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The WTO/TRIPS Agreement and Access to Medicines

By Robert Weissman

“The purpose of this consultation,” said Dr. K. Balasubramaniam, Advisor and Coordinator of Health Action International Asia Pacific in his introductory remarks to a Regional Consultation on the “WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses”, is “to move closer to making our collective dream come true. That is: every person in our region and rest of the world should have regular and easy access to the essential medicines he or she needs, irrespective of the ability to pay.”

Government representatives and health activists from eighteen countries in the Asia Pacific region attended the Regional Consultation, held in Colombo, Sri Lanka from 17-19 April 2003, which was hosted by the Ministry of Health, Nutrition and Welfare of Sri Lanka in collaboration with Health Action International Asia Pacific, Third World Network and the World Health Organization.

The participants gathered to analyze the terms of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), to assess how it impacts public health and access to essential medicines, and to examine the most pro-public health policy options that are available to countries.

THE TRIPS FRAMEWORK

TRIPS evolved, noted Martin Khor, Director of the Third World Network, largely as a multinational pharmaceutical industry response to the international forces that were operating to limit the multinationals’ power in the 1970s and 1980s.

Led by Health Action International (HAI), activists were calling attention to abusive industry practices, such as inappropriate labelling; HAI emphasized that governments should focus on essential drugs, and not spend funds on drugs with no efficacy. Both efforts shifted power away from the multinationals.

Meanwhile, UN agencies were trying to give meaning to the call for a New International Economic Order. The UN agencies were looking to enhance country flexibility, plus negotiating a code of conduct requiring technology transfer. WHO, meanwhile, gave a philosophical underpinning to these efforts by highlighting and trying to make real the right to health. WHO’s advocacy of essential drugs also threatened multinationals’ sales in developing countries. UNIDO worked to facilitate transfer of pharmaceutical technology to the Third World.

Some countries, such as India, took steps to enable development of robust generics industries. Health activists in Bangladesh designed a pharmaceuticals policy that emphasized both essential drugs and local production.

All of this worried the multinationals, who recognized it as a genuine countermovement, a people’s health movement with strong links to Ministries of Health.

The companies’ quiet response was TRIPS. After a decade’s negotiation, it came into force in 1995.

Countries that are members of the World Trade Organization (WTO) must develop national legislation that is in conformity with the WTO’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). This national legislation determines the kind of patent protections afforded in a particular nation.

TRIPS places constraints on WTO Members. It requires countries to provide patents for all qualifying inventions, including pharmaceuticals. It requires countries to provide patents on both products and

processes. It requires patents to extend 20 years. These are all minimum requirements; WTO member countries may provide more patent protection than TRIPS requires, but they should not provide less. And, unlike other WTO agreements, TRIPS provides no special and differential treatment for developing country members; after a transition period has expired, they must follow the same rules as industrialized nations.

All of this marks a major change from the pre-TRIPS world. As University of Argentina's Professor of Law Carlos Correa noted, "...at the time TRIPS came into force, 50 countries did not provide pharmaceutical patents at all".

But TRIPS does include key flexibilities. These include:

- Compulsory licensing – the government grant of licenses to initiate generic competition while drugs remain on patent.
- Government use provisions – which enable governments or their contractors to make use of any patent, without prior negotiation with the patent holder, conditioned only on payment of a reasonable royalty to the patent holder.
- Parallel importation – enabling a country to import patented products put on the market in another country so long as the patent holder's rights have been "exhausted" – used – in the other country. These imports are permissible without the permission of the patent holder.

There have been numerous tensions in recent years between intellectual property protections and public health concerns. Patent monopolies have led to high pricing of pharmaceuticals, an issue receiving the most attention in the context of antiretroviral treatment for HIV/AIDS, since the only effective treatment for the disease relies on patented drugs. High-profile disputes involving South Africa and Brazil have highlighted conflicts between intellectual property protections and public health priorities. The World Health Assembly has considered the issue, stipulating that public health should take priority over commercial concerns.

