Decision. This is a legal document which is in effect until WTO members agree on a final position, i.e. until there is a permanent amendment of TRIPs Agreement mandated in March 2005.

That means the decision can be used and relied on by WTO members in their policy-making decisions. This decision provides for a waiver of TRIPs particularly on:

- export restriction on 31 (f),
- double compensation in 31 (h),
- compensation in importing countries and exports within regional trading arrangements (RTAs), applicable only in small groups of countries on the condition that the RTA had 50 per cent of its membership as least developing countries (LDCs).

Paragraph 9 of the August 30 Decision also says that other flexibilities in TRIPs are not affected. Therefore, there is a broad range of options available even if a country does not use the Aug. 30 decision.

Elements of August 30 Decision

A WHO study provides an interpretation of the August 30 decision to achieve public health objectives. According to the study, the decision provides for:

- Broad coverage of diseases and medicines
- Equality of opportunities for countries in need
- Sustainability of quality supply at affordable prices
- Facilitation of multiplicity of suppliers of required medicines
- Simple and speedy legal procedures
- Transparency and predictability of applicable rules
- Stable international legal framework

The following are the elements of the August 30 decision:

- a) eligibility - It must be emphasized that it is important for countries to mention their intention. However, no country has ever informed the WTO that they intend to use the August 30 Decision.
- b) purpose/use – must be used in good faith and not for developing industrial capacity though Doha says that it enhances capacity;

- c) scope – any patented product or product manufactured through a patented process of the pharmaceutical sector needed to address the public health problems
- d) conditions –
 - 1) for importing country – institutional granting of Compulsory License and lack of sufficient manufacturing capacity
 - 2) for exporting country – notification and identification of products and Compulsory License for production and export
 - 3) anti-diversion measures – a concern of developed countries, which may be devoted to countries not included in the arrangements

To implement the August Decision, there is need to:

- 1) determine patent status – so as to ascertain patent data in importing and exporting countries; the 2016 extension for LDCs definitely should mean that they will not put out new patents
- 2) meet legal challenges – particularly on the grounds for the grant of Compulsory Licensing and the rate of compensation to patent holders
- 3) make changes to national laws – to provide for compulsory licensing for export and import and to determine compensation in importing countries

National laws have to provide for:

- 1) compulsory licensing for import – which should be based on broad grounds and prior negotiation, also does not provide restrictions on products or diseases
- 2) compensation – royalty or compensation payment waived in importing countries
- 3) appeal procedure – should provide for non-suspension of implementation of compulsory licensing in cases of appeal which is important on public health grounds.

The national law in Canada, as an exporting country provides for: right of first refusal, list of medicines and compensation formula. The WHO says that this scheme goes against the Doha Declaration. In Norway, the law is not very useful as it does not produce drugs useful for developing countries.

Barriers to using TRIPS Flexibilities

Despite the flexibilities provided by TRIPS, Doha Declaration on TRIPS and Public Health, as well as the August 30 Decision, there are new barriers for developing countries to use the flexibilities provided by TRIPS, as discussed below.

- 1) There have been inadequate or no changes to national laws. For some reason developing countries seem to be waiting for the Amendment of the TRIPS Agreement in March 2005.
- 2) Data exclusivity: Article 39.3 of TRIPS requires protection of marketing approval data under certain conditions. Further, Article 39.3 requires countries to protect against "unfair commercial use" of marketing approval data. It needs to be noted that the US and the EC protection of data for registration of pharmaceuticals go beyond the TRIPS requirement
- 3) Bilateral and regional trade agreements: challenges include the requirement of developing countries to strengthen IP rights beyond minimum requirements of TRIPS Agreement or TRIPS –plus situations. In that case, countries might not be able to use flexibilities provided by TRIPS and the Doha Declaration as well as

the August 30 Decision. Some TRIPS-plus provisions in the bilateral and regional trade agreement are:

- a. Patent-DRA 'linkage' requirement
- b. No marketing approval without consent of patent holder
- c. 5 years data exclusivity
- d. Compensation for unreasonable delays in patent grant in the form of extension of patent duration beyond 20 years.
- e. Restrictions on right to determine grounds for compulsory licensing.

Despite these challenges, some countries have actually implemented the flexibilities provided by TRIPS to ensure access to drugs at the national Level. For example, in October 2003 Malaysia issued a Government Use authorization for importing drugs from India, to be used by the government for HIV/AIDS treatment. Mozambique issued Compulsory Licensing in March 2004 and Zambia in September 2004.

Karin Timmermans from WHO, Indonesia on the issue of Manufacturing and Marketing: rules and reasons said that medicines were among the most regulated products on the market. There are good reasons for the extensive regulatory intervention in pharmaceutical markets, mainly:

- Market failure, especially information imbalance between manufacturers, prescribers and consumers;
- Ineffective or dangerous medicines may undermine confidence in the entire health care system;
- Money spent on ineffective or dangerous medicines is wasted;
- Misuse of certain medicines (such as antibiotics) can have serious implications for the individual and for public health.

Medicines are subject to two sets of rules: (1) Intellectual property rights - Registration requirements; (2) Authorization to put a medicine on the market. She discussed the second set of rules. The objective of rules that can authorize a medicine be put on the market is to protect public health by ensuring the quality, safety and efficacy of medicines available on the market. This is done among others through Good Manufacturing Process (GMP), Preclinical and clinical trials for original drugs and bioequivalence test for generic drugs. The determination of bioequivalence is based on data. And, this is where the confusion occurs over data exclusivity. Keeping the original data exclusive or confidential would hinder the process to determine bioequivalence, and therefore hinder the authorization of generic drugs.

A question is often raised whether registration authority should also deal with price or with 'value for money'. Indeed if registration fees are too high, they may discourage manufacturers from seeking registration. In this case, evaluation/registration process can become a 'bottleneck' that limits access to drugs, at least temporarily. There are strategies to overcome this problem, and they are:

- Some countries can rely on the evaluation and registration in other countries with well-developed regulatory authorities;
- Fast track registration for important drugs such as ARVs (incl. generic versions);
- Reduce fees for generics and/or for vital drugs;
- Temporarily waive registration or exempt from registration.

The next issue is domestic production of drugs. This needs to be supported, because producing drugs nationally can, among others, reduce foreign exchange needs, provide employment, advance industrial development and increase self-reliance. There are three stages in pharmaceutical production: (1) Primary stage which includes production of Active Pharmaceutical Ingredient (API) and intermediates; (2) Secondary stage, the production of finished dosage forms; (3) tertiary stage which is (re)packaging. For Asia

the main issue is the production of API. For example, Indonesia does not have API production capacity but has secondary and tertiary production capacities.

There are many issues to be addressed in terms of domestic drug production such as:

- Does domestic production really happen or is it perceived to happen?
- From the economic point of view, is the domestic market big enough to make production viable? And will the envisaged exports really materialize? Or is it more realistic to import?
- Will it affect quality standards and adherence to GMP?
- Should there be some sort of regional coordination?
- Is there a role for the public sector?

The answers will be country specific, as countries differ in their capacities. But regardless of the strategy chosen, governments need to make sure that the national laws and regulations support their strategy. Countries must also be vigilant with regard to efforts to harmonize regulatory requirements and standards.

During the next session the participants discussed country experiences with Compulsory Licenses as an NGO perspective. James Love from CPTECH explained that several countries have, recently, issued Compulsory Licenses (CL) for AIDS drugs. The Licenses is either for local manufacture or import of finished product, except South Africa. It needs to be noted that most of the licenses is exclusive, i.e. granted to one manufacturer or one importer. And this may cause problems. Countries need to issue CL in an open manner to avoid future problems.

Granting exclusive or limited CL for local manufacture may not be the cheapest way to provide access to medicine. CL for the import of finished product may guarantee cheaper prices. However, some countries may want to be able to manufacture and then export; this may not serve the interest of consumers as well.

Session 2: Country experiences

CPTECH is proposing a scheme to provide greater access to essential medicine, known as **Patent Pool for Essential Medicines (PPEM)**. The main objective is to obtain the lowest cost medicines of acceptable quality and sustainable supply. This would be possible by lowering registration barriers, expanding the generic market and opening up licensing of patents to generic suppliers.

The main benefits of PPEM are that:

- There is safety in numbers; countries need to operate as a group, to reduce bilateral pressure or investor backlash
- It creates sufficient economies of scale to induce efficient generic entry and lowest prices
- It can avoid corruption, favoritism and inefficiency
- It is more likely to achieve access goals

But, one must also note the problems involved. There is always a difficulty in launching a new idea. The negotiation on remuneration would also pose difficulty. Trade officials might block the idea due to protectionist impulses. Finally, politically connected generic suppliers might not want to lose preferences.

Muhammad Farid Wong Abdullah from the Ministry of Health, Malaysia on the use of government's rights to increase access to antiretroviral drugs in Malaysia cited Malaysia as being among the countries that have succeeded in increasing access to Antri Retroviral (ARV) drugs by using provisions on Government Rights. The country's Patents Act of 1983, amended in 2000 and 2003 allows the following flexibilities for public health:

- the issue of a Compulsory License for local manufacture or import (Sec 52).
- Parallel Import (Sec 58)
- Government to exploit a patent in a national emergency or in the public interest eg: security, nutrition, health or the development of a vital sector as determined by the Government (Sec 84).

In order to provide greater access to ARV drugs, the government takes the following actions:

- Provide free monotherapy in MOH hospitals.
- Provide free Highly Active Antiretroviral Treatment (HAART) to infected mothers after delivery, infected children, healthcare workers infected in the line of duty and patients infected through contaminated products/blood transfusion.
- Provide 1 free drug to other patients on HAART and require them to purchase 2 drugs. This is to ensure commitment to treatment.

To increase access to ARV drugs, the government tried to reduce the prices of HIV drugs through negotiations with patent holders as well as encourage local production of drugs not patented in Malaysia. The government also made use of Government's rights under the Patents Act 1983.

Thus, in November 2002, the Ministry of Health (MOH) submitted a paper to the Cabinet to import generic ARV from India (drugs under patent). The Cabinet approved the request based on Section 84 of the Patents Act 1983 which provides for Government's Rights to exploit a patent for public non-commercial use for reasons of health, emergencies or national interest. Then in January 2003, the MOH began price negotiations with Cipla's representative and applied for Compulsory Licence (CL).

There were some pressures on the MOH not issue the CL. In March 2003 other agencies asked MOH to reconsider issuing CL. In the meantime GSK offered to drop price for Combivir by 57%. GSK also met with the Minister of Health for further negotiations and dropped the prices of 3TC, AZT and Combivir by 31% - 57%. But MOH decided to proceed with the import of non-patented drugs first.

In August 2003, again other agencies suggested that the MOH does not use Compulsory Licence. But in November, the MOH obtained CL from the Ministry of Domestic Trade for AZT, ddI and Combivir. And, in February 2004, the Cabinet authorized MOH to proceed with CL despite request from another agency to the Cabinet to reconsider its decision. The MOH then issued contract to import generic Zidovudine, Combivir and Didanosine.

Once the generic drugs from India came, prices of patented price dropped and once the prices dropped, the monthly cost of treatment per patient also dropped.

There are other benefits arising from the issuance of CL, aside from price reductions. The success story has encouraged local manufacture of drugs that are not patented in Malaysia. To that end, in February 2004, the MOH received a proposal from local manufacturer to manufacture 3-in-1 ARV combination. In October 2004, the local manufacturer approached the patent owner for voluntary license. In addition, patent holders are currently more cooperative and willing to engage in dialogue with the MOH.

On the issue of compensation, the MOH proposed 4% of value of stocks actually delivered. So far, patent holders show no interest in claiming compensation. There may be several reasons for this ranging from reluctance to set a precedent to showing acceptance of MOH rights.

The Government's Rights license ends in November 2005. There are two options for MOH: negotiate prices of patented products to an acceptable level or apply for renewal of Government's Rights license.

Zhao Hong from the Ministry of Commerce of China speaking on China's recent experiences in Public Health oriented measures stated that China has a fairly comprehensive legal framework for the protection of public health. There are several laws, regulations and measures, including among others prevention of HIV/AIDS, SARS and protection of varieties of Chinese medicine.

