

## THE GENERAL AGREEMENT ON TRADE IN SERVICES AND PUBLIC HEALTH

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The Right to Health is a fundamental Human Right. A primary function of governments is to ensure this by protecting people's access to essential services such as health. Traditionally, this has meant that health service was considered a public good and governments owned and provided health services. Health services were never thought of as profit making concerns and the health sector has never been affected by trade till the General Agreement on Trade in Services (GATS) was put on the table for negotiations at the meetings of the World Trade Organization (WTO).

The General Agreement on Trade in Services (GATS) is the first ever multilateral legally enforceable set of rules to cover a wide array of services that have traditionally been publicly owned and provided. These include among others, healthcare services, education, water supply, sanitation services and electricity. These are essential services and are basic necessities which should never be left to the market to be sold and bought at prices decided by market forces. For developing countries, public provision of these essential affordable access to basic

services is of critical importance both for poverty reduction and economic development. Ensuring

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necessities such as health, education, water and sanitation is the key to poverty reduction strategies. The critical importance of these essential services makes it very clear that sovereign nations have a moral mandate to ensure that these essential services continue to be publicly owned and provided so that even the poorest have regular access to these basic necessities whether or not they can afford to pay.

GATS has come to be understood by people's movements, especially from developing countries, as a far-reaching instrument of neo-liberal globalization that threatens the freedoms, the very survival and future of peoples in developing countries. GATS is a legally binding set of rules that covers international trade in services. The range of services covered by world rules is very extensive and is organized according to 12 sectors: business, communication, construction and engineering, distribution, education, environment, financial services, health and social services, tourism, sports, culture and entertainment, transport and other services. In short many, if not most, aspects of our every day life access to health, water, education, electricity, sports

and recreation are very likely to be affected by GATS. This means that through GATS the fulfillment of our most basic needs will be governed by World Trade Rules and subjected to the drive for profit and open competition among private corporations.

GATS is not limited to the cross border trade in services. It also prevents some forms of government regulation of foreign investors, that is, of transnational corporations (TNCS) setting up business in host countries. GATS enables the transnational service providers to penetrate developing or host country markets. WTO members, are committed to entering negotiations on services. The goal of these rounds which first started in 2000 is “progressive liberalization in the services area through successive rounds of negotiations” that improve market access and extend national treatment to foreign service suppliers across an increasing range of sectors including those that have traditionally been public sector services; these include health, education, water and electricity.

The most important rules of GATS are:

Most favoured nation, which requires a WTO member government to treat all other members equally.

National treatment, which means that foreign companies must be given the same treatment as a national company. For example a foreign company which has contributed nothing to a developing country's development, would be eligible

for government loans on the same terms as a domestic service provider in those countries.

Market access, which requires that a country not impose new quantitative or structural restrictions on foreign service providers.

Domestic regulation which requires that local and national regulations not be “more burdensome than necessary” to the provision of the service.

Compensation to other countries if the host country has revoked a commitment in a particular sector.

### **Nature of GATS negotiations**

There are two forms of GATS negotiations:

**Bilateral request and offer** Two WTO members negotiate with each other, one requesting a service to be opened and the other offering to open under a bilateral agreement.

**Plurilateral negotiating framework**

Developing countries agreed to bring services into the WTO only if one WTO member could choose to accept or reject a request from another country to open up specific sub-sector service markets. However, developed country WTO members grew frustrated at the slow pace of market access for their TNCS through bilateral negotiations. They proposed a mandatory plurilateral negotiating process where several developed and developing WTO members participate. Agreements reached through these negotiations would pressure groups of developing country WTO members to open up

a whole sector or sectors to TNCs based in developed countries. At the sixth WTO Ministerial conference in Hong Kong all WTO members except Cuba and Venezuela formally accepted the adoption of a plurilateral approach to GATS negotiations.

Commitments made by governments under GATS are effectively irreversible. The privatization and deregulation of service provision is highly controversial, yet governments are not only signing away their own right to regulate but the right of future generations to implement different policies. Foreign corporations will be allowed to take over almost any public service on the basis of a secret “agreement” that is irreversible.

GATS is a one-sided investment tool that will only give global corporations unhampered access to markets and human services, and grant them as much, if not even greater, rights than citizens to exploit such access. For the peoples of the developing countries, the liberalization of trade in services, especially in areas like health, education and power (water and electricity) through GATS, would make such services less accessible and affordable. They would have to bear the cost of adjustments required in privatization and trade liberalization. Moreover, GATS ultimately weakens the position and ability of the people of the South to undertake decisions on matters that affect their daily lives and secure their future.

While examining and analyzing the impacts of GATS on public health, we should keep in mind two health

policy principles that can never be negotiable. These are:

- i. Right to Health is a Fundamental Human Right
- ii. Ensuring equity and quality and improving the access to and affordability of health-related services is the goal of a health care system.

Therefore in all negotiations related to GATS, negotiators from developing countries should keep in focus the following:

- i. The Right to Health as a Fundamental Human Right should inform and guide proposals to liberalize trade in health related services.
- ii. Liberalization of trade in health related services should produce better quality, accessible, affordable and effective health care services leading to greater equity in outcomes.

Our governments should ensure that the two non-negotiable health policy principles will never be undermined following liberalization. Therefore before beginning any negotiations and making any specific commitments under the GATS, governments and the negotiators should have thoroughly assessed the implications of opening health-related services to foreign service providers. Unfortunately there has been no study of the impact of liberalization on public health and other essential services.

In this context it is very relevant to recall a resolution adopted by the United Nations Economic and Social Council (ECOSOC) 15<sup>th</sup> August 2001 (E/CN.4/SUB.2/RES/2001/4)

The Sub-Commission on the

Promotion and Protection of Human Rights,

- **Affirming** the fundamental importance of the delivery of basic services, particularly in the areas of health and education, as a means of promoting the realization of human rights,
- **Emphasizing** the responsibility of governments to ensure the realization of all human rights, including those to which the provision of such basic services is relevant,
- **Recognizing** the potential human rights implications of liberalization of trade in services, including under the framework of the General Agreement on Trade in Services (GATS),
- **Acknowledging and emphasizing** the entitlement of Governments to regulate to achieve legitimate policy objectives such as to ensure the availability, accessibility, acceptability and quality of basic services such as medical services, education services and other necessary social services,
- **Noting** that in its General Comment 14 the Committee on Economic, Social and Cultural Rights defined the accessibility of a service as having four dimensions: non-discrimination, physical accessibility, economic accessibility and information accessibility,

1. **Calls upon** governments and international economic policy forums actively to ensure that, in the formulation, interpretation and implementation of policies in

relation to the liberalization of trade in services, the liberalization of trade in services does not negatively impact on the enjoyment of human rights by all persons without discrimination;

2. **Requests** the United Nations High Commissioner for Human Rights to submit a report on the human rights implications of liberalization of trade in services, particularly in the framework of the General Agreement on Trade in Services (GATS), to the Sub-Commission at its fifty-fourth session;

3. **Encourages** other relevant United Nations agencies, in particular the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO), to undertake analyses, within their respective competencies, of the implementation of GATS on the provision of basic services such as health and education services;

4. **Recommends**, through the High Commissioner for Human Rights, that the World Trade Organization and its Council for Trade in Services, in conducting its assessments of the impact of GATS in its current and future forms, include consideration of the human rights implications of the international trade in basic services (such as, inter alia, the provision of affordable and accessible health and education services) and the further liberalization thereof;

**5. Also recommends**, through the High Commissioner for Human Rights, that the World Trade Organization take into account any assessments of the implementation of GATS the report to be prepared by the United Nations High Commissioner for Human Rights and any analyses prepared by other United Nations agencies;

**6. Encourages** the United Nations High Commissioner for Human Rights and other relevant United Nations agencies that have not already done so to request observer status with the Council for Trade in Services of the World Trade Organization;

**7. Decides** to continue its consideration of this matter under the same agenda item at its fifty-fourth session.

This resolution coming from the highest global political level, alerts the world community of the need to ensure that the fundamental human rights such as the right to health, education and water are in no way endangered by the GATS process. The resolution mandates the UN agencies such as the World Health Organization (WHO) the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the World Trade Organization (WTO) to undertake analysis of the implementation of GATS on the provision of these basic and essential services.

The resolution also underscores the critical importance for developing countries to have clear understanding of the full impact of liberalization on health and human

development before opening essential service sectors to foreign investors. This has also been reiterated by the World Trade Organization (WTO). GATS article XIX.3 requires WTO Council for Trade in Services to carry out an assessment of trade in services both in overall terms and on a sectoral basis, prior to establishing the guidelines for each new round of GATS negotiations. Regrettably the WTO Council has not carried out studies on the impact of liberalization of trade in services on health and human development.

To understand the potential implications of opening healthcare services we should examine how healthcare services are supplied under the GATS process. There are four different ways in which services are supplied between countries. In the GATS parlance these are called four modes of supply. They are:

1. Cross-border supply;
2. Consumption abroad;
3. Foreign commercial presence;
4. Temporary movement of natural persons

Critical examination of these four modes of supply will show that liberalized healthcare services will result in a situation where the beneficiaries will be the transnational service providers leased in developed countries and the urban rich in developing countries leading to the reduction of public service provision to the poor.