In each of these disputes, public health activists and developing countries have won major victories. They made still further gains in November 2001, when WTO countries agreed on the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration states that "the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Still, despite these achievements, developing nations have generally been reluctant to exercise the flexibilities available in TRIPS.

Participants at the Consultation highlighted a number of reasons for these developing country reluctance to employ TRIPS flexibilities. Among them: pressure from multinationals and the U.S. government fear of sanctions even where none are likely ("the chilling effect") legal uncertainty among developing countries of their rights under TRIPS poor coordination among government ministries, poor technical assistance provided by international agencies such as the World Intellectual Property Organization, and fear of losing foreign direct investment.

An aim of the Consultation was to provide information and enable networking that could help overcome some of these hurdles.

Replacing TRIPS

Presenters at the Consultation emphasized repeatedly that TRIPS provides substantial flexibilities to countries. They looked in detail at the flexibilities, arguing that it was important for national legislation not just to reference the options available under TRIPS, but to provide specific provisions to facilitate use of the flexibilities, and to adopt administrative procedures to make use of the flexibilities fast, cheap and simple.

Key steps for TRIPS-compliant public health-oriented legislation, said several presenters at the meeting, include:

- Clear language establishing exclusions from patentability (including inventions that are not novel or useful, diagnostic and surgical methods, discoveries, and second uses for patented products).
- Clear language establishing exceptions to patent rights; these are activities that cannot be proscribed by patents. These include: early working of patents to register generic drugs ("Bolar" provisions),

research exceptions so that patents do not interfere with scientific research efforts, and exports of medicines to meet public health needs in another country.

- Grounds for issuance of compulsory licenses. It is not enough for countries to have legislation generally authorizing them to issue compulsory licenses. Governments have broad authority to establish liberal grounds for compulsory licensing, and it is important they use it. James Love of the Washington, D.C.-based Consumer Project on Technology, strongly urged adoption in law or jurisprudence of the Access Gap theory: Where a product is essential to public health, and where price is a barrier to access, then compulsory licenses should be issued to generate competition and price reductions (unless voluntary licenses are available).
- Compulsory license procedures and compensation. One of the major deterrents to use of compulsory licensing in developing countries is uncertainty about how to handle cases, and the need to manage cases through expensive judicial litigation systems. Governments have flexibility under TRIPS to adopt fast-track, administrative procedures to handle compulsory license claims. These can locate authority to hear compulsory license claims in government agencies, which can make decisions without the expense and delay involved in court cases. Countries may also establish royalty guidelines that establish a parameter for compensation in compulsory license cases. Such guidelines set expectations for all parties over compensation terms, and make determination of compensation – another deterrent to issuance of compulsory licenses in developing countries, because of its perceived complexity -- much simpler.
- Government use provisions. Governments have broad authority to use patents. Government use may be done through procedures even simpler than compulsory licensing for private parties. Notably, governments do not need to engage in prior negotiation with patent holders; they may simply use any patent or patented product they like, and negotiate later with patent holders over reasonable compensation. But to claim this kind of authority, countries need well-drafted national legislation that conveys it to government officials.

Presenters at the Consultation also emphasized the need for forward thinking in other intellectual property areas, both to avoid emerging problems and to create new opportunities for public health initiatives.

Participants noted concern about “TRIPS-plus” obligations required by bilateral and regional trade agreements. These agreements (such as the U.S.-Singapore Free Trade Agreement) contain provisions requiring countries to sacrifice many of the flexibilities available in TRIPS. Many such agreements are now in existence or under negotiation. And WIPO is considering treaty provisions that would create a single world patent, which could substantially impair countries’ ability to maintain patent exclusions permitted under TRIPS.