The legal basis for compulsory license is Article 49 of the 1992 Patent Law. It says, “*where a national emergency or any extraordinary state of affairs occurs, or where the public interests so require, the Patent Administration Department under the State Council may grant a compulsory license to exploit the patent for invention or utility model*”. Measures for Compulsory License for Patent Exploitation, adopted on 13 June 2003, and in force since 15 July 2003. However no CL has ever been issued for the purpose of public interest thus far.

This does not mean that there are no serious public health problems in China. The HIV/AIDS is a case study for public health issue. By end of 2003, it was estimated there were 840,000 HIV cases and 80,000 AIDS, although the number of cases reported is often less. It is estimated there were 2,359 death cases related to HIV/AIDS. Most HIV positive live in rural areas, with most of the infections affecting young adults. Infection among females is also increasing. There is an urgent need for treatment and prevention to control the epidemic in China.

The Chinese government considers HIV/AIDS prevention and treatment an important task. And therefore, the Government is committed to provide free medicines for HIV/AIDS patients who are in economic difficulties. This program will cover low-income HIV/AIDS patients in urban areas and all patients in rural areas. The government Initiated China CARES Program (China Comprehensive AIDS Response Area:in 51 counties nation wide). It focuses on ARV treatment as key intervention. And this is where price becomes an important issue.

Before 2003 imported drugs cost 8000 to 10000 RMB a month. With domestic production after 2003, the price of ARV drugs dropped to 400-500 RMB a month and it can be reduced further. The precondition for local production of ARV is that it is allowed only for products whose patents have expired.

In such a situation, the government should have taken measures to issue CL. This did not happen because China is under a great pressure from its powerful trading partners for IP enforcement. This is evident from the changes in the Patent Law. The 1984 did not provide IP protection for medicine and chemical compounds, as is the case with India. But, under pressures, that law was amended in 1992, to allow IP protection for medicine and chemical compounds.

But the situation in China is different from India, and nothing should hamper the Chinese government in taking public health measures. AIDS is one of the urgent public health issues and public policy is important for addressing the issue. There are many challenges ahead and quick responses are required. One of them is access to affordable drugs which is still hampered by patent protection. The government needs to move step by step to address this problem.

Presenting Indonesia's experience on access to generic ARVs drugs, **Frida Trihadi from the National Agency of Drug and Food Control, Indonesia** said like in many other countries, HIV prevalence has increased exponentially over the last few years in

Indonesia. By end of March 2002, there were 689 reported AIDS cases and 2.187 reported HIV-infection. The Ministry of Health (MOH) estimates HIV-infection at between 90.000 and 130.000 cases. In response, the Government of Indonesia intends to provide ARV to at least 5000 persons in 2004 and at 10,000 persons in 2005.

To increase access to ARVS, the government took the following measures:

- Enact a Fast track system for Drug Registration
- Import ARVs, using a 'special access scheme' from India and Thailand.
- Negotiate price with innovator to decrease the price and to eliminate distribution cost

However, to ensure sustainability of ARV supply at an affordable price, local production was one of the most effective measures. This can be directly and legally attempted if a product is not patented in the country. As in other countries, if a product is patented, production will be possible through voluntary and compulsory licensing. In Indonesia, voluntary licensing should be based on government regulation to determine patent fee or royalty and price control. While practically CL is difficult to apply because of the bureaucratic hurdles and difficult negotiations.

The most practical solution, therefore, is implementing the Rights of the Government to exploit patent. Based on this, the Government of Indonesia issued Government Regulation Number 27/2004 dated October 5th 2004 regarding Procedure of Patent Implementation by the Government and implemented by Presidential Decree Number 83/2004 dated October 5th, 2004 regarding Government Patent Implementation on Antiretroviral Drugs, in order to produce lamivudine and nevirapine locally.

The MOH may appoint a Pharmaceutical Factory for and on behalf of the Government to exploit the Patent, taking into account the recommendations of National Drug and Food Control Authority (NA-DFC). Also the Government shall give a 0.5 % compensation fee of net selling value of Anti Retroviral Drugs to the Patent Holder.

Meanwhile, Kimia Farma (a state owned pharmaceutical company) had submitted a proposal to produce ARV , at the cost 380.000 Rp/month (approx 47 US\$ for a triple regiment. The government is now considering that proposal.

The process of obtaining a Government Use Regulation had not been easy. The main problem was convincing government officials from other departments not to succumb to pressures from big pharmaceutical companies. So far, there has not been a serious challenge to the above regulation.

Yvonne Nkrumah representing the Food and Drugs Board in Ghana said that the price and CL issues are also crucial for public health in Africa. There are 6 million people infected with HIV/AIDS in Africa out of which 4.4 million is from sub-Saharan Africa, and 30% are in Southern Africa. South Africa and Zimbabwe had issued CL to procure ARVs from India.

In West Africa, Malaria is the number one cause of death as is the case in Ghana. On average one individual will suffer from Malaria at least 3 times or more during his/her lifetime. There is growing resistance to Chloroquine, the cost of which is US\$ 10 cents. To combat emerging drug resistance, Coartem (from Novartis) is used at the cost of US\$4, which is 200 times more expensive than Chloroquine. In Ghana the government provides most of the drugs in the public sector. Such a high price would hinder public health services thus far provided by the government.

However, the government of Ghana has not issued a compulsory license. Since most of the medicine in the country is imported, there is a need to amend the laws to include CL

for imports. As most of the drugs in Ghana comes from manufacturers in India and Thailand, these countries too should amend their laws to include compulsory licensing for exports. Access to drugs from these countries is important for public health service in countries like Ghana.

Session 3 – Health and Intellectual Property Rights: Thoughts on ensuring access to medicines in 2005 and beyond

Karin Timmermans once again addressing the gathering on Health and Intellectual Property Rights: Thoughts on Ensuring Access to Medicines in 2005 and beyond said to map strategies for access to medicines in 2005 and beyond, we need to look at two perspectives, i.e. new drugs with some patent term left; and future drugs which have not been developed yet.

In terms of new drugs it is necessary to identify patent issues of new drugs (where some patent term is still remaining) such as multiple patents and getting patent information is put in the public domain. Also there is lack of expertise at the country level to interpret patent claims. In India there is also the issue of mailbox applications in which more 6,000 applications are pending.

Some of the short term options to address the issue are as follows:

- Strict criteria for novelty & inventiveness must be applied, including no patents on polymorphs, dosage forms, formulations, 'new use', etc.
- Patent information must be easily accessible for instance through a searchable on-line database.
- The generic industry associations need to play an active role in monitoring patents, informing members about them and challenging pre-grant of trivial patents.
- Countries must ensure that domestic laws incorporate all TRIPS-safeguards and the 30 August Decision, while making sure that these laws are easy to implement. Learn from the experience of other countries in using safeguards in national laws.
- Countries need to avoid FTAs that impose TRIPS-plus measures.
- Countries must negotiate Voluntary Licenses at reasonable royalties and affordable prices.

On future drugs that have not been developed, we need to ask the basic question, whether the current model can deliver public health. The following statistics reflect the above statement. Only 30% of all new drugs introduced in 7 major pharmaceutical markets between 1975 and 1994, were "adding something to therapy". Of 1,223 new chemical entities commercialized between 1975 and 1997, only 13 (1%) are specifically for the treatment of tropical diseases. Five to six million people currently infected with HIV in the developing world need access to antiretroviral therapy to survive, but only 40,000 have this access.

Currently we are in a transition period and it is time to ask relevant questions as well as propose some actions. The first issue is how to change R & D priorities in order to meet public health needs. Some relevant actions would be:

- Domestic companies (in developing countries) need to have different R & D systems.
- Promote domestic production. There are three issues here. First whether it is viable for every country in terms of economize of scale, especially in countries that lack production capacity at this point. Secondly, collaboration with developed countries and MNCs. For example, large firms in China and India have moved to conducting R & D and collaborating with MNCs in order to continue the generic business. But this will not move very quickly. Third is the sourcing of

API. Not all APIs are patented or patentable; thus it may be feasible to think of promoting new investment in API production, but again based on economies of scale.

- Public-private partnerships to change R & D priorities. There are examples such as : Medicines for Malaria Venture, Global Alliance for TB Drug Development, Drugs for Neglected Diseases Initiative. But these initiatives need to be assessed based on they are able to develop new drugs and, if they do develop new drugs will they be available to people who really need them.

The second issue is drugs produced through biotechnology or bio-pharmas which can be considered as future pharmaceuticals. There are bio-generics being marketed yet. This is partly due to heavy patenting of processes and research tools which have hindered and delayed research. Another reason is the lack of regulatory standards for 'bio-generics'. The US is in the process of developing standards for bio-generics. But developing countries should also define their own standards in order to ensure that their interests can also be protected.

The third issue is of course patents. Developing countries need to insist on sufficient disclosure in patents. Next they can establish a patent bank or broker, who matches abandoned patents (or technology) for neglected diseases with producers in developing countries. Finally the possibility of pooling resources in a (virtual) regional patent office needs to be explored.

Finally there is the issue of pricing. As has been the experience of MSF in drug procurement, prices differ in different countries. Developing countries might want to formulate an international treaty on differential pricing for medicines to overcome price barrier. Also, the possibility of a role for 'non-profit manufacturing' needs to be explored in order to provide access to drugs at more affordable prices.

In facing the challenges above, developing countries need to be vigilant, based on the following strategies:

- Be more critical
- Be more assertive
- Increase openness
- Be more inclusive
- And, coordinate.

Pascale Boulet from the Campaign for Access to Essential Medicines, MSF

delivered her address on Access to medicines at risk - What to watch out for in US Free Trade Agreements. The US has been at the forefront in forging Free Trade Agreements (FTAs), with individual countries bilaterally or with a group of countries in a region. It has concluded FTAs with Jordan, Chile, Singapore, Central America (CAFTA), Morocco, Australia, Bahrain. The US is also in the process of negotiating FTAs with the Andean countries (Colombia, Ecuador, Peru), FTAA, Panama, SACU (Botswana, Lesotho, Namibia, South Africa, Swaziland), Thailand, and perhaps Laos.

There are public health related problems arising from these FTAs. The objective of the US is to strengthen the rights of IP holders beyond the minimum requirements of TRIPS, to comply with the US laws. These provisions overrule TRIPS and the Doha Declaration. Worse still, the FTAs are not negotiated in a transparent manner. The draft agreements are not made public before conclusion. Actually there is no true negotiations taking place, the US provides "take or leave IP proposal" and the participating countries are forced to agree to those 'proposals'.

The following are the IP restrictions that the US propose in the FTAs:

- 5-year data (market) exclusivity

- New role of ‘patent police’ for drug regulatory authorities (DRAs)
- Additional patent monopoly for new uses of known compounds
- Restrictions to countries’ right to issue compulsory licenses
- Patent extension beyond 20 years

She discussed some of the issues, the first one being **data exclusivity**. The provision for data exclusivity creates exclusive rights over test data required to show efficacy and safety of a medicine. It also prevents DRA to approve generics on the basis of original test data and this would last for 5 years following the date of approval of the original medicine. Data exclusivity is not related to whether the medicine is patented, but it has the same monopoly effect. Furthermore data protection is maintained by drug authority. The following are the effects of data exclusivity provision:

- Generic competition will be delayed for 5 years (in particular when the medicine is not even patented)
- Effective use of compulsory licenses is paralysed for 5 years because generic medicine cannot get registered
- Even if original medicine is not marketed, generics are not allowed to be marketed this means there would be a risk of a certain drug will not be marketed at all if the originator is not interested.

This is actually a TRIPS plus provision because Article 39 requires *ONLY* to “*protect ... test data against unfair commercial use ... [and] disclosure*”. Thus there is no mention of *exclusivity*, and there is no specified period of protection. And this is even waived for LDCs until 2016 based on the Doha Declaration.