**Mode 1: Cross border supply.**

This refers to the flow of health care services from one WTO member

country to another country in such a way that does not require the physical movement of the supplier or the consumer. The service crosses a border, but the provider and the consumer do not. A well known example of cross border supply is telemedicine: the provision of medical service from a practitioner in country A to a patient or practitioner in country B via Internet or satellite transmission of medical images.

The potential benefits of telemedicine are already seen within countries for diagnosis and treatment of patients in remote areas which are not easily accessible. In Asia videoconferencing or image transmission facilities have been setup between metropolitan and remote hospitals in Malaysia and Thailand. This, of course, is not a cross-border supply and is not a part of the GATS process.

Cross-border telemedicine in Asia  
Tele-links have been established between university hospitals in Japan and healthcare sites in Cambodia, Fiji, Papua New Guinea and Thailand. However, it is important to remember that these are maintained on a non-commercial basis.

Commercial cross-border trade in telemedicine poses great concerns. Telemedicine needs high technology, capital-intensive infrastructure and the limited budgetary resources available for health will be channeled from rural and primary healthcare towards specialized centres which will cater to the affluent few.

There is yet another major problem of regulatory control over

telemedicine. This was noted by the 50<sup>th</sup> World Health Assembly in 1997 resolution its on the uncontrolled sale of prescription drugs on the internet. This resolution focused on the public health hazard of counterfeit products entering a country and inappropriate use of potentially dangerous medicine without medical supervision. The World Health Organization had already exposed four companies selling prescription drugs over the Internet without detailed information which should accompany them.

### **Mode 2: Consumption abroad**

This involves movement of the consumer to the country of the supplier. There are two different types in these modes.

1. Patients from developing countries going to more advanced countries for specialized services not available in their own countries.
2. Health tourism Patients from the rich industrialized countries go to advanced developing countries which provide high quality specialized hospital services at costs almost a tenth of what it will cost in the industrialized countries.

Certain developing countries have identified provision of health services to foreigners as a potential growth area. A good example is Cuba. The government of Cuba setup Servimed to develop health tourism packages for foreigners. In 1995/96 a total of 25,000 patients from North and South America traveled to Cuba to take advantage of its low cost, high quality medical care bringing the Cuban economy US\$ 25 million. It should be

underscored that the National Health Service in Cuba was in no way affected by setting up Servimed. Infact Cuba has a surplus of doctors, many of whom are volunteering in sub-Saharan Africa.

The countries in Asia which have developed health tourism include India, the Philippines, Singapore and Thailand. However, the potential for developing countries to gain economic benefit from attracting foreign consumption of their health services is limited according to the World Trade Organization which noted, *“only a relatively small number of economically advanced developing countries, preferably located in the vicinity of the major export markets’ may be able to benefit from health tourism or mode 2 trade in the sector”*.

For the majority of the developing countries with limited resources, the economic benefits of health tourism will be outweighed by the social costs when limited resources are drawn away from national health priorities towards servicing foreigners.

In most developing countries there is now a two tier health system: the public sector where services are provided free at the point of delivery and a flourishing private sector particularly in the more prosperous urban areas. If health tourism is allowed, it will lead to a three tier health system by creating a third segment which caters to wealthy foreigners. There is also a possibility that the medical and para medical personnel who have been trained using the tax payers' money may be tempted to leave the

public sector altogether for the higher paid positions in private hospitals serving foreign patients leading to an acute shortage of health personnel in the public sector.

One of the arguments put forward for promoting health tourism is that additional incomes from foreign patients are harnessed to benefit the national health system. This will not happen since all the profits will go to the private sector because all the services to foreigners will be in the private sector. It is therefore clear, as noted by the World Trade Organization, only a small number of economically advanced developing countries may be able to benefit significantly from health tourism.

A recent publication by the World Bank (International Trade in Health Services and the GATS: Current Issues and Debates. Editors Chantal Blouin, Nick Drager, Richard Smith, World Bank, Washington 2006) posed the question; *“What can be done to limit the possible risks of trade?”*

This question clearly underscores civil society's key concern that liberalizing trade in health services will have a negative impact on equity of access and quality of care.

What follows by way of suggesting remedial measures is disappointing. The authors continue as follows:

1. “GATS does not impose any constraints on the terms and conditions under which a potential host country treats foreign patients, so, for example, foreigners may be charged extra for treatment and

these proceeds used to enhance the quantity and quality of basic domestic supplies”;

2. “There are no legal impediments in GATS that would affect the ability of governments to discourage qualified staff from seeking employment in the private sector, whether at home or abroad, such as through deposit requirement of guarantees that would, make it financially unattractive for young professionals to capitalize immediately on taxpayers investment in their education by seeking higher incomes”;
3. “It is difficult to see any crowding-out effects, to the disadvantage of resident patients that could not be addressed through adequate regulation that would not normally fall foul of GATS provisions. For example, a country might require all private hospitals to reserve a minimum percentage of beds for free treatment for the needy, to offer some basic medical services in remote rural areas, or to train beyond the number required for the purposes of these institutions”.

Taking into consideration the ground realities in most developing countries, a critical examination and analysis of the remedial measures suggested would seem to be unrealistic. These will be discussed by working groups during the Regional Consultation on the GATS and Public Health organized by Health Action International Asia Pacific in collaboration with the Ministry of

Health, Government of Sri Lanka. The consultation will be held in Colombo, Sri Lanka, 27-29<sup>th</sup> August 2007.

### **Mode 3 Foreign commercial presence**

This refers to situations in which service providers locate their business and operations in a country not their own. Establishing a presence includes ownership or lease of premises.

The establishment of commercial presence in a foreign country differs from the other three GATS modes in that this is essentially an issue of foreign direct investment (FDI) in hospitals, health clinics and health insurance. One of the aims of GATS (as noted in an earlier) article is to generate new opportunities for service companies to invest and operate in the service sectors of other countries. There are two operative words in this mode that needs closer examination: Commercial and Foreign.

#### **Commercial**

The negative impact of commercialization of health has been pointed out in several articles in previous issues of HAI News. The World Health Organization has stated, “by recognizing the right to health as a fundamental human right, international human rights law removes health from the status of a marketable commodity”. Therefore, if health is ever to become a fundamental human right which can be transformed into reality, it should cease to be a commercial product bought and sold in the market.

Even the neoclassical economists, as far back as the 1940s, had realized that the health sector is one where demand and supply cannot be regulated by the invisible hand of the market mediating between the buyer and the seller as in the case of other commodities. It was thus a combination of political and economic factors which together led to the first National Health Service (NHS) in the UK.

The evidence given above clearly proves that health should never be commercialized. Therefore mode 3 of the GATS process cannot be accepted because it makes health a marketable commodity.

#### **Foreign presence**

The single objective of foreign direct investment (FDI) is to get the maximum profit. Therefore, FDI will naturally be concentrated on high end technologies and not the kind of services which address the broader social needs of the population. This will result in excluding the middle and lower income groups and lead to a “cream-skimming” phenomenon whereby those who need less but can pay more are served at the expense of those who are more deserving but unable to afford the cost.

This practice of “cream-skimming” by the private for profit sector is not a new phenomenon. It is already familiar from the field of private health insurance where insurance companies typically favour the healthy and the wealthy over high risk customers, excluding the latter by prohibitive premiums.

There is one more long term

danger. Developing countries, on the advice of the World Health Organization, are looking into social health insurance to sustain a viable healthcare financing mechanism. The basic principle of social health insurance is cross-subsidization and risk pooling by which the healthy supports the ill, the young supports the old and the rich subsidizes the poor. The national social health insurance will be viable only if the whole population of the country is included in the scheme.

It is relevant in this context to quote from a 2006 World Bank document "International Trade in Health Services: Current Issues and Debates". Under the section on Mode 3 foreign commercial presence, the authors state as follows;

"There are considerable gaps in the knowledge base concerning foreign direct investment (FDI) and health services trade. Most of the issues highlighted are "data free", based on theory, assumption, experience in other sectors, or conjecture. Unfortunately, empirically very little has actually been done on FDI and health. Therefore, it is currently impossible to fully assess the potential impact of FDI on health because of:

- Uncertainty - there is no definitive interpretation of what existing agreements mean, together with opaque negotiations;
- Lack of experience in cross-border trade in health services;
- Lack of data generally; and
- Lack of analysis of impact (partly a consequence of the above).

This uncertainty, together with limited experience/evidence and analysis, means that informed decisions cannot be made. This is critical because there is no time limitation on GATS commitments: in principle, commitments made now, on the basis of inadequate information, will still constrain policy indefinitely, whereas circumstances may change profoundly over time. Countries can place any limitations on their commitments they see as appropriate but they have to specify what they are at the outset. The knowledge to make an informed decision about what limitations may be appropriate or necessary does not exist.