Carlos Correa emphasized the problem of bad patents. When countries issue patents for inventions that do not meet the tests for patentability, they restrict the public domain, and create monopolies and excessive prices where they are not merited under patent laws. Challenging bad patents is expensive and time-consuming, and rarely a task that generic companies in developing countries want to undertake. So bad patents often go unchallenged, leaving consumers the victims. The key to avoid such problems, said Correa, is for countries to invest more in patent examination, ensuring that their

patent offices do not rubber stamp patent applications, and creating processes that enable third parties to challenge patents administratively before they are granted.

Many participants at the Consultation raised concerns about the legitimacy of TRIPS, and challenged the meeting to consider how the TRIPS framework might be replaced. James Love argued that the key policy underpinning of TRIPS is that it provides an incentive for private parties to undertake Research and Development. To think about replacing TRIPS requires suggesting an alternative means to address R&D challenges. Love urged participants to consider proposals for an R&D treaty, under which countries would be required to support R&D, but would have flexibility on how to achieve this goal. They would be obligated to devote a certain percentage of their GDP to R&D, but could meet this obligation through any mechanism they chose, including public sector support for R&D or through the patent system. The treaty would be designed to

emphasize public health priorities – including neglected diseases, vaccines, and open source research; promote technology transfer; and facilitate transparency of R&D investment flows.

Presenters at the Consultation explained the ways in which rich countries make use of many of these flexibilities.

They emphasized in particular the aggressive use of government used provisions in both the UK and United States.

In the UK, the government maintains very broad rights to use patented inventions under the concept of “crown use”. The relevant legal provision states:

“...any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor, that is to say-

- (a) where the invention is a product, may-
 - (i) make, use, import or keep the product, or sell or offer to sell it; where to do so would be incidental or ancillary to making, using or keeping it; or
 - (ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines...

and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.”

These broad powers are available to the government and its agents, including ‘to purchase products for public distribution’. In *Pfizer v. Ministry of Health*, a 1965 case, the court upheld the power of the National Health Service UK, under the crown use provision, to buy drugs from sources other than the patent owner.

The key features of the crown use powers, said Christopher Garrison of Medecins Sans Frontieres (MSF) are:

- The crown use provisions may be employed in any circumstance to advance the public interest, not just to address abuse of patent rights.
- Powers are very broad, and even more extensive in case of emergency.
- The government agency does not need to consider any set of factors before exercising crown use authority – it may simply act.
- There are no complex procedures to be followed – the power applies automatically to all government departments and any person they designate in writing.
- Permission may be granted before or after use of the patent product
- Patent owners cannot stop crown use; they can only seek adequate compensation. Compensation is set either by a willing licensor, willing licensee formula (what would have been the terms of a voluntary negotiated license?) or the loss of profit through loss of contract to supply the government.

In the United States, government use provisions are at least as broad. The U.S. government use statute states: “Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”

The statute covers all cases. There are no conditions on government use without a license, no prior negotiation necessary. The government use right is an automatic right, available to any government officer.

The right extends to government contractors. Such contractors might be manufacturing for sale to the U.S. government, or providing a service to the government.

The patent holder’s only remedy is for compensation. The patent holder does not have the ability to block or delay government use, through litigation or otherwise.

Disputes over compensation are heard in a special court. This is an element of the U.S. procedure that developing country governments should definitely not emulate. The experience on compensation is uneven;

generally, courts look to the commercial royalty rate, not the lost profits to the patent holder. Royalty rates vary, from as low as 1 percent, depending on the circumstances of each case.

The U.S. uses the government use provision very frequently and aggressively, for the purpose of getting the best price available, irrespective of patent issues. Some commentators say the statute induces “the contracting of patent infringement.” The basic idea is the government wants to buy from the cheapest provider of a product or service, without regard to who holds patents.

Rich countries perhaps do not make use of general compulsory licensing as frequently as government use, but here too the experience suggests the rich countries make use of TRIPS flexibilities far more than developing countries. And again, it is the United States that is probably the most frequent issuer of compulsory licenses.