The second issue deals with the role of DRAs as ‘patent police’. The effects would include :

- No generic approval during the lifetime of the patent
- Public health agencies will be requested to enforce private commercial rights instead of concentrating on public health services
- Enforcement of bad quality patents without assessment which is normally the role of the court
- Use of compulsory licenses blocked.

None of the above issues is required by TRIPS.

Next is the issue of additional patents for new uses. A country will be obliged, through FTAs to grant patents to protect any new therapeutic use of known medicine. This would mean an additional 20-year monopoly for a known product (already patented). It would also be impossible to prescribe generic versions of the medicine for the new indication. In effect this is a weakening of patentability standards because actually there is a lack of novelty. And, again this is TRIPS plus because TRIPS only require patents for “products and process”.

The US also tries to restrict compulsory licensing through FTAs by requiring participating countries to refrain from using their inherent right to grant compulsory licenses for whatever reason, as acknowledged by Doha Declaration. Countries are also required to limit measures to create competition from generic drugs in order to lower drug prices. The last issue deals with patent extension beyond 20 years. The US requests this as a compensation for (unreasonable) delays in drug marketing approval or in patent granting. This would extend patent monopoly and high prices beyond the usual 20 years. The US also wants developing countries to grant patents straight away without proper examination; this would lead to granting bad quality patents. Again, none of these is required by TRIPS.

To conclude, TRIPS plus provisions in FTAs prevent countries parties to FTAs to make use of TRIPS flexibilities and especially to promote access to medicines for all as confirmed by Doha Declaration. IP rights are already well protected under TRIPS and therefore countries can reject additional IP protection in free trade agreements. Developing countries should not “trade” away public health by making sure that FTAs have no provisions that will erode the Doha declaration.

Implications of FTAs on Access to Medicines: Thailand experience

Jiraporn Limpananont from the Faculty of Pharmaceutical Sciences, Chulalongkorn University based her delivery on the implications of Free Trade Agreements on Access to Medicines: Thailand experience.

The US-Thai FTA will have several implications on public health in Thailand. During the negotiations, the US forced Thailand to become a member of other international agreements such as UPOV 1991 and the Patent Corporation Treaty.

The US will force Thailand to take stronger IP protection measures, as has been done in the US-Singapore FTA, such as

- Extension of patent term
- Market Exclusivity via Data Exclusivity
- Limit the use of Compulsory Licensing and Parallel Imports
- Provide patent protection on plants and animals and use UPOV to protect IP over plant varieties.

In this case, Thailand needs to learn from past experiences. The country’s 1979 Patent Act excluded pharmaceutical products from patentability, although processes in pharmaceuticals could be patented. Under trade pressure from the US, Thailand amended its patent law in 1986 to include all inventions especially pharmaceutical products. Then again the patent law was amended 1992, so that Thailand did not enjoy the 6 year transition period for developing countries in implementing TRIPS. One of the items amended was extending the patent period from 15 years to 20 years. At present the U.S. uses FTA to again pressurize Thailand to yet again strengthen IP protection. One of the most important issues is extension of market exclusivity from 20 to 25 year, through the introduction of data exclusivity.

The public health implications of IP protection are apparent twelve years after the 1992 Patent Law amendment. Thailand is now facing increased price of patented drugs, drug accessibility problems, the slow down of technology development of Thai local drug industries and the decreasing market share to imported drugs. For example, in the past Thailand had a drug patent committee whose task was to control the price of patented drugs. After ratification of TRIPS, that committee had to be abolished and therefore at present there is no control over domestic drug prices.

The situation might be worse if US-Thai FTA is not amended. Such an FTA should limited to the trade issues and exclude IPR on pharmaceuticals from the negotiation agenda, taking into account that access to drugs is a human rights issue. It is also important that the FTA negotiations do not create a TRIPS plus condition, and/or any restrictions on the use of TRIPS flexibilities.

Finally, the FTA negotiation process should provide opportunity for full stakeholder participation. One way to do this is to ensure that draft agreements are drawn up in the national language as well as English. Finally, Thailand should reject joining UPOV, and instead join the CBD.

The potential impact of the Australia-USA Free Trade Agreement (AUSFTA) on Australia's Pharmaceuticals Benefit Scheme

Sanya Smith from Australia explained Australia's Pharmaceutical Benefits Scheme (PBS) and the potential impact of Australia - USA Free Trade Agreement (AUSFTA) on PBS. The AUSFTA was signed on 18 May 2004 and is scheduled to come into force on 1 January 2005. The necessary implementing legislation has been passed by the Australian Parliament on 13 August 2004. The AUSFTA is the first international trade agreement to include specific commitments that relate to domestic pharmaceutical pricing systems, the details of which are still being finalized.

The negotiation process and potential impacts of AUSFTA are not different from the FTAs between US and developing countries. For instance, in the agreement text there is "constructive ambiguity" on politically sensitive issues so they can be worked out by bureaucrats behind closed doors away from public attention. Also, The AUSFTA apparently is the first to include special provisions addressing market access for pharmaceuticals.

In reality, Australia is not a big market, but because the PBS is being used as a model for pharmaceutical cost effectiveness pricing systems internationally challenging the validity of this system in Australia has global precedent setting benefits. Indeed it is estimated at a very conservative level that Australia's PBS will have to pay at least one third more (i.e. rise by more than 30%) for its drugs with the FTA than without it. If the likely FTA effects are applied to 2003 figures, the extra cost of the PBS to the government last year would have been around \$1.5 billion for the same drugs at the same levels of use and with no increase in the health benefit to Australian patients. Through the AUSFTA, the USA expects prices of medicines in Australia to rise

In addition, the following impacts are predicted as the AUSFTA comes into force:

- There will be a delay in the introduction of generics and decrease of prices,
- There will likely be detrimental effects through the increased influence the AUSFTA is likely to give pharmaceutical companies although the full effects will not be felt for 5 years as it mostly applies to new drugs and it will take a while for the new legislation to take effect.
- It will prevent future Australian governments from removing Australia's TRIPS plus provisions (unless they are prepared to pay the penalties in the AUSFTA). Some examples of existing TRIPS plus provisions in the AUSFTA are: (a) 5 years of data exclusivity, (b) patent extensions to compensate for unreasonable delay in marketing approval/patent issuing process, (c) patentee's right to restrict parallel importing.

Support from USA Possible?

In the process of the AUSFTA negotiations, it was discovered that there are possible support against TRIPS plus provisions from within the US, i.e. from parliamentary representatives. The following illustrates such support.

- 'Domestic healthcare policy should not be decided in trade agreements--It is wrong for us to interfere with another country's domestic health policy, particularly when it comes to the affordability of medicine which is an equally sensitive issue here in the US (Representative Henry Waxman speaking during US Congressional debate on the FTA, US Congressional Record- Extensions of Remarks, 16 July 2004, p.E1397-E1398).
- Mark Udall: I am concerned about the potential precedent of the Administration meddling excessively in the internal affairs of a trading partner. With regard to

this treaty, the USTR initially sought substantial changes in Australia's drug-pricing program. Though the USTR was not completely successful, the agreement does give U.S. drug companies more say in what drugs are included under Australia's universal drug coverage program. While market access for U.S. goods is important, we shouldn't be in the business of bullying the world and potentially undermining a country's ability to provide prescription drugs to its citizens (Udall, 2004).

-'By the [Bush] Administration's own admission, this FTA is part of a larger policy designed to dismantle so-called drug price control/reference pricing systems in other countries. I question whether it is appropriate to use trade policy to interfere in other nations' health systems. We certainly wouldn't accept such a demand from other countries. The United States will win no friends if our trade agenda becomes a heavy handed tool to raise drug prices on the citizens of our trading partners'

But how far such a support can change US policies in the FTA is questionable.

CONCLUSIONS AND RECOMMENDATIONS OF THE WORKSHOP

1. Participants stressed that access to medicines and health services are vital for the Asian region, especially since this region has the largest share of the world's people. They also noted that the globalization process has had an impact on health care. Women, children and the elderly are among the most affected. There was also concern expressed over the loss of purchasing power among the impoverished that worsened access to medicines and health care.
2. The workshop heard presentations and discussed the relationship between patents, prices and access to medicines. Data on prices of various products within and across Asian countries were presented by resource persons showing that prices of branded products are significantly (and often greatly) higher than similar generic products, and also that the presence of generics brings down the prices of branded products in the same country. Countries that do not have access to generics pay much higher prices than those that do have such access for the same products. It is therefore essential that patented drugs do not enjoy monopoly and that competition from generics should be enabled, so that the patients have more choice and prices can be brought down. Many participants also called for price controls to be placed by governments on medicines since these are essential items.
3. The Workshop also discussed how the TRIPS Agreement, by requiring patentability of medicines under certain minimum standards, has constrained the ability of governments to institute pro-health policies, such as the exclusion of medicines from patentability, which some Asian countries had done prior to the coming into force of TRIPS. The Doha Declaration has clarified that there are some flexibilities and safeguards including the ability of governments to implement measures such as compulsory licensing, government use/rights and parallel importing, to offset the monopoly of patents.
4. Many participants asked that governments undertake a serious review process of TRIPS so as to expand the policy flexibilities in TRIPS, for example to consider that countries are enabled to exclude patents on medicines and food,. Several speakers pointed out that before TRIPS, countries had excluded medicines from patentability, for example in the India Patent Act 1970.
5. In the immediate term, governments are urged to urgently review their patent laws and amending them to bring them in line with the best options and provisions possible, especially in light of the Doha Declaration on TRIPS and Public Health. The patent laws should enable the country to provide compulsory licenses, government use orders and parallel importing in simple and effective ways. The governments in the region should then exercise their rights by taking these measures required to treat ailments. The workshop recommended that the Manual on Good Practices in Public Health Oriented Patent Policies and Laws and its supplement (published by TWN) be used as a key reference point for review of policies and laws.
6. The participants expressed concern and also anxiety whether there will be continued and expanded supply of medicines to countries that have no or inadequate manufacturing capacity. This arises from a constraint in TRIPS Article 31(f) that production under compulsory license has to supply predominantly for the domestic market, thus limiting export supply. The "interim solution" to this through the WTO's 30 August 2003 decision was found by participants to be impractical for dealing with this problem. Many participants pointed out that the measures required, such as notification of amounts of drugs and special labeling and packaging, on top of the issuing of compulsory licenses, will most likely deter generic drug producers from making use of this mechanism. They called for a more appropriate permanent solution that revises TRIPS and that removes the Article 31(f) constraint without placing new constraints so that the export and import of generic drugs can be smoothly facilitated.
7. The participants were concerned about the post-2005 situation since an important generic-producing country, India, has to start allowing drug product patent applications, under its TRIPS obligation. Participants urged that the proposed amendments to the India Patent Act 1970 should be made in ways that take full advantage of the rights and flexibilities

of the TRIPS agreement and the Doha Declaration, and that obligations that are not required by TRIPS (that are i.e. TRIPS-plus) need not be included. Many participants signed a joint letter drafted during the workshop to the President and Prime Minister of India to this effect. The participants also hope and expect that the relevant Indian authorities will establish systems that enable applications for compulsory licenses to be rapidly processed and acted on. It was emphasized that it is critical that the supply of generic drugs from India should not be reduced or hampered, including to African countries, in the new post-2005 situation.

8. The workshop participants also heard presentations from drug generic producers or their representatives from Thailand, India and China about their activities, problems and prospects. The participants expressed that it was important for generic producers to maintain and increase their capacity, and for countries in the region to develop local manufacturing capacity. Generic producers were urged to organize themselves better nationally as well as regionally and be able to meet the challenges as well as represent their case for compulsory licenses, where needed and for expanded production to the governments.

9. The workshop heard presentations from several countries about the pro-health measures they have taken recently or are contemplating. The participants were greatly encouraged and very much welcomed the presentations of Malaysia and Indonesia which provided information on the recent government use orders they had each undertaken for the import (Malaysia) or local production (Indonesia) of HIV-AIDS anti-retroviral drugs. These measures were seen as milestones of progress in the region for the provision of more affordable medicines. The experiences of countries outside the region, such as Zambia, Mozambique and Zimbabwe which have recently issued compulsory licenses were also discussed, and also the experiences of the developed countries such as the UK and US.