We have now adequate evidence to show that developing countries should not at this stage, commit to mode 3 of the GATS process.

#### **Mode 4 Temporary Movement of Natural Persons**

This refers to temporary movement of natural persons to provide a service abroad. Mode 4 has generated great interest in developing countries since there is already a substantial movement of medical personnel from South to North.

It should be underscored that the very large number of physicians from developing countries, particularly from Asia to Europe and North America, had not gone under the GATS process. The health sector is highly regulated and all the physicians who had migrated had successfully gone through complex licensing requirements. Countries are still drawing up commitments to Mode 4. At the moment country

commitments to Mode 4 are relatively small and relate to highly skilled migration which is relevant to the health sector.

It is relevant at this point to note that the GATS defines the movement of natural persons as people seeking 'non-permanent' entry or 'temporary' stay for the supply of services. There is no specified time frame for "temporary". Each country may interpret this according to its own specific national legislation which may be reflected in the GATS specific commitments. These may extend from a few months to several years. However, permanent migration is explicitly excluded.

#### **Implications of migration of skilled health professional**

Although developing countries have lobbied for Mode 4, the implications for the health sector of increasing temporary migration of skilled health workers will result in shortages of skilled health professionals in these countries.

Physicians who migrate will want to work in developed countries as long as they can and not return to their countries. What is perhaps not realized is the enormous loss of investment when doctors trained in national medical schools migrate to developed countries. Considerable resources go into doctors' training and tax payer's money provides the resources. What do the tax payers get in return for their investment when doctors migrate? Nothing!

In this context it is relevant to note that the unskilled workers, who migrate for employment, particularly women going to the Middle East, regularly remit their

savings back to their home countries. This is one of the top foreign exchange earnings for developing countries in Asia. However, doctors who migrate do not remit any money back home. They keep all their savings abroad.

Another result of migration from South to North is that the skills and training they get are designed to the health needs of developed countries. The opportunities to develop new skills are always related to high technology equipment which will not be available in the public sector in their home countries. If and when they return, they will opt to join the high-tech hospitals in the private sector where they can use the high-tech skills they had acquired and of course with much more remuneration. The public sector will lose their services.

The evidence presented shows that commitment to Mode 4 will lead to brain drain and investment loss to developing countries and is therefore not beneficial to developing countries.

### **Conclusions**

#### **Being informed negotiators**

Negotiators from developing countries need to be well prepared to enter into negotiations related to liberalizing trade in services. At present they have no guidance or direction. The Sub Commission on Human Rights resolution 2001/4 of the ECOSOC recognized this

lacuna and called upon the United Nations agencies in particular World Health Organization (WHO), United Nations Educational, Scientific and Cultural Organization (UNESCO) and the World Trade Organization (WTO) to carry out studies on the impact of the implementation of GATS on the provision of basic services, such as provision of affordable and accessible health and education services. Unfortunately no such studies are available.

Developing countries, therefore, cannot make any specific commitments till such time the UN agencies carry out relevant studies and make the reports available. It will then be possible for negotiators from developing countries to study the impact assessments and understand the potential gains and losses of opening up trade in health related services to foreign investors.

When negotiators from developing countries are fully equipped with the knowledge of the consequences of liberalization they will be in a position to ensure that the GATS process will not in any way adversely affect the national health policy goals nor will it undermine the two non-negotiable health policy principles.

Secondly there has been little or no public debate about the way in which privatization of public services such as healthcare at the national level is linked to the global trade expansion policies of the

three international institutions, the WTO, the World Bank (WB) and the International Monetary Fund (IMF) which are overseeing the grand globalization plan, although it has been shown that opening up of health care services poses a serious threat to public health. Why has there been no public debate on the GATS in countries of the region? A social scientist gave the answer, "a misinformed and ignorant public can hardly participate in a critical public debate". An informed and educated public is, therefore, a prerequisite for any meaningful public debate.

#### **Why public debates**

An informed and educated public can certainly influence a country's response to the GATS by bringing pressure on the negotiators to keep in focus the national policy goal, that the Right to Health is a Fundamental Human Right during their negotiations and resist the WTO, WB and IMF agenda to make health a marketable commodity.

HAIAP is organizing a Regional Consultation on GATS and Public Health in Collaboration with the Ministry of Health 27-29<sup>th</sup> August 2007, Colombo, Sri Lanka. Health activists from 15 countries will participate in the consultation.

This consultation, will hopefully, create a critical mass of health activists knowledgeable on the GATS who will be able to initiate/catalyze public debates on the GATS in countries of the region.

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# Network News

## ASIA-PACIFIC

### India

## Medicine price component survey in Delhi, India

WHO/HAI completed seven medicine price surveys in six states in India, between 2003 and 2005. The surveys were conducted according to the WHO/HAI medicines pricing methodology.

The surveys showed low availability of drugs in the public sector, reflecting the dependency and importance of the private sector. It also showed an unexpected variation in prices between public and private sectors, among therapeutic equivalents, and between scheduled (medicines whose price are controlled by government) and non-scheduled medicines (medicines whose prices are not controlled by government).

### An in-depth study

A more in-depth study of medicine price regulation and drug policy of India was conducted in Delhi in February/March 2007, in order to investigate the relationship between medicine prices, price composition and pricing policy. The survey was conducted by Dr. Anita Kotwani (VP Chest Institute, Delhi University) and Libby Levison (Public Health Consultant, Boston, USA). The survey utilized the WHO/HAI medicines pricing methodology on 8 medicines in the public and private sectors of the National Capital Territory (NCT) of Delhi.

Data on public sector procurement systems was collected from 4 public health care providers of NCT Delhi. They are; Central government, Directorate

Health Services (DHS) of the government of NCT Delhi (state government), two local bodies Municipal Corporation of Delhi (MCD) and New Delhi Municipal Corporation of Delhi (NDMC).

Data on the private sector procurement systems was collected from 3 manufacturers, 1 superstockist/wholesaler, 4 wholesalers and 7 retailers.

Few important findings obtained from the survey are as follows: -

### Public sector:

The NCT Delhi (state government), MCD and NDMC have generic formularies and functioning procurement systems.

The Central government has 2 medicines lists: one generic (600+ items) and one proprietary (500+ items). Proprietary medicines are mainly for central government run dispensaries (health centres) for central government beneficiaries. Procurement for Central Government hospitals and dispensaries is done by MSO (Medical Store Office, under ministry of health and family welfare) and an external procurement agency, HSCC (India) Ltd. respectively; fees of 10% and 4.5% are charged.

MSO and HSCC poor performance results in low availability; facilities resort to significant local purchase.

NCT Delhi tertiary facilities

report erratic supply requiring unplanned local purchases.

### Private sector:

Trade schemes are common in pharmaceutical trade

The retailer's low purchase price of branded-generic equivalents indicates the real manufacturing cost of branded medicines.

Detailed discussion with 2 medium-sized manufacturers shows weak correlation between cost and Maximum Retail Price (MRP) of branded medicines.

Evidence suggests that MRP is set significantly higher than cost. Data collected on Carrying & Forwarding and wholesaler margins match established markups.

### Taxes:

Numerous taxes are levied on active pharmaceutical ingredients and reapplied to finished products (e.g. excise tax, education cess, value added tax [VAT]).

All four public procurement systems pay 4% VAT; MCD also pays 4% CST (Central Sales Tax). HSCC collects service tax of 12% and education cess on orders.

India being an efficient producer of low-priced generic medicines, can do much to improve availability in the public sector and to reduce medicine prices in the private sector. The pharmaceutical industry and all those interested can look forward to a detailed report which will be published in the near future.

Source: Anita Kotwani, Department of Pharmacology, Vallabhkhair Patel Chest Institute, University of Delhi, Delhi 110007, India, E-mail: [anitakotwani@yahoo.com](mailto:anitakotwani@yahoo.com) Anita Kotwani is a member of HAI Asia-Pacific.

## Promotion of Pharmaceutical Care in Indonesia

Acknowledging that pharmaceutical care is increasingly important for the nation with a population of nearly 240 million, the National Agency of Food and Drug Control of Indonesia promotes the 'Takeryuk' Program (Takeryuk refers to Tanya Apoteker Yuk, literally meaning "Go Ask the Pharmacist") with the release of the DOWA (Daftar Obat Wajib Apotik) list; meaning drugs requiring mandatory provision by pharmacies.

A number of generic medicines that were previously available only by prescription, can now be purchased in pharmacies under the supervision of the pharmacists. The medicines on the DOWA list are for illnesses and symptoms that require minimum interface or contact with a doctor following diagnosis and initial prescription, such as tuberculosis, gastrointestinal disorder, rheumatic disease, asthma and other commonly used drugs and oral contraceptives.

This new decree, and the DOWA list has made a deliberate shift of responsibility in medication from the doctor to the pharmacist. It has given the pharmacist the authority to diagnose and prescribe. At the same time it has given the patient greater involvement and increased access to the process of

medication and therapy.