10. The workshop heard presentations on the nature of the bilateral free trade agreements that have been concluded, for example between the US and many countries or regions around the world, and of similar agreements that are currently being negotiated, for example with Thailand. Participants were extremely concerned that many aspects of the IPR chapters of these agreements removed or eroded the flexibilities available in TRIPS and the Doha Declaration. The FTAs for example seek to extend the lifespan of drug patents, establish exclusive rights over test data (which would prevent generic products from being registered) and restrict the grounds for compulsory licenses. These negative traits are likely to appear in FTAs that Asian countries are negotiating with the US, unless the governments are alert and reject such TRIPS-plus proposals. The participants expressed support for the Thai movements and NGOs that are working to ensure that the US-Thai FTA does not include such negative traits, and pledged to undertake activities to prevent such negative traits in other bilateral or regional FTAs.

11. The workshop discussed issues and processes related to drug regulation and registration and good practices in procurement of drugs. It was stressed that all drugs distributed (whether by innovators or generic producers) should meet the requirements of quality, safety and efficacy. Presentations in the workshop clarified that the TRIPS Agreement does not require that exclusive rights be granted over the test data submitted for the approval of the originator drugs. There was concern among participants that a major developed country is attempting to have Asian countries accept that exclusive rights over test data be granted to the originator drug company, through FTAs. Participants expressed the view that this would have extremely damaging effects on access to medicines, as this would block the implementation of supply (through import or production) of generic drugs to compete with originator drugs including those that are not patented in the country. A presentation was also made about good practices in negotiations with companies to reduce prices during the procurement exercise. The WHO's system of prequalification was recognized as an important mechanism for countries to choose medicines that meet the safety and efficacy tests; the system should be improved further to suit the needs of developing countries.

12. Some participants also brought up the problem posed by the patenting of life forms and the protection of intellectual property regarding plant varieties, which arose from Article 27.3(b) of the TRIPS Agreement. They urged that patenting of life-forms should be prohibited and that the seeds and other genetic resources of farmers should not be subjected to patenting or IP protection having similar effects. As this affects food security and access to food, it is also a health issue.

RECOMMENDATIONS

1. Governments are urged to initiate or continue review of patent laws and amend these to take full advantage of flexibilities in TRIPS and the Doha Declaration
2. A committee or group of experts should be made available to the governments and NGOs to assist in the law review and amendments.
3. National patent laws should set appropriate scope and criteria for patentability and patents so that frivolous and ineligible applications are not entertained.
4. The review of TRIPS should be taken seriously by Asian governments which should advocate reforms so that flexibilities can be expanded in relation to access to medicines, including consideration to allow exclusion of medicines from patentability.
5. Policy makers should seriously consider taking safeguard measures such as compulsory license, government use and parallel importation, to facilitate access to affordable medicines to the public.
6. Best practices in legislation and policies on safeguard measures should be shared among countries in the region.
7. The TWN Manual on Good Practices in Public Health Sensitive Patent Policies and Laws was adopted by the workshop as a valuable resource and reference material.
8. There should be closer collaboration among relevant departments and Ministries (health ministry, trade ministry, patent office, attorney general office, etc) on the basis of protecting and promoting public health interests.

9. Fast track registration mechanism should be established for generic drugs that are required to treat serious ailments.
10. There should be priority to activities to sensitise policy makers so that there will be strong political will to establish health-sensitive laws and policies regarding patents and access to medicines and safeguard measures.
11. Pool procurement for essential drugs in the region should be explored.
12. It was also agreed that regional patent pools among groups of states should be explored, aimed at sharing patents and licenses through international agreements to provide essential medicines at affordable costs to citizens.
13. National databases on patents and patent applications for pharmaceutical products should be set up and made available to the public to enable appropriate responses if needed.
14. A regional centre or network for collection of information on drug patents should be set up, from where people can access the information.
15. Guidelines for procurement of medicines should be drawn up.
16. The organizers (TWN, HAIAP), and the WHO, etc. should set up a stronger system to assist developing countries to understand international IP regimes (e.g. TRIPS), and options for patent laws, so that countries can choose the appropriate options.
17. Awareness for the public and policy makers on patents and access to medicines should be raised through national workshops and seminars which raise the problems and increase knowledge about options in patent laws and safeguard measures, etc.
18. Information dissemination on these issues should be expanded.
19. Technical support and technical assistance should be provided to policy makers and NGOs that would like to act on these issues.
20. Policy makers in Asia should be on the alert and reject proposals in free trade agreements that introduce TRIPS-plus obligations such as data exclusivity, extension of patent term, linking drug registration to patents and limiting the grounds for compulsory license, etc. NGOs and health movements should strengthen their work to raise awareness and prevent these types of provisions. Regional cooperation among policy makers and NGOs/social movements on this issue is urgently required.
21. Urgent measures must be taken to ensure that in the post 2005 situation, that there should not be a break or reduction or disruption to the supply of required drugs from generic producers in exporting countries to importing countries in Asia as well as Africa and other developing regions.
22. International agencies especially the WHO and UNDP should expand their capacity to assist countries in the region in a wide range of issues and activities, including information, analysis and assistance on issues relating to patents and access to medicines.
23. The co-organisers, TWN and HAIAP are requested to review the proposals put forward in the workshop and to initiate work programme and activities to implement as many of them as possible.
24. Similar regional workshops should be organized every one or two years so that policy makers and health movements can share information and experiences and improve laws, policies and practices.
25. Participants agreed that: We reaffirm our commitment to provide essential medicines and health services so as to protect and promote public health. There is a crucial need to make medicines affordable and accessible to all the people. We call on policy makers, parliamentarians, international and regional organizations, and all other organizations to act urgently as lives and health of people in the region are at stake.

Report compiled by Hira Jhamtani, Third World Network Associate for Indonesia/Asia For further information about the workshops please write to passanna@haiap.org or log onto our website on www.haiap.org.

- Network News -

ASIA AND TH PACIFIC

Enhancement of consumer safety and rational use of drug: an important role of Drug and Therapeutics Committee (DTC)

It is a well accepted statement that no drug is absolutely free from Adverse Drug Reactions (ADRs). ADRs are responsible for a significant number of hospital admissions, major causes for patient non-adherence, increased healthcare costs and diminished quality of life. ADRs also contribute to morbidity and are known to cause death. There are several means through which drug safety can be ensured. Drug and Therapeutics Committee (DTC) is a policy framing and recommending body on matters related to the drug use in hospitals, comprising of doctors, pharmacists and nurses. The role of DTC becomes much more important in a country especially where pharmacovigilance program is not well established and there is no other avenue available for monitoring ADRs. The DTC of Manipal Teaching Hospital (MTH), Pokhara, Nepal has been performing a professional and important role in ensuring drug safety in the hospital. The DTC of the

MTH met in February 2005 and decided to withdraw all the products containing phenylpropanolamine, combination products of cloxacillin with ampicillin and amoxicillin and did not approve the use of nimesulide in the hospital.

Withdrawal of Phenylpropanolamine (PPA)

PPA is a sympathomimetic agent used to relieve nasal congestion associated with the common cold, acute or chronic rhinitis, hay fever and other respiratory allergies and to reduce weight. The result of a study named “PPA and risk of hemorrhagic stroke: final report of the hemorrhagic stroke project” (2000) reported an association between PPA use and hemorrhagic stroke in women. The increase in risk of haemorrhagic stroke was found for women using PPA for weight reduction and as nasal decongestant. Based on this safety data and other available reports, the DTC of MTH decided to ban all the preparations having PPA in them for use in the hospital.

Nimesulide- denied for approval

Nimesulide is a non-steroidal anti-inflammatory drug (NSAID) used in the treatment of certain inflammatory conditions and fever. The hepatotoxic effects of the drug have created a major concern recently. There are several reports of fatal hepatotoxicity associated with the use of this drug and hence it is also banned in a few countries as well. Considering the possibility of hepatotoxicity due to the drug and the availability of other safer and effective alternatives, the DTC of MTH has decided not to approve this drug.

Withdrawal of irrational antibiotic combination

Although a fixed dose combination of Ampicillin + Cloxacillin and Amoxicillin + Cloxacillin is vigorously promoted for several infectious conditions, this combination is not recommended by any of the standard guidelines, formularies and supported only by minimal sources of drug information. The DTC of MTH strongly felt to discontinue these combinations from the hospital drug list to ensure consumers’ safety through rational use of drugs. However, these drugs are available separately and hence can be prescribed if found to be indispensable.

It is worth mentioning that all the above mentioned drugs and combinations are widely promoted and prescribed in Nepal and the Department of Drug Administration (DDA), Nepal, the regulatory body permits the use of the above mentioned drugs and combinations.

Source: Reported by Dr Pranaya Mishra our network partner at the Drug and Therapeutic Committee of Manipal Teaching Hospital (MTH), Pokhara, Nepal

Teaching and learning about rational use of medicines at the Manipal College of Medical Sciences, Nepal

Dr. P.Ravi Shankar from the Department of Pharmacology at the Manipal College of Medical Sciences, Pokhara, Nepal reports on how students are taught to choose and prescribe essential medicines rationally at the college. Among the various exercises carried out are solving common clinical problems, critical analysis of drug advertisements and drug promotional materials, assessing the rationality of prescriptions, evaluating drug use according to WHO/INRUD prescribing indicators and role plays detailing the interaction between medical representatives and prescribers.

Delivering drug and non-drug information to a simulated patient, selecting P-drugs (Personal-drugs) for common disease conditions, delineating drug use problems and possible steps for their solution in Pokhara city and Nepal are other exercises. The students visit the Drug Information Center (DIC) and become acquainted with different sources of drug information. The concept of Evidence-Based Medicine (EBM) is

introduced and the students are taught how to solve specific problems related to medicines using the resources available in the DIC.

The students also visit the Medication Counselling Center (MCC) and witness the patients being counseled regarding the use of various devices like metered dose inhaler, spacer, insulin pen, insulin syringe, rotahaler, suppositories, pessaries etc. Role plays are enacted by the students regarding counseling for common disease conditions. The student exercises are carried out in small groups and faculty members act as facilitators.

Topics like compliance and ways to improve it, adverse drug reactions (ADRs), ADR monitoring, and the various phases of testing before a drug can be introduced in the market. The randomized double-blind placebo-controlled clinical trial and the interpretation of the results of such trials are discussed. The learning process is problem-stimulated and activity-based. During visits to the Pharmacovigilance cell the students learn about the system of spontaneous reporting for adverse events carried out in our hospital. The importance of ADR reporting is emphasized and we are happy that a few students have reported adverse events to the cell during the clinical phase of their training. Visits to primary healthcare institutions in the periphery are organized in collaboration with the department of Community Medicine of our institution and the Essential Medicines for different levels of primary healthcare delivery in Nepal are discussed. (The Nepalese primary healthcare system operates at three levels. The level of first contact is usually the sub-health post followed by the health post and the primary health centre. The lists of Essential Medicines for the three levels are different.) The working of the Community Drug Programme is demonstrated.

Analysis of drug advertisements is carried out as a group activity and the groups are given advertisements from medical journals or other promotional material to analyze according to the WHO Criteria for Drug Promotion. The strengths and weaknesses of the advertisement, the points covered and the percentage (approx.) to which it meets the WHO criteria are elicited. The students plan out role plays of the interaction between Medical representatives (MRs) and prescribers. The role-plays are of around 4 to 5 minutes duration. We stress on optimizing time spent with MRs and the students are taught to take control of the discussion right from the start and to ask for monographs of the drug and compare the facts recited by the MR with those in the monograph. Reference materials for various claims made should be provided. Emphasis is laid on not accepting free gifts and invitation to dinners and other events hosted by the industry. The different groups present their role plays and this is followed by comments from the house and the facilitators.