### Study of response to the DOWA list

The Indonesian Consumers Organisation (Yayasan Lembaga Konsumen Indonesia YLKI) based in Jakarta initiated a study; 'Implementation of Pharmaceutical Care in Indonesia' in 2006, to get an insight into the response by consumers and pharmacists to the release of the DOWA list, the increased responsibility to the pharmacist and accessibility of medicines to the patient.

### Study methodology

The sample frame for the study represented all the registered pharmacies in Jakarta. Twenty four pharmacies were selected for the study. The pharmacies were purposively chosen, representing different categories of pharmacies depending on its size and location, consumer preference (popularity), ownership status (government owned and private chains).

Field observations, interviews and focus group discussions were used to make observations. Participants also used the participatory observation method and approached pharmacists as patients requesting information, advice and guidance to purchase medicines.

### Observations of the study

Pharmacists were present only in

36 per cent of the pharmacies and most of them did not remain till the closing hour. 6 per cent of the pharmacies voluntarily gave information that patients found satisfying and 29 per cent gave information on request. The rest of the pharmacies did not provide any information or required the patients to make an appointment to meet the pharmacist.

### Conclusion

The problem often encountered by consumers is that when pharmacists are not available, as is mainly the case revealed from the field study, patients need to rely on information provided by pharmacy keepers who are not trained pharmacists.

The study revealed that the pharmacy owners/managers lacked formal education on pharmacology, not to mention knowledge of the DOWA list, its function, advantages and challenges. They were also not equipped with critical competence such as recommending generic drugs under cost constraints.

The overall study revealed that consumers lack necessary information required to make the new ruling put forward with the aim of increasing patients' access to medicines effective.

*Source: Ida Marlinda, Yayasan Lembaga Konsumen Indonesia (YLKI), Jl. Pancoran Barat VII/1, Duren Tiga, Jakarta 12760, Indonesia, Tel: 62 21 797 1378 , Fax: 62 21 798 1038, E-mail: [konsumen@rad.net.id](mailto:konsumen@rad.net.id), Website: [www.ylki.or.id](http://www.ylki.or.id) YLKI is a member of HAI Asia-Pacific.*

## Creating skilled teachers in pharmacology in Nepal

The Manipal College of Medical Sciences (MCOMS), Pokhara, Nepal has taken the first steps towards creating future teachers who can strengthen pharmacotherapy teaching in Nepalese medical colleges. MCOMS started a MSc course in Medical Pharmacology in 2004. The MSc programme is affiliated to the Kathmandu University. The goal of the postgraduate programme (PGP) is to create skilled teachers in pharmacology for medical colleges. Learning the importance of the rational use of medicines has been incorporated into the PGP through the practical examinations and the assessment system it follows.

The assessment process at MCOMS takes both the formative and summative approach.

### Formative evaluation process:

Formative evaluation involves assessment of the teaching ability of the students using microteaching sessions. The ability to read, assimilate, understand and present topics is assessed during the postgraduate (PG) seminars. Lectures and problem-based learning (PBL) sessions are the two main learning modalities assessed during microteaching.

The assessment criteria for lectures are planning, delivery, coverage of the topic keeping in

mind the requirements of the undergraduate students, quality of the audio-visual material used, time management and encouraging students to ask questions. In the PBL sessions PG students are assessed on facilitation of learning sessions, ability to direct group dynamics and encourage self directed learning.

Along with the above, PG seminars are conducted every week in the department and students are assessed on these. In addition to the traditional pharmacology topics, MCOMS have also included 'Essential medicines', 'Access to medicines in Nepal' and 'Problem based learning of Pharmacology' as seminar topics.

### Summative evaluation:

**Communication skills, prescribing indicators & simulated exercises:** The PG students are assessed in communication skills where they communicate drug and non-drug information about a common disease condition to a simulated patient. Calculation of prescribing indicators and simulated experiments one carried out.

**Critical analysis & problem analysis diagram:** The students are given a published clinical trial, a drug advertisement, a website and a common drug use

problem to critically analyze and present the strengths and weaknesses of the study/material and whether the study/material is of relevance to a Nepalese setting.

**P-drug and role plays:** The PG students have to play the role of a medical representative and, ethically promote a medicine to a doctor. They have to select a (Personal -drug) (Priority choice drugs for given indications) for a given disease on the basis of efficacy, safety, cost and convenience. Then they have to verify the suitability of the selected P-drug for an individual patient problem and write the prescription.

### Drug information centre:

The department runs a drug information center (DIC) and pharmacovigilance and medication counseling centers in the teaching hospital. The PGs are actively involved in the working of the DIC and the pharmacovigilance center.

The teaching and assessment process reflects the commitment of the department to essential medicines and rational drug use. It aims to produce teachers who would be able to teach rational use of medicines in their academic careers and who are able to encourage self-directed, problem-based learning of pharmacology and therapeutics among the students.

Source: Contributed by Dr. P Ravi Shankar, Manipal College of Medical Sciences, P.O. Box 155, Deep Heights, Pokhara, Nepal, Tel: 00977-61-440600, Fax: 00977-61-440260, E-mail: [ravi.dr.shankar@gmail.com](mailto:ravi.dr.shankar@gmail.com)

**Pacific Islands**

**POLHN Learning Centres**

The World Health Organisation's Pacific Open Learning Health Net (POLHN) provides courses, course materials and health resources to health professionals in Pacific Island countries. Its purpose is to improve quality and standards of practice of health professionals through training and continuing education using self-directed eLearning. The POLHN has set up resource centres in 11 Pacific island Countries: Cook Islands, Federated States of Micronesia (Chuuk, Kosrae, Pohnpei and Yap), Fiji (Lautoka and Tamavua), Kiribati, Marshall Islands (Majuro and Ebeye), Nauru, Palau, Samoa, Solomon Islands, Tonga, and Vanuatu.

**CDROM on Management of Essential Medicines**

An interactive CD ROM on the management of medicines has been prepared by Beverley Snell primarily for the WHO POLHN. It provides for 20 to 30 hours of student interaction in collaboration with the Coordinator of the POLHN. The subjects included in this learning module are not usually included in the formal pharmacy curricula yet graduates are expected to return to their countries and implement all areas of pharmacy management.

In each section of the curriculum an outline of the topic is provided together with practical illustrations

of related issues. Reference material is hyperlinked to the text and can be accessed without leaving the CD so it is not necessary to be online to participate in this course. The reference material is also available in a separate reference section. There are some extra reference links that do need to be accessed through the web.

Exercises are included at the end of each chapter to test the knowledge gained from that chapter. It is suggested that satisfactory completion of the exercise will be rewarded with a Certificate and the possibility of accreditation with the Fiji School of Medicine. This possibility is still being explored. An evaluation form is included in the last chapter and feedback is encouraged with a view to continually improving the course. The information is extensively illustrated and permission was obtained for reproduction of material from other sources and those sources are credited throughout the document. The CD ROM provides a self-paced training program. It can also be used as the primary source of information for a 6 week instructor led course. The material is auto run and designed to run using Apple, Microsoft and Linux Operating Systems.

**Contents of the Course**

- Chapter 1. The introduction includes the history of the

essential drugs concept and the concept of National Medicines Policies.

- Chapter 2. Selection of medicines; includes the principles of selection, treatment guidelines, standard medicines lists and drugs and therapeutics committees.
- Chapter 3. Procurement; includes sources and prices (tenders), quantification, quality issues and logistics (importation and port clearing).
- Chapter 4. Management; includes storage and stock control, distribution to different levels of the health service and management at peripheral levels of the health service.
- Chapter 5. Rational Use of Medicines; includes sections on what is rational use of medicines, what is not rational use of medicines, what are the implications, training for rational use of medicines and dispensing according to the treatment guidelines
- Chapter 6. Monitoring and review; includes sections on the supervision and support of health workers and identification of targets for further education or review of protocols and guidelines.
- Chapter 7. Conclusions and References

*Source: Beverley Snell, Centre for International Health, Burnet Institute for Medical Research & Public Health, GPO Box 2284, Melbourne 3001 Australia, E-mail: [bev@burnet.edu.au](mailto:bev@burnet.edu.au) Information on the Pacific Open Learning Health Net is accessible on <http://www.polhn.com> Beverley Snell is a member of HAI Asia-Pacific.*

## EUROPE

### World Health Assembly 2007: Lot of Controversy, Little Outcome

Without doubt the 60<sup>th</sup> World Health Assembly (WHA) held from the 14<sup>th</sup> - 23<sup>rd</sup>, May, Geneva, Switzerland is the annual highlight of international health politics. Health ministers of almost all member states met, together with huge delegations, discussing concepts for global health issues. The following outlines the main outcomes of the assembly.

#### Rational Use of Medicine

In many cases medicines are not used in the right way. This may have many reasons including wrong prescription, ignorance of patients or disinformation by pharmaceutical advertising. Globally only 40% of people are treated according to clinical guidelines.