Communication skills training is carried out for common diseases or problems like tuberculosis, leprosy, scabies, hypertension, bronchial asthma, diabetes mellitus, oral and injectable contraceptives, diarrhoea, amebic dysentery, acid peptic disease, insomnia, malaria and epilepsy. One student acts as the doctor and another as the patient. We emphasize the use of simple, non-technical language. The doctor is expected to define the patients' problem in simple language, suggest relevant lifestyle modifications and non-pharmacological measures. He/she is expected to make a proper choice of medicine/s, take a drug history and tell the patients how to use the medicines. Common and important adverse effects should be covered. We teach the importance of feedback (where the patient repeats the doctor's instructions) as a means of checking patient understanding. For devices like a metered dose inhaler or insulin pen the doctor is expected to demonstrate the correct use of the device to the patient.

The WHO Guide to Good Prescribing, the Essential Drugs Monitor, How to Investigate Drug Use in Health Facilities and the National List of Essential Drugs are used as course material. Copies of the publications are accessible to the students. The department publishes a quarterly Drug Information Bulletin which discusses various topics related to Rational Use of Medicines (RUM) and EBM and is often used as a reference material.

For guidelines regarding the framing of clinical problems the Teachers Guide to Good Prescribing is used as a reference.

The students are assessed in RUM during the practical examinations in Pharmacology. Assessment of communication skills is carried out using a standardized checklist and simulated patients. The students are asked to critically analyze a given drug advertisement, calculate prescribing indicators from the set of given prescriptions. Exercises on assessing the rationality of prescriptions are also included. Writing prescriptions and solving common clinical problems are other exercises.

RUM has been taught during the practical sessions in Pharmacology for over two years at our institution. Feedback obtained from the students through discussions and questionnaire-based surveys suggest that the students find the sessions on RUM interesting, informative and useful although there are no formal sessions on RUM during the clinical years of study.

It is recommended that training sessions on RUM for the interns and medical officers are taken up as a matter of priority. The sessions should be strengthened and continued during the clinical years of study.

Drug and Therapeutics Committees (DTCs) in Thai hospitals: Lessons learnt from a study of performance indicators

Hospital Drug and Therapeutic Committees (DTCs) are used with varying strategies and degrees of success, as a tool to improve rational drug use (RDU) in many countries. In Thailand, hospitals under the control of the Office of the Permanent Secretary, Ministry of Public Health (MOPH), were first required to set up DTCs [called Pharmacy and Therapeutics Committees, (PTCs)] in 1987, in accordance with directions in a Manual of Drug Management, The Office of the Permanent Secretary, B.E. 2530. The manual listed the expected structure, roles and responsibilities of DTCs. Since 1997, Thai hospitals have faced economic crises and the challenge of hospital quality improvement and accreditation, a new National List of Essential Medicines (NLEM), universal health care coverage and structural change in the MOPH.

The current situation of Thai DTCs including definitions of DTC good performance from the different perspectives of DTC stakeholders was explored in a doctoral research project. The project also examined the performance indicators that are currently being used and regarded as useful for evaluating DTCs in Thai hospitals. Ways of improving DTC performance and decision-making, such as improving the functioning of DTCs and/or providing external support were also considered.

A combination of quantitative and qualitative methodologies was used for data collection. The quantitative method used was a self-completed questionnaire survey. The survey aimed to seek broadly representative views of the current situation of Thai DTCs from a representative sample of 452 DTCs chairpersons and secretaries respectively in 25 regional hospitals, 67 provincial hospitals and 360 district hospitals.

Qualitative techniques were used to provide a better understanding of the situation and to supplement the quantitative research. The qualitative methods used were a field survey in 17 hospitals (consisted of two regional, three provincial, and 12 district hospitals) in four regions of Thailand. This field survey comprised a document review, in-depth interviews with ten key informants (the chairperson, the secretary or members of the DTC) and participant observation.

In addition, in-depth interviews were conducted with fifteen key informants and a focus group was held with 8 participants, all of them were internal and external DTC

stakeholders. The people involved were from the Thai Ministry of Public Health, the Food and Drug Administration, the Hospital Accreditation Institute, the Health Insurance Office, an University drug information Centre, Hospital DTCs and the pharmaceutical industry.

Finally, DTC meetings of three regional hospitals in southern Thailand were observed; the Chairpersons and Secretaries were interviewed and all DTC members including all Doctors and Pharmacists who had worked at least 3 years in each hospital were surveyed.

The data collection was conducted from mid-December 2002 to mid-December 2003. The questionnaire response rate was 36 per cent from DTC Chairpersons and 66 per cent from Secretaries. It was found that around 90 per cent of DTC Chairpersons were Hospital Directors and 90 per cent of Secretaries were Heads of Pharmacy Department. The average number of DTC members in regional, provincial and district hospitals was 19, 20, and 10 respectively.

In the fiscal year 2002 (October 2001 to September 2002), there were only two DTC meetings on average in regional and provincial hospitals. This was because of cost pressures caused by the introduction of universal health care coverage (30 baht scheme) into hospitals. DTC Chairpersons limited the number of meetings to delay the selection of new or expensive drugs into hospital drug lists and also limit the hospital drug lists as required by the MOPH. In district hospitals, there were only one to two DTC meetings on average because problems relating to drugs were already discussed at the monthly Administration Committee meetings. DTC meetings mainly focused on drug selection, consumption and budget problems as this was the main focus of the 1987 Manual. Members of DTCs usually played only a passive role, and subcommittee reports received little discussion.

There were 13, 12 and 15 performance indicators regarded as applied and important by both DTC Chairperson and Secretaries in regional, provincial and district hospitals, respectively. However, performance indicators selected by the regional hospitals were markedly different from those selected by the provincial and district hospitals with the exception of three indicators which were common to all hospitals. The three indicators that all agreed were important (and had been applied) were about drug selection:

- Is the DTC authorized to select drugs to be excluded and included in the hospital drug list?
- Does the DTC have a good document providing criteria for addition and deletion of drug in the hospital drug list?
- Does the DTC report the list of drug included in the hospital drug list?.

Additional DTC performance indicators recommended by participants were the number of DTC meetings, the number of drug items in hospital drug lists and indicators that related to drug selection process. In short, the performance indicator survey showed that the focus of Thai DTCs was primarily on drug selection with little attention paid to rational drug use.

The study found a number of internal and external barriers that prevented DTCs from functioning better. Internal barriers included the following:

- DTC Chairpersons were also Hospital Directors who were usually very busy; another reason for why only a few DTC meetings were held each year.
- The DTC Secretary was usually very busy with other tasks and was not given enough time for the preparation of meeting agendas and minutes.
- There was a lack of clarity and orientation with respect to the roles and responsibilities of DTC members.

External barriers included the following:

- There was no distinct organization supporting DTC performance.
- There were no recent local guidelines for DTC activities.
- There were no ongoing educational programs to assist DTC members.

A number of internal and external enablers were recommended by this study to address the above problems. Internal enablers included the following:

- Providing the DTC Chairperson and Secretary with a Manager who has complimentary professional, organizational and communication skills; and
- Reinvigorating DTC members and subcommittees by putting a greater focus on improving drug use, problem solving, performance indicators and better coordination between DTC and related hospital committees.
- Running more effective DTC meeting.
- Having a defined budget for DTC activities.
- Printed documents (newsletter, manual of standard drug treatment and drug list,) and other ways of DTC communication and promotion DTC activities.
- A mechanism to receive feedback from hospital staff regularly.

External enablers included the following:

- Updating the 1987 Manual to assist DTCs (using the World Health Organization (WHO) Management Sciences for Health (MSH) “Drug and Therapeutics Committees: A practical guide” as a model);
- Providing a website where DTC problems and solutions could be shared, including information from the MOPH to assist hospital drug procurement;
- Creating coordination between professional councils and universities to set up education programs about DTCs; and
- Requesting the Institute of Hospital Quality Improvement & Accreditation (HA-Thailand) to assess DTC performance indicators.

To reduce the barriers and implement the enablers established, it is recommended that a Thai National Rational Drug Use (RDU) Unit be established with links to supporting international agencies such as WHO and International Network for Rational Use of Drugs (INRUD). This unit would have responsibility for supporting DTCs as well as other functions.

An initial task of such a unit would be an updated DTC Manual containing practical guidance, including the additional performance indicators. Topics that this research has found to be particularly relevant to an updated Manual include an expanded list of DTC functions, structural models of DTCs and their various subcommittees or working groups, rational drug use activities, performance indicators, a yearly plan of DTC activities and sources of information and organizations to assist DTCs. As part of this research, a recent WHO-MSH manual on DTCs has been shortened, localized (and translated) to the Thai situation in order to provide the basis of an updated and practical Manual.

Additional tasks would be providing training courses for DTC members and assisting professional councils and universities to set up relevant education programs about DTCs in universities or colleges and establishing a website where DTC problems and solutions could be shared, including providing information from the MOPH to assist hospital drug procurement.

Finally, it is recommended that the RDU unit would liaise with the Thai Institute of Hospital Quality Improvement and Accreditation to establish a broader range of DTC performance indicators which would then be monitored on a regular basis.

Pharmaceutical Benefit Scheme 2003 – 2004

The Pharmaceutical Benefits Scheme (PBS) grew by 8 per cent in 2003–04; a slower rate than the 12 per cent pa average growth over the last decade. Nevertheless, the sustainability of the Scheme remained an ongoing concern given an aging population and the continued introduction of useful (but increasingly expensive) new medicines. There was also concern that the Australia-United States Free Trade Agreement could place further pressure on the Scheme. In 2003, as in 2002, the government proposed a 27 per cent increase in PBS patient co-payments and safety-net thresholds in order to transfer more of the cost of the PBS from the government to consumers. While this measure was initially blocked by the Senate, the forthcoming election resulted in the Labor Party eventually supporting this policy. Recommendations of the Pharmaceutical Benefits Advisory Committee to list, not list or defer a decision to list a medicine on the PBS were made publicly available for the first time and the full cost of PBS medicines appeared on medicine labels if the price was greater than the co-payment. Pharmaceutical reform in Victorian public hospitals designed to minimize PBS cost-shifting was evaluated and extended to other States and Territories. Programs promoting the quality use of medicines were further developed coordinated by the National Prescribing Service, Australian Divisions of General Practice and the Pharmacy Guild of Australia. The extensive uptake of computerized prescribing software by GPs produced benefits but also problems. The latter included pharmaceutical promotion occurring at the time of prescribing, failure to incorporate key sources of objective therapeutic information in the software and gross variation in the ability of various programs to detect important drug-drug interactions. These issues remain to be tackled.

Source: By Prof Kenneth Harvey, La Trobe University, Australia taken from The Australian and New Zealand Health Policy on <http://www.anzhealthpolicy.com>. The electronic version of the complete article can be found at <http://www.anzhealthpolicy.com/content/2/1/2>

Cooperating with Timor Leste

Timor Leste formerly known as East Timor has a population of 924, 642 and 13 districts, 65 sub-districts, 446 sucos (village municipalities). After more than 25 years occupation by Indonesia, following the Portuguese colonialism, a referendum led to national independence.

The post-referendum violence in Timor Leste, in 1999, devastated the whole country and obliterated the health system. The priority was to address immediate health needs and resource inequities and coordinate external assistance to the health sector. Simultaneously, long term health system development could not even be considered. It was necessary to react to external offers of support, demands for information and action and the sometimes clashing agendas of INGO's, the UN, other donors and external actors. Of the utmost importance, the East Timorese Health Staff organized themselves several months after the conflict to form the East Timorese Health Working Group (ETHWG). The ETHWG put together a plan and led the development of the health system throughout the 'interim' period leading up to the official formation of the Ministry of Health. There was a clear vision for the Health System and an activation plan to achieve it.

Current health responses

The current health system addresses priority life threatening diseases and illnesses within the community. Health services are delivered through the Basic Package of Services within the principles of the Health Policy Framework and the National Development Plan. The system is structured around a Primary Health Care framework extending basic services and interventions right to the community.

In June 2005, a Conference, Cooperating with Timor Leste was organized by the Victoria University and the Australia - East Timor Association. The aim was to explore how Australians and others can help the East Timorese consolidate their independence through effective dialogue and cooperation. It would examine what is involved in good practice for collaboration in a wide range of fields to help strengthen democracy and build capacity for sustainability.