However, experience from many countries show that drug policy implementing the “rational use of medicine” can lead to a change. The resolution on rational use of medicine, passed at the 60<sup>th</sup> WHA ([http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R16-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R16-en.pdf)) is the first step towards implementing such a policy in all countries. The resolution requests the WHO member states to implement such a policy and to provide adequate financing. It promotes an integrated health systems approach to promoting more appropriate use of medicines. All countries were requested to establish national drug regulatory bodies and a full national programme and / or

multidisciplinary body, involving civil society and professional bodies to ensure among others high quality drug information, act against misleading advertising and train health professionals on rational use of medicine. The WHO based on its experience and expertise was appointed to give support on all these issues.

Passing this resolution was a real success for many years of HAI work, based on excellent cooperation with WHO the Ecumenical Pharmaceutical Network (EPN) and many other networks.

#### Medical Research and Development (R&D)

In 2006 WHO established a working group to develop an action plan for medical R&D (Intergovernmental Working Group on Public Health and Innovation IGWG PHI). This was with the intention of closing the R&D gap for diseases mainly affecting poor countries. The working group has been slow to get off the ground, and especially countries from Africa were concerned about insufficient WHO support for this process. During the WHA it was unclear for a long time, if there would be any resolution on this issue at all. While the EU and the US pushed to discuss this topic at the working group level in the upcoming months, countries led by Kenya and Brazil requested the implementation of additional activities by a WHA resolution

([http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R30-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R30-en.pdf)).

The WHA resolution has two main points. One, it gives a clear statement that no country should be prevented from taking measures to protect public health by using the TRIPS flexibilities (e.g. compulsory licensing). This is a clear message to Thailand, currently suffering from enormous political pressure against their decision to grant a compulsory licence. WHO was in fact requested to support countries willing to make use of TRIPS flexibilities. Two, the WHO working group (IGWG PHI) has been requested to consider new mechanisms for promoting R&D, that address the linkage between the costs of R&D and the price of medicines. This is a great opportunity to develop new models that makes drug prices independent from R&D costs, and including models for R&D without patent monopolies.

WHO will now organize regional meetings for countries to discuss their needs and their positions. The WHO secretariat will publish a first draft for an action plan in July 2007, followed by a public hearing.

#### HAI action

HAI has been following this work for many years. To strengthen our work, HAI decided to form a platform together with organisations working on the same issue. The platform “Innovation plus Access (I+A)” is guided by the

principle that everybody must have access to the results of medical R&D. Equal Access to medicine therefore needs new concepts for R & D, working without monopolies and without high prices for medicines. The platform is joined by Third World Network (TWN) Doctors without Borders (MSF), Knowledge Ecology International (KEI) from the US, Oxfam and Drugs for Neglected Diseases Initiative (DNDi). Christian Wagner from BUKO Pharma-Kampagne is coordinating the HAI members activities.

#### **Avian Flu**

How to deal with avian flu virus was one of the most difficult tasks at the 60<sup>th</sup> WHA. The issue was how to share virus samples needed for development of a vaccine. Usually countries give virus samples to WHO Collaborating Centres and based on a combination of different virus strains a vaccine is developed. In general this system works for the well-known flu vaccine that has to be adapted each season. The same system is being used for creation of an avian flu vaccine, with one exemption: Indonesia had announced to stop delivering virus samples some months ago. Even though it is one of the countries hardest hit from avian flu, they don't send their virus samples to WHO Collaborating Centres any more. This decision is meant as public resistance against patenting of virus strains. The Indonesian

government has stated that they will recommence sending virus samples as soon as they have the security of affordability of the vaccine based on their virus samples.

While the US insisted on the need for selfless cooperation from each country, Indonesia got support from other developing countries. In the end an agreement was reached even though several points are still not clear. Indonesia will continue to share virus samples with WHO centres, but on the condition that a regulation for benefit sharing be developed. How Indonesia will get profit from a vaccine in future will be discussed during a follow-up conference in Jakarta in October, 2007.

The resolution ([http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R28-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf)) states clearly that each country has the sovereign right over its biological resources, including pathogens and that the health of the population shall not be endangered by patent protection. Before the assembly WHO had already promised to support increased vaccine production capacities in Asia - an important measure to secure local supply.

#### **Fight against Malaria**

The resolution for fighting Malaria ([http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R18-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R18-en.pdf)) clearly mentions that every country should use the TRIPS flexibilities to ensure access to medicines. To

halt the spread of resistance against artemisinin, the WHA agreed on the use of combination therapies and to stop monotherapy with artemisinin.

#### **Small Pox**

The biggest disappointment was the repeated failure of a resolution to destroy the last stocks of the small pox virus. Small pox was eradicated in 1977; yet there are two laboratories left worldwide that still keep some virus stocks. In 1999 the WHA proposed to destroy these last virus stocks, but still US scientists wanted to continue research on the virus. Once again the final decision could not be made. The discussion on the research and conclusions concerning the need for any further research will be taken up again only in the year 2011 at the 64<sup>th</sup> WHA.

#### **Other issues**

Some other points were also taken up at the assembly. The WHO will increase its budget by nearly 1 billion US\$ to 4.2 billion US\$ for the period 2008-2009.

The assembly among a record number of resolution also passed a resolution on better medicines for children. The aim is to create a framework to promote better use of existing medicine and more R&D in future. WHO will develop a 'Model List of Essential Medicines for Children' and identify key areas for research requirements.

*Source: Dr. Christian Wagner, HAI coordinator for R&D issues and represents HAI within the I+A platform. All those interested in joining this work on the national level by lobbying national governments or international level, please contact Christian: [cwagner@bukopharma.de](mailto:cwagner@bukopharma.de) BUKO pharma-kampagne, August-Bebel-Str. 62, 33602 Bielefeld, Germany Fax: +49-(0) 521-6 3789*

## The Netherlands

### Health Action International Responds to the Revival of DTCA discussions

The proposal to weaken the EU's ban on advertising prescription-only medicines to the public was overwhelmingly rejected by the European Parliament in 2002. Yet, only two years later the European Commission "openly regrets" this decision and calls for a reform of the European pharmaceutical products legislation. HAI Europe deplores this move to reopen the direct-to-consumer advertising (DTCA) debate.

Once again, the European Commission has established a body, the Pharmaceutical Forum, to address public health issues including the review of pharmaceuticals in the EU. Chaired by DG Health & Consumer Protection and DG Enterprise & Industry, the forum, which includes many representatives from the pharmaceutical industry, has been convening 2-3 times the year.

Consumer and independent health groups without pharmaceutical industry funding, like HAI-Europe, have been largely excluded from this process. The Pharmaceutical Forum follows on from the G10 Medicines Group (set up in March 2001 to advance the competitiveness of the European Pharmaceutical industry); both advisory committees are heavily dominated by the pharmaceutical industry and appear to have an industry-driven agenda.

#### Is the involvement of the pharmaceutical industry necessary?

The EU Commission has recently issued an open consultation on information to patients, comprised of a draft information package on diabetes and a set of principles on good quality information.

The covering information with the consultation states: "The reason for preparing this diabetes information package was to test, for the first time at the European level, whether and how information on treatments could be developed based on a disease area in a partnership involving public authorities and key stakeholders including the industry."

The main aim of this initiative appears to be to involve the pharmaceutical industry in provision of health information to the European public. This is despite an overwhelming vote by the European Parliament and Council against such an introduction.

The European Parliament only asked the Commission to examine ways to improve provision of patient information in Europe; and not examine ways to assist the industry in promoting its products to the European public.

The consultation process has been skewed towards aims other than the provision of the best possible

information to meet patients' needs. HAI-Europe disagrees fundamentally with the way the consultation has been framed, both in terms of the types of questions asked and the manner in which the documents appear to have been produced.

The key concerns raised by HAI-Europe in its response to the high level Pharmaceutical Forum consultation and diabetes information package can be outlined as follows:

#### 1. Conflict of interest

The Pharmaceutical industry has no role in providing the public with comparative information on drug treatments, or in the provision of information on disease epidemiology or prognosis. These are information needs that can only be met by information providers without conflicts of interest.

#### 2. Lack of methodology

The lack of transparency of the Pharmaceutical Forum, as well as the absence of any clear methodology resulted in an obscure process and poor quality outcomes.

#### 3. Insufficient information to consumers

The "diabetes information package" which is being put forward by the Pharmaceutical Forum omits important information. It provides no useful information on disease reversal, prevention of progression, prognosis, complication rates,

relative effectiveness of different treatments in preventing complications, common harmful effects of treatments, or serious adverse events.

**4. Unsuitable instruments of quality measurement**

The quality principles being proposed have serious shortcomings. They do not include any reference to conflicts of interest, are vague and do not take into account other instruments to measure the quality of health information (that are already available), such as the United

Kingdom's DISCERN questionnaire.

**5. Non-inclusion of critical organizations & individuals**

Organizations and individuals with experience in providing health and medicines information to the public have not been consulted in the high-level Pharmaceutical Forum.

**6. Unethical initiative**

The legitimacy of the initiative is open to question. Both the Pharmaceutical Forum's lack of transparency and lack of explicitly described methods remain

unacceptable. Health Action International (HAI) and the International Society of Drug Bulletins (ISDB) deplores the fact that since its inception the Pharmaceutical Forum has operated with an almost total lack of transparency. This consultation provides additional evidence of this: two documents have been submitted for public consultation with no explanation on methods that were used to produce them, nor any disclosure of information on authors or their potential conflicts of interest.

**Big Pharma TV Channel: Diagnosis Advertising**

Four of the world's biggest pharmaceutical companies (Johnson & Johnson, Pfizer, Novartis and Procter & Gamble) have recently come up with a proposal to launch an interactive television channel called "European Patient Information Channel", to "inform" the public about their drugs. As reported by the Guardian on 21<sup>st</sup> May 2007, "Pharma TV" would be a dedicated interactive digital channel funded by the industry with health news and features but, at its heart, detailed information from drug companies about their own medicines.

The EU Commission is about to launch the second round of the EU Pharmaceutical legislation's Review Process. As it stands, Directive 2001/83/EC bans direct-to-consumer-advertising (DTCA) of prescription-only medicines. Nevertheless, the present legislation does allow the industry to provide information to European citizens, provided they do not

directly or indirectly promote their products.

**The industry's arguments backing the TV pilot**

- The industry argues that lifting restrictions would help its competitiveness and has hinted that companies may relocate to the US, where they can advertise to patients who then demand drugs from their physicians.
- It is worth noting that the industry has not presented "Pharma TV" as a promotional strategy but as an informative tool complying with patient's need for information on medicinal products. The channel would be available on the internet as well as TV, and would offer "on demand" information about drugs.
- The TV pilot was welcomed by a number of influential patient groups, including the European Patients' Forum, which is the only patient organization admitted to the high-level Pharmaceutical Forum set up by

the commission to discuss legislative changes.

**Consumer and Health organizations' arguments against "Pharma TV"**

- These organizations jointly agree that it is inherently difficult, if not impossible, to make a real distinction between information and advertising when it is being provided by a company which has a product to sell. Even information that has a firmly objective factual basis will be presented in a promotional manner. The International Society of Drug Bulletins (ISDB) consumer and healthcare professionals' publications, which analyze the benefits of drugs and draw comparisons between them, warns that the industry is not a reliable source of trustworthy information. In both the US and New Zealand, where drug companies are allowed to advertise to the public, "Pharmaceutical companies" messages are focused on

relatively few top sellers, exaggerating effects and concealing risks, confusing patients and putting pressure on doctors to prescribe drugs they would not use otherwise," says ISDB.

- A self regulation system to ensure the consistent provision

of objective and non-promotional information by the pharmaceutical industry would be ineffective. Such a structure is likely to be based on post hoc sanctions, which in turn would encourage attempts to push any applicable quality standards to their limits.

- Health Action International Europe and Association Internationale de la Mutualité were interviewed by the BBC on this theme and were adamant to diagnose Pharma TV as a clear example of unethical promotional practice.

*Source: Teresa Alves, European Campaigns Coordinator, HAI Europe, Jacob van Lennepkade 334T, 1053 NJ Amsterdam, The Netherlands, Tel: +31 20 489 1864, Fax: +31 20685 5002, Email: [teresa@haiweb.org](mailto:teresa@haiweb.org), Web site: <http://www.haiweb.org>*

## LATIN AMERICA

### Peru

### **Shame! Democrats are doing the Andean and Peruvian negotiators' work**

During the negotiations of the Free Trade Agreement (FTA) between the USA and the Andean countries, including Peru, the negotiators of the Andean countries were yielding in their demands as the United States Trade Representative (USTR) negotiators maintained their original position. The US did not need to compromise on their position as the negotiators of the Andean countries did not have the will or the support from their governments to push forward their proposals.

For example, on the issue of data exclusivity, it was proposed by the Andean countries that exclusivity should be counted from the first marketing approval of the medicine. This was not accepted by the USTR and the Andean countries compromised on their stand. On the linkage between patent granting and marketing approval, the Andean countries proposed that there should be no such linkage. Again, the USTR rejected the Andean proposal. Another position

of the Andean countries that was rejected by the USTR was on not accepting any compensation regarding delays on the patent granting process. It continued in the same manner with other issues such as the definition of new chemical entity, the explicitness of the Doha principles, and use of the TRIPS safeguards.

The FTA between USA-Peru was signed with the original proposal of the USTR. None of the modifications proposed by Peru and other Andean countries were accepted. It was not a negotiation, but an imposition of an agreement. Even the limited "red lines" set up by the Peruvian Ministry of health were crossed out. The intellectual property section was used by the USTR as a tool to blackmail: if you do not accept this text on IP there won't be an agreement. Peruvian negotiators were erroneously convinced of the benefits of the FTA in other fields included in the agreement, and accepted the USTR text. Likewise, the Minister of

Health was also convinced.

With the change on the composition of the US Congress last year, democrats started a discussion on some important issues of the FTA negotiations. The first issues that arose were related to the labour conditions. Afterwards, it also included Intellectual Property issues.

At present Democrats and Republicans are looking for a consensus on a new text related to several issues:

- a) data exclusivity will be counted since the first marketing approval is granted;
- b) the compensation for delays on patent granting process won't be mandatory, but it would depend on any part;
- c) there will be no linkage requirement between drug regulatory authorities and the patent granting;
- d) the "side letter" on Doha declaration should be part of the text clarifying that the

agreement should not prevent countries to use measures to protect public health using TRIPS flexibilities;

- e) there should be an exception on data exclusivity in the event of a measure to protect public health.

This attempt for consensus by

the new Democrat members of US congress is a great advance, but not enough. However, what the Democrats are proposing is almost the same as what the Andean countries proposed at the beginning of the negotiations. A lack of will to negotiate, lack of focus on the

public interests, the disparities of the negotiating countries and the illusion of the supposed benefits of the FTA made Peruvian negotiators abandon their original proposals which are now being taken up by US Democrats.

*Source: Roberto López Linares, Coordinator, HAI Latin America and the Caribbean, Apdo 41 128 Urb Javier Prado, Ca. Mario Florián Mz 3 Lote 22, San Boria, Lima 41, Peru, Tel/Fax: + 511 3461502, E-mail: robertolopez@aislac.org Website: <http://www.aislac.org>*

## Journal Scan

### FDA Says No to Vioxx Successor

The U.S. Food and Drug Administration (FDA) turned down Merck & Co.'s request to market Arcoxia, a successor to its banned arthritis drug Vioxx.

The decision came as little surprise, since an FDA advisory panel of medical experts had already voted 20-1 against the drug's approval on April 12.

Arcoxia (etoricoxib) is a cox-2 inhibitor, the same class of drugs that includes Vioxx, Bextra and Celebrex. Vioxx was withdrawn from the market in September 2004, after studies showed it doubled the risk for heart attack and stroke. Bextra was withdrawn for similar reasons early in 2005. Celebrex remains on drug store shelves, albeit with a strong warning label highlighting potential heart risk.

But "just having a similar drug in the market is no reason to approve this drug (Arcoxia) or any other similar drug," Dr. Robert Meyer, director of the FDA's Office of

Evaluation, in its Center for Drug Evaluation and Research, said after the advisory panel's vote.

Meyer told a news conference at the time that the panel wanted any new non-steroidal anti-inflammatory drugs (NSAIDs), which include cox-2 painkillers, to undergo head-to-head comparisons to similar drugs before applying for U.S. approval.

The FDA decision was preceded by a barrage of criticism over Arcoxia's potential risk for increasing heart attacks and strokes, particularly among people with existing heart disease.

Arcoxia is designed to treat the pain of osteoarthritis without the harsh stomach effects associated with painkillers such as aspirin.

But in his testimony before the agency's advisory panel, FDA scientist Dr. David Graham said drug safety studies performed on Arcoxia were neither adequate nor reasonable to support its approval, the Associated Press (AP) reported.

"What you're talking about is a potential public health disaster," Graham said of Arcoxia. "We could have a replay of what we had with rofecoxib (Vioxx)."

Another strong critic, Dr. Eric J. Topol, director of the Scripps Translational Science Institute, also found fault with the new drug. Topol first published data on the danger of Vioxx in 2001.

"We don't have the data to know the boundaries of Arcoxia's safety," he said in an interview in April, before the advisory panel's vote. "There is a difference now that there is awareness of heart risk with these drugs. There was not awareness, in fact, there was denial back in 2001."

"If the drug is approved, it would not be the same as what happened years ago," he added. "But I still am concerned that we don't have the cardiovascular safety issue assured. There can be misrepresentation of the drug when it's marketed."

A top Merck official told the advisory panel that the company has "comprehensively characterized the safety and efficacy profile" of Arcoxia.

"We at Merck believe etoricoxib represents a valuable treatment option for patients with osteoarthritis. We would like to emphasize there is more long-term safety data for etoricoxib than any other NSAID," said Peter Kim, president of Merck's research laboratories.

But other experts were not convinced.

In prepared testimony for the panel, Dr. Sidney Wolfe, director of the Health Research Group at Public Citizen, said the drug should not be

approved in the United States and should be pulled from the market in the more than 60 countries where it is now sold.