Beverly Snell and Clement Malau from The Centre for International Health, Macfarlane Burnet Institute for Medical Research and Public Health were responsible for convening the health sector sessions in the Conference. Detailed consultation with the Ministry of Health was undertaken to develop an approach that would allow East Timorese to lead the discussions within a capacity building environment. Four delegates from the Timor Leste Ministry of Health were sponsored to participate. They were Dr Nelson Martins from the Universidade de la Paz in Timor Leste and Informal Advisor to the Ministry of Health; Dr Odete Maria Freitas Belo, District Health Officer, Viqueque; Ms Lidia Gomes, MCH and Ms Misliza Vital IMCI.

Among the major problems in Timor Leste are extremely high infant mortality and maternal mortality. Lidia Gomes described the components and interventions included in the Reproductive Health Strategy that were directed to improving the all round health of women. They included: Young People's Sexual and Reproductive Health, Reproductive Choice (Family Planning), Safe Motherhood and General Reproductive Health. Misliza Vital explained that Integrated Management of Childhood Illness (IMCI) is the main child health strategy for Timor Leste at the moment. It is an integrated approach to child health that focuses on the well-being of the whole child under 5 years of age. IMCI includes both preventive and curative elements that are implemented by families and communities as well as by health facilities. It covers the main problems that affect Timor Leste children: upper and lower respiratory infections, diarrhoeal diseases, malaria and other fevers and malnutrition.

The importance of a strong health system from village to central level was stressed by Dr Martins. Dr Odete Belo provided a picture of activities at the District levels, the first point of access for most of the population. Human resources in the Ministry of Health still need to be expanded to undertake all the tasks involved in implementation of the strategies. Numbers of staff with technical experience are still relatively limited, especially in consideration of the massive tasks that face them in the ongoing rebuilding of the health system.

In some areas, Timor Leste still relies on external technical support to assist implementation and to strengthen capacity. However, the Ministry of Health has developed a range of policies and guidelines, including the Essential Drugs List and Treatment Guidelines and Guidelines for Donations. Of particular importance is the Guiding Frame for Developing Proposals for Interventions in the Health Sector of Timor Leste a pro-forma for agreements between individuals and agencies wishing to provide assistance and the Ministry of Health. By entering into an agreement with the Ministry of Health, external agencies can develop meaningful partnerships that will lead to sustainability and ownership.

The presentations from the conference and the Timor Leste policies and strategies can be accessed at

EUROPE

Three new policy papers by Health Action International (HAI) Europe confront head-on key issues of medicines policy where the interests of consumers are coming second best to the interests of commerce.

1. In Running on empty: HAI Europe exposes the fact that medicines can play an important part in the control and treatment of disease, if they are produced to respond to public health needs, and if the policies that support their production provision and use remain in line with this goal. It is therefore of concern that although more and more money is given over to the production of medicines, fewer and fewer are being produced to meet the urgent health needs'. Health Action International (HAI) Europe believes this to be a consequence of emphasis on competitiveness at the expense of public health in both the pharmaceutical industry and the policy making that informs it.

2. In Bending the rules: HAI Europe describes Information as an essential ingredient of medicines. Information enables people to make rational treatment decisions and to adopt healthier lifestyles. It makes people feel more at ease and in control of their health. People need information that they can trust and which is easy to understand. Health Action International Europe believes that many information providers fail to recognize that consumers have different needs and capacities to respond to information. Too often consumers are the target for information distorted by commercial imperatives.

3. Unhealthy Influence: Health policy-makers at the national and European level recognize the benefits of listening to the public and shaping policy in the light of the experiences of users of healthcare systems. But too often, listening to the public is reduced to listening to a small number of patients' organizations, without questioning those groups' claims to legitimacy, nor examining their sources of funding. Health Action International Europe calls for a truly democratic approach to the development of medicines' policy, one that is open to the views of all citizens, meets high standards of transparency and clearly exposes conflicts of interest.

Source: To access the full policy papers please log onto www.haiweb.com

Documentary on Roll Back Malaria

In Tanzania, every 5 minutes someone dies of Malaria. In Africa alone, every year one million people die of the disease, especially pregnant mothers and children. It is a new trend to eradicate diseases like Malaria through partnerships with governments, private corporations, non-governmental organizations and institutions of the United Nations. An example of such a partnership is Roll Back Malaria, in which Tanzania is also involved. The Intentions are good, but there are also side effects.

Wemos has produced a new 20 minute documentary titled, 'Good Intentions with Side Effects', including the Tanzanian Minister of Health, the Dutch Minister of Development Cooperation, representatives of the pharmaceutical industry etc.

The video VHS-pal copy can be ordered in Dutch and English through sending a message to privatesector@wemos.nl.

- *Journal Scan* -

World Health Assembly opens with calls for more health financing

The World Health Assembly (WHA) opened on 16 May 2005 with speeches by the President of Maldives Maumoon Gayoom and Microsoft founder Bill Gates, both urging that more funding be given to health to reduce global health inequities.

World Health Organization Director-General Dr Lee Jong-wook warned that although health was at the centre of the Millennium Development Goals (MDGs), progress towards meeting them was not reassuring. He and President Maumoon warned about the impending avian flu pandemic, which could kill many millions if measures are not taken now.

Among the highlights on the agenda of the Assembly, which ended on 25 May, were the achievement of health-related MDGs, revision of the International Health Regulations, and health action in relation to crises and disasters.

In view of the avian flu problem, the item on pandemic influenza preparedness and response was also a closely-followed item, as was the issue of scaling up treatment of HIV/AIDS. The Assembly also discussed controversial proposals to allow genetic engineering experiments on remaining stocks of the smallpox virus.

At the opening plenary session, the President of the Assembly, Spanish Health Minister, Ms. E. Salgado, highlighted two issues that will occupy the Assembly: assessment of the attainment of health-related MDGs, and the adoption of a revised draft of the International Health Regulations.

The revised regulations, which will replace the 1979 regulations, had been discussed for two years and were finalized late night on 13 May. They pertain to prevention and control of international spread of disease, particularly in relation to transport, travel and trade.

WHO Director-General Dr Lee Jong-wook, in his opening speech, said that health issues are at the centre of the MDGs, yet the translation of those goals into reality is very far from completion, and progress towards them was not reassuring.

Unless there are major changes in the very near future, the targets for reducing child mortality will not be achieved by 2015, warned Dr. Lee. Although the coverage rates in some areas rose as planned, "we have not yet seen improvement in health indicators. In some areas death rates have actually risen due to extreme poverty and epidemics." The technical know-how exists to do what is needed for global health, but "we have not yet found ways to apply it on a larger enough scale."

Dr Lee added that the rise in funding for health development was encouraging, having risen steeply, but was still a small fraction of what is needed. "We have at least begun to overcome lack of resources, one of the biggest obstacles to meeting MDG targets." He cited the Framework Convention on Tobacco Control (which has entered into force with 64 contracting parties) as a "shining example" of negotiation ensuring that knowledge leads to action.

He mentioned the launching in March of the Commission on Social Determinants of Health which will define and confront major underlying causes of ill-health in the 21st century and the Commission on Intellectual Property which will present its findings to next year's WHA.

On specific diseases, Dr Lee mentioned the campaign to treat 3 million HIV/AIDS patients by end-2005. He said the milestone of 700,000 people on treatment was passed last December but did not reveal what the present level of achievement was, except to say that the next progress report was due in June 2005. On tuberculosis (TB), the treatment success rate reached 82 per cent but case detection is still lagging at 45 per cent. In Africa, the HIV epidemic is fuelling TB resurgence.

On Malaria, which kills over a million people annually, under-investment in control activity has accelerated drug resistance and excluded whole populations from protection. The new artemisinin-based combination therapies and insecticide-treated nets are effective and WHO is preparing a major initiative based on these.

He ended by warning about avian influenza, which he described as "the most serious health threat the world is facing today". While the timing cannot be predicted, "rapid international spread is certain once the susceptible virus appears." He said this was a grave danger for all people in all countries, adding that the magnitude can be gauged by the 20-50 million deaths from the Spanish flu epidemic in 1918.

Dr Lee added that there is time to prepare for the next global pandemic. "When this event occurs, our response has got to be immediate, comprehensive and effective."

The President of the Maldives, Maumoon Abdul Gayoom, made an eloquent plea for international cooperation to come to the aid of small countries like his, which were threatened by natural disasters such as the recent tsunami and the effects of climate.

He gave a wide-ranging panorama of the health problems and crises facing the world. He said the tsunami directly affected one-third of the people of the Maldives, with two decades of development and the equivalent of 62 per cent of the Gross Domestic Product washed away. An early warning system alone is not enough, what is needed is a strategy for people to find refuge once the alert is sounded.

Though substantial funds have been committed for recovery and reconstruction, he feared the promised aid would take too long to materialize, with particularly slow reaction in aid for repairing water and sewerage infrastructure and the clearing of debris and waste.

He highlighted the need for treatment for HIV/AIDS and drug-resistant TB, and warned that globalization, travel and trade were rapidly spreading infectious diseases. While the challenges of dealing with old diseases like malaria, TB and cholera remain, the emergence of new pathogens such as SARS and avian flu were equally worrying.

He warned that the avian flu could transform into a new pandemic strain against which human beings have no immunity, and such a pandemic could kill over 100 million people.

Localized health hazards are equally more devastating, he added, citing that one in five persons in the Maldives is a Thalassaemia carrier. Bone marrow transplantation, the only permanent cure, is not available locally. The cost of treatment is projected to consume over 40 per cent of per capita health expenditure in 50 years, if preventive

steps

are

not

taken.

President Maumoon Gayoom also stressed the importance of the environment, citing that over 5 million children die annually from illnesses caused by the environment they live in. He pointed out the health effects of global warming, which could kill the corals and starve the Maldives of fish supplies, and would increase vector-borne diseases, lead to more virulent forms of tropical diseases and poison water aquifers and soil with excess salination as the seas rise.

Bill Gates, speaking in his capacity as founder of the Bill and Melinda Gates Foundation, said the world is failing billions of people as governments in rich and poor countries are not putting enough funds in health, while the private sector is not developing vaccines needed in developing countries as they could not afford to buy them.

The story, however, is changing, he said, with the application of more scientific research on treating diseases such as pneumonia, malaria, sleeping sickness and AIDS, giving examples of projects funded by his Foundation.

Delivery and distribution of medicines were also important, and he urged that the design of medicines be shaped by the needs of delivery, for example, by developing a pill to be taken once a month instead of AIDS patients who now have to take three pills a day.

Gates said governments in rich countries must match resources to meet the scale of the problem, governments in developing countries should increase the share of their budgets going to health, and all countries should increase research on diseases that claim the most lives, while scientists should design inventions with delivery in mind.

Earlier, the Assembly proceedings were held back by consideration of the issue of whether to place on the agenda the issue of whether Taiwan could be accepted as an observer in the WHO. Chad and Malawi supported placing the issue on the agenda, arguing that the WHO would lose credibility if it marginalizes small and weak members.

Pakistan spoke against the proposal. China said the WHO had repeatedly rejected the request of a few countries that Taiwan should take part as an observer. It said that to admit Taiwan as an observer would be against the UN Charter, UN General Assembly and WHO resolutions and the WHO rules of procedure on observer status. It added that China would safeguard its sovereignty and would not allow anyone to conduct secession activities through the WHO.

The Assembly decided not to include this issue on its agenda.

Source: By Martin Khor, Geneva, 17 May 2005. For more details on the World Health Assembly please log onto <http://www.who.int/entity/mediacentre/events/2005/wha58/en/index.html>

Prostratin agreement with Samoa

(Follow up from HAI news 131, Ethnobotanical Research, page 22)

Paul Cox, who heads the Institute for Ethnomedicine at the National Tropical Botanical Garden in Hawaii, spent a year living on the remote Samoan island of Savai'i in the Pacific, and there he observed and recorded the practices of traditional healers: women who have passed on their law of plants and healing for generations. There was one particular remedy that really sparked his interest: the bark of the mamala tree, used to cure acute viral illness like hepatitis.

'My colleagues thought I was cracked. They said, 'You're quitting your job, you're leaving to just go sit with witch doctors? And you've got a Harvard PhD – what a waste!' But they do not say that any more, because we made a few discoveries from Grandma. And part of my interest now as an ethnobotanist is not only adding dignity to what Grandma knows, but trying to find a way to get finance returns and to get Grandma the patent.'

'I was actually looking for something to treat breast cancer, this is after my mother had died. One day one of the healers who had really helped me a lot, told me about a plant that she called mamala. She said she could take the bark of the mamala tree, crush it up, and produce a potion that would treat a disease she called 'Fiva Sama Sama'. As I tried to figure out what Fiva Sama Sama was, the symptoms were that the person became yellow, their eyes turned yellow, their urine got dark, in bad cases they could haemorrhage and die. And so I wrote in my notebook, 'Yellowing fever, acute viral syndrome'. And what really grabbed my attention was when she told me that she could cure this with only one or two treatments.

I learned the same thing from another healer in Savai'i, Paela Lilo, who was unrelated to Epenessa, and from a different village. So having these two different healers got me really interested, so I collected the bark and the healer's samples, I shipped them off to my college at the National Cancer Institute who were studying AIDS then, and it was run against AIDS cells in cell culture. The results were stunning. None of the cells that was infected with HIV died, and what was even more interesting was that it did not seem to attack the virus directly, it worked by protecting the cells from invasion by the virus.

Patent papers were shipped to me, I was in Sweden at the time, lecturing, and I really had a difficult time signing these, because they wanted me to assert that I invented this stuff, and my thought was, I did not invent anything; I learned this from two old ladies. They told me they learned this from their mothers, who learned it from their grandmothers, who learned it from their great-grandmothers, so I felt in some way that I was holding intellectual property that belonged to the entire Samoan people.

As reported in HAI News 131, Prostratin was investigated by the National Cancer Institute. It was patented in 1997 but they agreed that it could not be commercially licensed unless a fair and equitable return was negotiated with the Samoan people.

Paul Cox felt there was very little interest at first, partly because of the success of the HAART therapies, which revolutionized the treatment of AIDS. He explained 'Soon after 2000, it became clear that we still had a problem, which was that you could treat people with highly active anti-retroviral therapy, but if they ever stopped their medications, the virus roars out again; it hides in viral reservoirs, it goes latent where the drug cannot get it. And a lot of times it would come back, and it would evolve resistance. Prostratin exposes this hidden virus. So in 2001, I was approached by the AIDS Research Alliance.

The AIDS Research Alliance is a not-for-profit organization in Los Angeles. I think they have sponsored 14 of the 21 AIDS drugs that are out in the market. They approached me and said that they were really interested in eliminating viral reservoirs, were therefore interested in this drug Prostratin and to help them with it. I said I would be happy to, but first of all, before I helped them, they had to go with me to this little village in Samoa, they have to listen to these long kava speeches, to talk to these 80-year-old ladies and be polite, because they decide whether or not they can do the work. They had to go and negotiate directly with the Samoans. So they did that. They met with the villagers, the chieftains, the healing families; they met with the Attorney-General, the Prime Minister, the Minister of Health, and negotiated an agreement between the AIDS Research Alliance and the people of Samoa. A total of 20 per cent of the AIDS Research Alliance profits from Prostratin will be returned to the people of Samoa. 12.5 per cent would be returned

to the government of Samoa, 6.7 per cent would be returned to the village that allowed Paul Cox to do the work in the first place, and 0.4 per cent would be returned to each of the two families of the healers, because both Paela and Epenesa died by that point. The pre-clinical trials are almost complete and studies on animals have been very promising. In the next few months, Phase 1 clinical trials on humans will begin in Los Angeles.

Last year, a team from the University of California, Berkeley, approached Paul Cox about genetically engineering the drug so as to manufacture it more cheaply. Researchers in the laboratory of Jay Keasling a Professor of Chemical Engineering plan to clone the genes from the tree that naturally produce prostratin and insert them into bacteria to make microbial factories for the drug. The lab is also experimenting with a similar technology to produce the anti-malarial drug artemisinin. Before negotiations could begin, a presentation was prepared in the Samoan language.

As Paul Cox stated a portable power point projector was taken, they hung up sheets in huts, and went to three different villages and presented the entire village genetic engineering, so they would understand the concept of taking the gene from the plant, putting it in a bacterium. They also wanted to explain to them that if this was successful, then it would undercut any future agricultural industry. The people might be growing the plant, and once the genetically engineered drug was available, the market would just drop right away. They wanted the villagers to understand that. The researchers would need access to these villages to get living material from the plants, and they wanted the villagers to understand that. And then we began the negotiations.

What was fantastic was that the Samoans, who are very clever people, are signatories to the Convention on Biodiversity (CBD). Part of the CBD argues that every country is sovereign over its own biological resources. The Samoans decided to extend that national sovereignty to the gene sequence for Prostratin. The Samoan government then sought to negotiate a partnership agreement with the University of California, Berkeley. And so they have now become equal partners in the development of the Prostratin genes, and they have agreed to share 50-50 all commercial proceeds from the gene product.

This just sent a lightning bolt around the world, because a lot of small countries now are very excited about this, the idea that they can claim sovereignty over gene sequences. And the Samoan case in my opinion, is very strong. So the Samoans are quite happy to let other countries that own the plant, to go ahead and use it for traditional uses, there's no effort to stop that, and part of the agreement is that they will provide at cost or free of charge, the gene product for Prostratin to developing countries around the world.

In other words, the Samoans' interest was to ensure that the gene product is given to AIDS sufferers around the world, to help eradicate AIDS and UC Berkeley had that same concept, so that's part of it. The work is beginning. It will probably be five or six years at the minimum before the gene product is developed, and the Samoans are very excited. The other things the Samoans asked, and this came from the Attorney-General, is they want their own people trained in the genetic engineering techniques, so UC Berkeley will be including Samoans in the laboratory, and it is a really exciting collaboration between really some of the top genetic engineers in the world, and these wonderful people in Samoa who have protected for generations, this plant lore that led to this discovery.'

Source: Beverley Snell, Centre for International Health, Macfarlane Burnet Institute for Medical Research and Public Health, From the transcript of a radio program broadcast in Australia on Radio National, Saturday June 11, 2005.

Circulation of medicines labelled with wrong concentrations stopped

The General Department of Pharmacological Administration (GDPA), Vietnam, has issued a correspondence requesting to stop the nationwide circulation of Marcaine Spinal and Marcaine Spinal Heavy produced by Swedish company AstraZeneca and imported by the Central Equities Pharmacological Company No. 2. (CEPM2).

According to this correspondence, GDPA asked Provincial Health Departments, Representative Office of AstraZeneca (179 Vo Thi Sau Street, District No. 3, HCMC) and CEPM2 to stop nationwide circulation of lots No. GB1067 of Marcaine Spinal 0.5%, registration No. VN-8885-04; lots No. GD 2288; GB 2269 and GC 2271 of Marcaine Spinal Heavy 0.5%, registration No. VN-8886-04, produced by Swedish company AstraZeneca and imported by CEPM2.

The Representative Office of AstraZeneca and CEPM2 were requested to work together with providers to urgently withdraw these medicines which had stated the concentration wrongly and to send concrete reports of quantities introduced into the market with results of the withdrawals and cases with accidents (if any) due to these medicines.

This withdrawal process was decided based on correspondences No. AZ06/05-35/PC&R of AstraZeneca and No. 476/DL2-XNK dated 8/6/2005 of CEPM2 informing the mistake in labelling – instead of the active element's concentration 5mg/ml, on the label it appeared as 0.5mg/ml for lots GB1067 of these medicines.

Source: Vietnam Net, 24/06/2005 and translated by Dr Diem Hang

WHO to launch first Internet-based system for tracking counterfeit drugs

The World Health Organization it will launch the first web-based system for tracking counterfeit drugs, which account for up to 10 per cent of medicine on the world market.

WHO noted that a 2001 study in Southeast Asia's Mekong region showed that more than one-third of antimalaria artesunate products in Cambodia, Laos, Myanmar, Thailand and Vietnam contained no active ingredients, and the situation worsened last year, with 99 out of 188 samples found to be fake.

Fake drugs are estimated to generate almost \$44 billion in sales a year, WHO said, and the problem is most serious in developing countries.

The Rapid Alert System, to be launched this week in Manila, will transmit reports on the distribution of fake medicine to national authorities so they can take rapid action.

"We hope that the Rapid Alert System will considerably strengthen our hand against the counterfeiters," said Dr. Budiono Santoso, WHO's Regional Adviser in pharmaceuticals for the Western Pacific region. "Rapid communication and efficient exchange of information are crucial to combating counterfeiting."

The agency said national health authorities and other partners will be linked to the system.

Source: Associated Press, Manila, Philippines, May 2, 2005 <http://www.washingtonpost.com/wp-dyn/content/article/2005/05/04/AR2005050400277.html>

Ranbaxy Gets US FDA Approval for Generic AIDS Drug

India's top drug maker, Ranbaxy Laboratories Ltd. in May became the first Indian drug maker to have regulatory approval for the generic antiretroviral drug lamivudine to be included in a major U.S. anti-HIV programme.

Ranbaxy received tentative approval from the U.S. Food and Drug Administration to make and market lamivudine tablets for the \$15 billion programme. The 5-year U.S. President's Emergency Plan for AIDS Relief programme, launched by George W. Bush in 2003, aims to pay for treatment for 2 million AIDS sufferers and provide care for 10 million others in 15 target countries, mostly in Africa.

New Delhi-based Ranbaxy had filed for FDA approvals for four antiretroviral drugs for inclusion in the programme. Analysts say the approval could mean more sales, but profits will not be affected much given the cheap prices for the drugs.

"It is an important development, and could open up more opportunities for Indian drug makers and their generic AIDS drugs," said Giridhar Iyengar, an analyst at ABN-Amro Securities.

Rival drug maker Cipla Ltd. has been roped in to supply paediatric AIDS drugs as part of former President Bill Clinton's \$10 million fund to help treat children afflicted with AIDS/HIV in 10 countries, particularly in rural Africa.

Ranbaxy withdrew all its anti-AIDS drugs from a World Health Organisation list of approved drugs last November, after discovering discrepancies in tests done to show the generic drugs were equivalent to brand-name drugs. Ranbaxy has since submitted 11 antiretrovirals for WHO approval and has said it plans to submit its entire range.

Source: Posted Ip health, Thursday, June 16, 2005 Originally from Reuters 31 May 2005

Trade deal won't hit Thai generic AIDS drugs - U.S.

The United States assured Thailand early May that a bilateral free trade deal under negotiation will not prevent Thai companies making cheap, copycat AIDS drugs, which are being used to treat thousands of patients.

U.S. Deputy Secretary of State Robert Zoellick said the issue of manufacturing generic anti-retroviral AIDS drugs, which eats into the profits of U.S. pharmaceutical giants, would not fall under the remit of the deal.

"In all our free trade agreements, we made very clear that the agreement to which the United States joined -- and in fact I helped put together -- dealing with access to medicines, dealing with HIV AIDS, would not be affected at all by any aspect of this agreement," Zoellick told reporters.

"I understand the anxieties, but I think there is a very good answer," he said after meeting Thai Foreign Minister Kantathi Souphamongkorn at the start of a six-country tour of Southeast Asia to drum up support for U.S. trade deals in the region.

Thai and U.S. negotiators have held three rounds of bilateral free trade. Academics and AIDS protesters demonstrated outside the U.S. embassy in Bangkok and sent a letter to chief Thai negotiator Nitya Pibulsonggram asking that anything relating to generic AIDS drugs be left out.

Developing countries such as Thailand, which also have established pharmaceutical industries, are allowed to make generic copies of patented drugs to cope with medical emergencies, such as the AIDS epidemic.