"How can the approval of etoricoxib and the large numbers of preventable, life-threatening cardiovascular adverse reactions be justified?" Wolfe said in a prepared statement. "Why should the similarly dangerous offspring of Vioxx be approved? The answer is that it should not."

Wolfe noted that trial data presented by Merck on cardiovascular risks compared etoricoxib with the arthritis pain reliever diclofenac (brand name Voltaren), which he said is much more cardio-toxic than older, safer pain relievers.

"It is time to shut the door on further additions to this dangerous class of cox-2 inhibitor drugs," Wolfe said. "The idea that there may be certain patients, however unidentifiable they are, who might benefit from this drug is just not good enough as a basis for its approval. In addition, further trials on these cox-2 drugs are unethical and should be stopped."

However, as recently as Tuesday, officials at Merck said they would continue to push for Arcoxia's U.S. approval, the AP reported.

Since pulling Vioxx from the market, Merck has faced more than 10,000 lawsuits from former patients and their families.

Source: *Healthday*, 27 April 2007, [http://www.nlm.nih.gov/medlineplus/news/fullstory\\_48531.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_48531.html)

## The Efficacy of Compulsory Licenses and International Cooperation

*Thailand and Brazil, the Clinton Foundation on HIV/AIDS and generic companies, and (an International drug purchase facility) and WHO all combine forces to lower AIDS drug prices. Bold moves on several fronts are helping to lower the price of key second-line and improved first-line therapies for HIV/AIDS helping to pave the way to Universal Access by 2010.*

Access to medicines has undertaken a great leap forward following the decisions of Thailand and Brazil to issue TRIPS-compliant compulsory licenses on important AIDS medicines, following the Clinton Foundation HIV/AIDS Initiative's work with generic companies to lower costs

and to provide co-formulations of essential second-generation medicines, and following the new procurement money and expertise put together in UNITAID and prequalification services provided by the WHO. These combined forces will result in quality assured, heat-stable form of lopinavir/ritonavir (a Kaletra equivalent) being available soon at \$695/per person per year (pppy) even in middle income countries, undercutting Abbott's last offer by over 30%. There is also a once-a-day, fixed-dose combination of tenofovir/lamivudine/efavirenz, a WHO recommended therapy equivalent to Gilead and Merck's Atripla, now available for \$339/pppy, making it 45% cheaper than the current rate available for

low-income countries and 67% cheaper than the current rate for middle-income countries. Purchases of these medicines and their rational procurement for 27 countries will be supported by UNITAID through 2008 to the tune of \$100 million, funded with a recent air travel tax. The quality of these medicines will be assured through prequalification at the WHO which should provoke fast-track registration of medicines by national drug regulatory authorities.

### History of this breakthrough

At the Toronto International AIDS Conference last August, Medecins Sans Frontieres (MSF) and AIDS activists alerted the world to the impending crash between anaemic funding for universal-access-by

-2010 and the looming costs of more expensive first-and second-line therapies, frequently 10 to 36 times more expensive than older first-line therapies in low- and middle-income countries respectively. Although the cost of older, first-line therapies had continued to plummet, and are now as low as \$90/pppy in some instances, the costs of improved and more highly recommended first-line therapies were much higher because of patent protections. The costs of second-line therapies, especially those involving tenofovir or Kaletra were even higher because of the absence of any generic competition whatsoever, meaning that the future costs of universal access (9.8 million on treatment by 2010 and as many as 3-4 million new patients per year thereafter, many of whom would need second-line therapies after 5 or 6 years) were set to explode.

The difference between the affordability of older first-line therapies and the unaffordability of newer therapies had two explanations. First, the older therapies were unpatented in India, where equivalent generic medicines could be produced cheaply and also unpatented in most African countries, where the bulk of latent demand existed. In contrast, newer medicines were much more widely patented, with patent applications pending in India's 1995-2005 transitional patent mailbox and already granted throughout Latin America, Africa, and Asia. Second, the market dynamics were different.

Whereas, millions of people immediately needed access to more affordable first-line therapies and no-patent markets could be aggregated to encourage generic entry by multiple producers, the market for cheaper second-line therapies was much smaller because few developing countries had started wide-scale treatment programs before the creation of the Global Fund. Because of this slow start for treatment, the numbers of patients needing second-line therapies, either because of adverse side-effects or because of the inevitable development of drug resistance over time, was relatively small, producing fewer market incentives for generic entry and reduced prospect to quick economies of scale.

Brazil was the main exception to paralysis in treatment rollout as it committed to universal free access to care almost immediately after highly active antiretroviral therapy (HAART) was discovered. Accordingly, a patient that began treatment in 1997-98 began to need alternative therapies by 2003. Unfortunately, however, instead of helping to create a generic market by actually issuing compulsory licenses for second-line medicines, Brazil threatened compulsory licenses but ultimately settled on temporary price discounts.

As the growing demand for HAART threatened AIDS budget in several developing countries, a few countries boldly granted compulsory licenses on AIDS medicines, including Malaysia,

Indonesia, Ghana, Eritrea, Zambia, Zimbabwe, and Mozambique (the threat of compulsory licenses in a South African competition case prompted multiple voluntary licenses). These licenses were relatively uncontroversial because they primarily affected first-generation medicines. However, this past November and January, Thailand took the lead and issued government-use licenses for Merck's efavirenz and Abbott's Kaletra, immediately creating market pull for generic entry. Two months later, on May 4, Brazil followed suit and issued a compulsory license on efavirenz, thereby adding market demand for nearly 75,000 patients who will be on efavirenz by the end of 2007.

**How compulsory license have led to price reduction both from Pharma and from generic producers**

The efavirenz story is especially instructive. Until Thailand issued its compulsory license, Merck priced efavirenz at \$276/pppy in first-tier countries and \$697/pppy in second-tier countries, including Thailand and Brazil. (Generic prices ranged from \$217-\$299 from various producers to various countries.) When Thailand issued its compulsory license on efavirenz, Merck responded in February by reducing its price in Thailand to \$237, a price it later extended to least-developed and higher prevalence countries (above 1%) in February. Because Thailand could still purchase 17% more cheaply from India at approximately \$197/pppy, it has

already ordered 66,000 bottles from Ranbaxy in India. Also, in February, Merck proportionately reduced its price in medium human development index countries to \$657/pppy, a price that Brazil found inadequate. When Merck refused to budge, Brazil notified Merck of its intent to issue a compulsory license at which time Merck offered a further 30% reduction to \$401.50/pppy. Because Brazil can procure from India for \$170, it has rejected Merck's last ditch offer and issued a compulsory license.

The history of Kaletra prices is similarly dramatic. Historically, Abbott charged highly variable prices in low- and lower-middle-income countries ranging from \$3000-\$6000/pppy. In August 2006, in response to activist pressure, Abbott announced a uniform mid-tier price of \$2200/pppy, still far too high for cash strapped developing countries and their residents. Although negotiations with Thailand continued and Abbott's president claims to have offered a \$1700/pppy price, Thailand issued a compulsory license on January 24, 2007. Abbott retaliated by withdrawing seven medicines from Thai's regulatory approval process, including the heat-stable form of Kaletra. In response to public outcry, however, Abbott offered a further mid-tier price reduction to \$1000, but refused to resume registration proceedings in Thailand until the license was withdrawn. In the meantime, Brazil, which had entered into a six-year price-discount agreement

with Abbott, was stuck with an annual price tag per patient per year of approximately \$1500 for Kaletra. Fortunately, for it, Abbott's mid-tier price discount extended to Brazil, but Brazil is still bound to purchase from Abbott. However, Thailand and other countries without patents on Kaletra or countries that issue compulsory licenses can purchase a heat-stable version of lopinavir/ritonavir for only \$695/pppy, a 30% saving. These prices will fall even further as more generic producers enter the market, gain WHO prequalification, and compete for a growing population of PWAs (people living with HIV AIDS) needing second-line therapies.

#### **The role of the Clinton Foundation, generic companies, UNITAID and WHO**

At the same time that developing countries were escalating their prosecution of compulsory licenses, the Clinton Foundation HIV/AIDS Initiative was working behind the scene with generic companies Cipla and Matrix to source cheaper active pharmaceutical ingredients, to identify production economies, to identify needed second-line and fixed-dose combination medicines, and to help expedite the filing of data dossiers to the WHO Prequalification Project. Although the pharmacists and technical experts played a critical role in these negotiations, they were greatly aided by the presence of new purchasing power for second-line medicines organized by UNITAID, the beneficiary of a new airline travel tax. UNITAID had

identified additional purchasing power and simplified procurement of second-line medicines as a key step in the road to universal access, so it harnessed its energy and technical expertise to the new second-line initiative. Finally, WHO is playing a critical role as it expedites review of product dossiers already filed. It is hoped that prequalification will be announced in the next few months.