As a result, the cost of treating patients with anti-retroviral drugs in Thailand - where there are an estimated 700,000 people with HIV or AIDS -- has dropped from 10,000 baht (\$250) a month for patented drugs to just 1,200 baht.

Source: Drug Info, May 04, Originally from Reuters May 4, 2005; 3:16 AM

WIPO seminar debates intellectual property and development

An international seminar on Intellectual Property and Development held at the World Intellectual Property Organization (WIPO) on 2 May discussed the theme "intellectual property and public policy", with sessions on public health, biodiversity and traditional knowledge, copyright and competition policy.

The two-day seminar was organized by WIPO jointly with the UN Conference on Trade and Development (UNCTAD), the UN Industrial Development Organization (UNIDO), the World Health Organization (WHO) and the World Trade Organization (WTO). The holding of the seminar was mandated by the WIPO General Assembly last October, as part of the activities of the Development Agenda for WIPO initiative taken by several developing countries.

In a session on public health, Sisule Musungu of the South Centre drew attention to the WIPO Development Agenda and the submission by the Group of Friends of Development that stated that WIPO must address all features of existing IP rights, including the economic and social costs that IP protection may impose on developing countries, as well as on consumers of knowledge and technology. WIPO must also consider alternative non-IP systems for fostering creativity, innovation and the transfer of technology while recognizing the benefits and costs of each system.

In taking the WIPO Development Agenda forward on public health issues, Musungu stressed the need for WIPO to establish principles and guidelines to safeguard the protection of public health; technical assistance on developing principles and guidelines to ensure public health-sensitive policies and laws; and to have evidence-based objective analysis through a proposed WIPO Evaluation and Research Office.

Richard Wilder, a US lawyer, spoke on the development of medicines for developing country diseases and the role of IP. "When diseases afflict mainly patients in developing countries, the free market may not support the development of a new medicine, even with patents and data protection," he said.

Pointing out that of 1,393 medicines approved between 1975 and 1999, only 13 medicines were for the treatment of neglected diseases that most impact developing countries, he advocated "public-private partnerships" to develop medicines for neglected diseases to be made available at lowest cost. He spoke on IP as "a tool to manage public-private partnerships to develop medicines for the treatment of neglected diseases."

William Hare, a lawyer for the Indian drug company Ranbaxy Laboratories, said the newly amended Indian Patent Act has struck a balance between protecting public health interests and the promotion and protection of innovation. Hare said that the amendments provided stricter patentability criteria, pre-grant opposition and

compulsory licensing provisions, adding that "India's ability to be a supplier of cost-competitive drugs to the developing world has been safeguarded."

Mohga Smith, Health Advisor of OXFAM UK, said that in the light of serious health crises in the developing world, peoples' needs should dictate research and development for medicines, especially for neglected diseases, and pricing mechanisms to ensure peoples' access to medicines. "There is a need for another model away from IP protection to ensuring R&D in new medicines," she said.

In advancing the WIPO Development Agenda, she called for IPRs to be seen as only one means to innovation and not an end in itself. She said that there was resistance in WIPO to change but WIPO needs to wake up to the realities. "There should be no more high standards for IP rights in developing countries, and there is a need to look at the implications of the TRIPS agreement before imposing higher standards," she added. "In the longer term, TRIPS needs to be reformed according to health and development needs."

On biodiversity and traditional knowledge, Graham Dutfield from the Queen Mary IP Research Institute in the University of London said that from the 1980s, the knowledge, innovations and practices of indigenous and local communities have been barely tapped as a source of technologies. However, said Dutfield, patents, copyrights and other currently existing IP formulations are inadequate in providing positive protection for traditional knowledge and technologies, and in some ways also make defensive protection more difficult.

In the session on competition policy, Martin Khor of the Third World Network said that a discussion on competition policy and IPRs should look at whether IPRs affect the competitiveness of developing countries and their enterprises, as well as the access of their consumers to essential goods and services and the access of small enterprises to technology and production inputs. Both IP and competition policies at global and national levels should assist and not hinder developing countries' quest for industrial development and access to essentials. There has to be proper balance between IP and development and the balance between IP holders' interests and the public interest, said Khor. However, this balance had significantly shifted against development and the public interest due to inappropriate upward harmonization of IP standards resulting from the TRIPS agreement (which removed or eroded policy space for developing countries) and some recent WIPO treaties, and this could worsen if more IP treaties are concluded along the present lines at WIPO and in bilateral and regional agreements.

Khor said that studies showed that there were problems arising from recent trends in the US patent system, with the rise of patents on trivial "inventions", the use of patents by big companies to extract payments from competitors and run them out of business, and the inappropriate extension of patents to new areas and discoveries. For example, a big food company had obtained a patent for the making of sandwiches with the bread crust removed, and had sued small grocery shops for selling sandwiches.

Many small firms had been forced to pay up as they could not afford legal fees, and this reduced competition. Farmers were also being sued large amounts for using genetically-modified seeds, even if these seeds had blown over from neighbouring farms. The system was also granting patents for naturally occurring lifeforms and for biological resources originating from other countries.

Many academic experts had concluded that the system was getting more dysfunctional, and it would be ironic and inappropriate if elements of the system were to be transferred to developing countries through the harmonization process, for example, through new WIPO patent or copyright treaties. Khor said that developing countries had characteristics that made it inappropriate for them to adopt IP standards existing in developed countries. Most patents are held by Northern institutions. As a result of TRIPS, developing countries had obligations to pay \$60 billion extra annually, according to World Bank-related estimates.

Local researchers and firms in developing countries find it more costly and difficult to make use of patented materials or technologies, thus reducing the South's competitiveness. The cost of medicines and information had shot up, reducing consumer access and welfare.

Even well-known free-trade economists such as Jagdish Bhagwati and Sreenivasan have taken strong positions against the imposition of high-level IPRs on developing countries, claiming that they had become monopolistic royalty-collecting mechanisms impoverishing poorer countries.

Khor cited examples showing how inappropriate application of IPRs had increased monopolization of industrial structures, increased drug prices, affected farmers' rights and facilitated biopiracy in agriculture and led to wrongful patenting of naturally occurring genes and microorganisms.

He said the best way to control the anti-competitive effects of IPRs is to establish patent systems that prevent the wrongful granting of patents. It should be ensured that patents should not be given for "inventions" that are trivial or that are already in the public domain, nor for living organisms. Exceptions, limitations and flexibilities in IPRs should be expanded or strengthened in TRIPS and other global treaties, and technical assistance should stress their significance and use in developing countries.

Pro-competition elements in TRIPS should be fully used, and expanded, and competition policies could also be used to limit the abuse of IPs. However, the main changes had to come within IP law and practice itself. Khor also said there was a need to review existing global IP treaties in light of development and public interests and further harmonization of IP laws and practices should be halted until there was a change in fundamental principles in the IP framework that makes it balanced.

Philippe Brusick of UNCTAD said there seemed to be a clear conflict between IPRs, which grant monopoly rights, and competition policy which aims to counter monopoly. In the longer term, there could be what he called "dynamic coherence" between the two since both IP and competition policy are essential for innovation.

Brusick said however that conflict situations do arise between IPRs and competition policy. For example, IPR holders can attempt to monopolize essential facilities. They can use patents to block all possibilities to develop the same kind of innovation, for example, patent pools aimed at blocking any R&D by competitors. Another example was a company obtaining a patent but not making use of it. There could also be excessive duration of IPRs, with attempts by rights holders to prolong control after expiry of the IPR.

Another conflict exists in abusive provisions in licensing contracts, a problem recognized in TRIPS Article 40. Such abusive provisions could be aimed at controlling and dividing markets by controlling inputs through tying of supplies; or by prohibiting exports through market allocation; or by price fixing of sales through collusive pricing.

Some companies use IPRs to artificially divide markets by prohibition of parallel imports. TNCs argue that differential pricing allows them to fix lower prices in poorer countries. However, critics point out instead that differential pricing does not always defend poorest markets as it depends on the bargaining power of the countries. For example, LDCs that have less bargaining power may have to pay higher prices.

Menzie Simelane, Commissioner of the Competition Commission in South Africa, said that competition law deals with abuses of dominance and this has relevance to IP issues as a patent holder is market dominant by nature. He gave a case study of the case initiated by his Commission against companies selling HIV/AIDS drugs for refusal to issue voluntary licenses to other companies, and charging excessive prices by abusing their market dominance.

The case was settled out of court and the firms were asked to issue three voluntary licenses each, with reasonable royalty fee (eventually agreed between the companies at 4-10 per cent). Simelane concluded that both IP and competition laws were not ends in themselves and both had to serve the public interest.

From the floor, a question was raised as to whether it was better to tackle problems arising from IPRs through competition law or through changes in patent laws. Several of the speakers, including Simelane, Khor and Peter Plompen (of Phillips International) agreed that the problems arising from the patent or copyright systems, such as the issuing of wrong patents, would best be resolved through reforms to the IP laws and system, rather than expecting competition law to offset the problems.

Source: TWN Info Service on WTO and Trade Issues (May05/7), 11 May 2005, By Meena Raman, Geneva, 3 May 2005

- Resources -

WTO/TRIPS Agreement and Access to Medicines : Appropriate Policy Responses

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*Report prepared by Robert Weissmann
Year: 2004 ; No. of pages: 124*

A Regional Consultation on "WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses" was held in Colombo from 17-19 April 2003. It was hosted by the Ministry of Health, Sri Lanka. Health Action International Asia-Pacific (HAIAP) and the Third World Network (TWN) were the co-organizers while the Department of Essential Drugs and Medicines Policy, Drug Action Programme, (EDM/DAP), World Health Organization (WHO), Geneva and the South-East Asian Regional office of WHO, New Delhi, co-sponsored the consultation. Among the participants were senior health and trade officials and representatives of health-related NGOs and social movements from 18 Asian and Pacific countries, as well as international experts and resource persons. This is a summary report of the proceedings.

The Third World Network is an independent non-profit international network of organizations and individuals involved in issues relating to development, the Third World and North- South issues. Health Action International Asia Pacific (HAIAP) is a network of organizations and individuals involved in health and pharmaceutical issues. HAIAP upholds health as a fundamental human right and aspires for a just and equitable society in which there will be regular access to essential medicines to all who need them. HAIAP actively promotes the concept of essential drugs, their rational and economic use through advocacy, research, education and action campaigns.

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The Current Negotiations in the WTO Options, Opportunities and Risks for Developing Countries

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By Bhagirath Lal Das

At the end of July 2004, member states of the World Trade Organization (WTO) approved a document that charts the future course of the wide-ranging multilateral trade negotiations launched by the WTO's Doha Ministerial Conference in 2001. Together with the Doha Ministerial Declaration, the July decision sets the basic outline and direction of trade reforms in the broad swathe of sectors covered by the negotiations, including agriculture, industrial goods, services and intellectual property rights.

The ongoing negotiations to flesh out this framework of commitments present developing countries with an opportunity to redress the myriad imbalances in the existing WTO rules which have denied them a fair share of the benefits arising from international trade. This book examines the current state of play in the talks and discusses how the developing countries can best make use of this opportunity, within the negotiating parameters set by the Doha mandate and July decision. For each of the subjects under negotiation, the author puts forward detailed suggestions on negotiating positions the developing countries can take to advance their development interests and guard against the risk of new commitments which will only add to the prevailing inequities. The book also considers ways to create a negotiating environment in the WTO which is conducive to securing outcomes that are mutually beneficial to all members, developing and developed countries alike.

The book is a useful and timely guide to the developing countries in the ongoing negotiations. The range of available options it sets out will help them to select those best suited to them. It may also help in the assessment of the final outcome of the negotiations based on where the outcome is located within this spectrum of options. In addition, the book will be of use even beyond the current phase of negotiations as it lays out the basic interests of the developing countries in the context of the WTO framework.

Bhagirath Lal Das, the author was formerly India's Ambassador and Permanent Representative to the General Agreement on Tariffs and Trade (GATT) forum. He has also served as Director of International Trade Programmes at the United Nations Conference on Trade and Development (UNCTAD). At present he is an advisor and consultant to several organizations.

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