#### **Threats on the horizon**

Although great progress has been made, there are threats on the horizon from drug companies, from the U.S. government, and from the rigidity of the post-TRIPS intellectual property regime. The drug companies have responded with monopoly-profit-related anxiety to the announcement of compulsory licenses in Thailand and Brazil and have gone on public relations disinformation campaigns directly and through their proxies such as 'USA for Innovation. Even though the TRIPS Agreement and the Doha Declaration make it exquisitely clear that countries are free to issue compulsory licenses on any grounds they choose and to forego negotiations when the licenses are for government, non-commercial use, Big Pharma has cried "foul," claiming erroneously that Thailand and Brazil are too rich to issue compulsory licenses, or that protracted prior negotiations other than what already occurred was required, or that licenses cannot be granted to government-owned pharmaceutical companies. Even more egregiously, companies like Abbott are threatening to withhold

life-saving medicines from developing countries that issue compulsory licenses. Though we can hope that these threats will not cause Thailand and Brazil to back down, there is a risk that they will deter smaller, poorer, and weaker developing countries.

Fortunately, the price reductions, threats, and distortions from Pharma are becoming less and less significant as licenses are issued and generic producers offer substantial price discounts. However, there is another threat on the horizon in the form of trade threats from the United States Trade Representative (USTR), which has just put Thailand on the Special 301 Priority Watch-List because it dared to issue three TRIPS-compliant government-use licenses. The USTR used the same kind of watch-list pressure when negotiating the original TRIPS Agreement and again when South Africa passed a law that would have allowed parallel importation of branded medicines sold more cheaply in another country. Unfortunately, the US is not content with trade threats, it has also been on an intensive campaign to impose TRIPS-plus and US-law-plus intellectual property protections on developing countries in regional and bilateral free trade agreements. Even though the

Trade Promotion Authority is set to expire at the end of June, a dozen negative FTAs are already signed or in the pipeline, and it is not obvious that the new Democrats majority in Congress is fully committed to curtailing **Pharmaceutical hegemony**. Finally, the international architecture of the TRIPS regime has only just been implemented in the most important producer countries like India. Although sources for older pre-1995 generic medicines are secure, options for sourcing newer, post-1995 medicines will get increasingly harder as patents are granted in India and elsewhere. The cumbersome Paragraph 6 Implementation Decision of August 30, 2003, creates a procedural labyrinth which must soon be navigated with multiple quantity specific licenses is drug-by-drug and country-by-country in both importing and exporting countries. Although these obstacles are not insurmountable, they will complicate efforts to find good quality generic producers who can continue to act as pharmacies for the poor.

### **Conclusion**

Developing countries, activists, and international organizations must stand united in condemning drug company retaliation, US

threats against use of lawful flexibilities for accessing more affordable medicines, and the inefficiencies of the new import/export regime. In the meantime, other developing countries should take heart from the example of Thailand and Brazil. After making sure to amend their laws to avail themselves of all needed flexibilities for accessing medicines more cheaply, they should negotiate for voluntary licenses or grant compulsory licenses on essential, life-saving medicines, not just for AIDS but for other conditions as well. Their efforts will be simplified if they cooperate with UNITAID and with proposals for patent pools for essential medicines that will allow for collective management of intellectual property rights, including patents and registration data rights. Through increased cooperation, coordination, and determination, developing countries can expedite the emergence of a dynamic generic market that will inevitably lead to even lower drug prices. If those efforts are combined with efforts to expand funding for Universal Access and to even greater efforts to increase human resources for health and to rehabilitate tattered health systems, universal access might pass from a hope to a reality.

*Source: Ip-health, Tuesday, May 08, 2007, Health GAP, Essential Action NGO Analysis authored by Professor Brook K. Baker, Health GAP, Northeastern U. School of Law, Program on Human Rights and the Global Economy, 400 Huntington Ave., Boston, MA 02115, USA e-mail: [B.Baker@neu.edu](mailto:B.Baker@neu.edu)*

## AUSFTA pressures drive changes to PBS policy

The Australian Health Minister Tony Abbott introduced legislation on May 24 proposing changes to the Pharmaceutical Benefits Scheme (PBS) that he claims will lead to savings for the government of \$580 million over four years. These savings are due to lower wholesale prices paid by the government for generic versions of some common medicines with expired patents. Some of these lower costs will be passed on to consumers through reductions in the PBS subsidized prices consumers pay at the chemist, currently \$4.90 for pensioners and \$30.70 for others.

But hidden behind these trumpeted savings is an important change to the pricing of new medicines that are patented, which will mean that pharmaceutical companies can charge very high prices for them. The PBS has in the past kept the wholesale prices of medicines low by comparing the cost of new medicines with the cost of existing medicines with the same health outcomes, known as reference pricing. Prices in Australia are three to ten times lower than in the US because of this policy. Pharmaceutical companies and the US government argued that reference pricing was a violation of their intellectual property rights when the AUSFTA was negotiated, and have lobbied for changes both in public through the media and through the joint US-Australia Medicines Working Group set up under the AUSFTA. AFTINET has obtained some papers through a Freedom of Information application

that shows that such changes were discussed at the Medicines Working Group in January 2006, well before they were first announced by the government in November 2006.

The legislation introduces a new category of medicines known as F1, which will not be subject to reference pricing, and for which the government will pay much higher prices. This is a change that the pharmaceutical companies and the US government have strongly supported. The Australian government calculates that the reductions in price for generic medicines will outweigh the higher prices for new medicines, but this may not be the case in future.

Moreover, some of the higher costs of new medicines to the government may be passed on to consumers. Over the last few years, pharmaceutical companies have been allowed to charge “special patient contributions” and “brand premiums” for PBS medicines on top of the usual PBS subsidized prices paid at the chemist. These can range from a few dollars to hundreds. Health academic Dr Lesley Russell in an article published in 'the Age' on May 8, 2007, estimated that extra charges are now applied to one in every six PBS medicines. In some cases, doctors can get an exemption from these extra charges for patients if they show that there is a specific medical need for that drug rather than a cheaper one. But not all doctors do this, and there are no figures on how many patients are

actually paying the extra charges.

The PBS Bill section 85b (4), (page 8 of the explanatory memorandum), states that the Special Patient Contribution will be imposed where the Minister and the drug company have been unable to reach agreement about prices.

The patient would have to pay this except “in very special circumstances” where a doctor certifies that other cheaper brands are not suitable. This is a development which could undermine the principle of uniform affordable prices for medicines through the PBS.

What is known is that many Australians are missing out on prescription drugs and other health care because of rising costs. A recent international study by the Commonwealth Fund health policy think tank found that 34% of Australians have not filled a prescription, or have not had recommended tests, or failed to see a doctor, because of costs. In the UK that figure is only 13%, and in Canada it is 26% ([www.pharmacydaily.com.au](http://www.pharmacydaily.com.au), May 18, 2007).

AFTINET is working with health and consumer groups to analyse the legislation, which is likely to be referred to a Senate Committee for review over the next few weeks. AFTINET will provide more information and may ask members to send a strong message to the government against undermining of the PBS.

*Source: Haianz, Thursday, May 31, 2007. Originally from AFTINET Bulletin No. 137 May 2007, written by Dr Patricia Ranald, <http://www.aftinet.org.au/>*

HAI News reports 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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## African Activist wins Olle Hansson Award 2007



**In recognition of the work of an individual from a developing country who best demonstrates the qualities of Olle Hansson in promoting the rational use of drugs.**

Dr. Eva Ombaka, a Tanzanian Pharmacist, has been committed to the goals of 'Access to Essential Medicines' and 'Rational Use of Medicines' over the years. She is currently a Member of the Pharmaceutical Advisory Group (PAG) of the World Council of Churches (WCC), Coordinator of the Ecumenical Pharmaceutical Network (EPN) and is the Board Member Chair of Sustainable Healthcare Foundation in Kenya.

Educated and trained as a Pharmacist at the University of Aston in Birmingham, UK she also received her PhD for research in Pharmaceutical Microbiology from the same institution. Dr Ombaka was also a Fulbright Senior Research Scholar in 1986-1987. Her 30-year career in pharmacy has included hospital practice, work in academia

and in the manufacturing sector.

Among her many achievements are:

- spearheading advocacy campaigns via EPN to help shape pharmaceutical policies and guidelines based on the concept of essential medicines, the WHO Model list of Essential Medicines and the Interagency Guidelines on Drug Donations;
- contribution to the development of the Tanzania National Drug Policy;
- designing training curricula and organizing courses for pharmaceutical institutes to produce many graduates focusing on Essential Drugs and their rational use;
- contribution as an active member in the model list expert committee at WHO which regularly updates the List of Essential Medicines;
- providing leadership for EPN members and WHO for evaluating faith-based drug supply organizations in a number of African countries where the lessons learnt have led to the development of 'Guidelines for Effective and Efficient Pharmaceutical Services' that are now in use in health institutions in several countries.
- developing EPN's mission statement of 'facilitating the development of compassionate, just and sustainable quality pharmaceutical care in and through the church health care system'

*Source: HAIAP Press release on 23<sup>rd</sup> May, 2007 <http://www.haiap.org>*