The U.S. does not have a single compulsory licensing statute – authority is vested in many different government authorities, via multiple laws. Sources of authority include competition (known in the United States as antitrust) laws, and sectoral specific statutes (for example, clean air technologies, nuclear power technologies). Compulsory licenses are granted frequently as a condition of approving mergers, and also as a remedy for findings of anti-competitive practices. Such licenses are granted frequently in pharmaceutical cases.

The U.S. experience is particularly important because of the frequency of U.S. use of compulsory licensing and government use provision; and because the U.S. designs WTO, bilateral and regional free trade agreement provisions to be compatible with what the U.S. does. There is a legal and political safe haven in following the U.S. example – though developing countries will of course want to adapt the U.S. experience to meet their own particular needs.

A Manual on Public Health, Sensitive Policy Measures and Patent Laws

A centerpiece of the Consultation was the presentation of a Third World Network-prepared Manual on Good Practices in Public Health Sensitive Policy Measures and Patent Laws. Cecilia Oh of the Third World Network is the manual’s primary drafter. It is informed by three separate workshops at which there was debate and discussion from intellectual property experts from around the world.

Martin Khor introduced the manual, noting that, especially following approval of the Doha Declaration, developing countries face a problem: How to maximize the use of TRIPS flexibilities in their national law. There is no point in having flexibility, if countries do not use it, or do not use it in the best way possible. There is not much clarity among developing country governments on how to do this. The manual is an effort to provide some easy-to-understand guidance in this technical area.

The manual considers three sets of questions:

1. What policies do governments have to make or use to import drugs they need?
2. What legal provisions do they need to have in national law? – mindful that many countries have or are reviewing their laws for TRIPS compliance and maximize their flexibility post-Doha.
3. What are the best administrative procedures to take advantage of TRIPS flexibilities?
 - a. What kinds of compensation should be provided in compulsory licensing cases?
 - b. What kind of appeal system need be established for compulsory licensing and other disputes?
 - c. How can countries best position themselves to negotiate effectively with the multinational drug companies?

The first part of the manual goes step-by-step through the TRIPS-compatible options available to countries to import or locally manufacture affordable medicines.

If a product is not patented, then a country is free to do as it chooses in terms of local production or importation.

If it is patented, then the country still has an array of options. The manual discusses these options in detail, evaluates their advantages and disadvantages, and describes the conditions that must be met before a country

can exercise each option. If a country wants to import a patented medicine, it may: import the drug under a government use provision; import the drug through a compulsory license; import the drug through a compulsory license issued to address an emergency or urgent circumstance (certification of an emergency enables the use of simplified and expedited procedures); or import the drug through parallel importation.

If a country wants to manufacture domestically a generic version of a patented medicine, it has a similar set of options. It may authorize local production pursuant to a government use provision, and for use by the government or its contractors. It may issue a compulsory license authorizing local production; and it may use expedited procedures to do so in case of emergency or extreme urgency.

The second part of the manual features an in-depth discussion of each the key issues considered – parallel importation, government use, exceptions to patent rights and compulsory licensing. The analysis of each issue is broken up into four parts.

First, is a model provision, accompanied by an explanation of the provision – what effect would it have?

The second element discusses the rationale for the provision: what is the purpose of the provision, why is it important.

The third component explains the TRIPS-compatibility of the model provision. It explores the flexibility inherent in the relevant portions of the TRIPS Agreement, and how the model proposal fits the terms of TRIPS.

The final element of each section examines state practice. It focuses particularly on the experience of the industrialized countries, which have made much greater use of the TRIPS flexibilities than have developing countries.

Part II of the manual is intended to serve as a yardstick against which existing or proposed laws can be measured. Where there is a disparity, the manual is intended to provide suggested alternatives that are worthy of consideration.

Part III of the manual focuses not on substantive law, but on administrative models for implementing the TRIPS flexibilities. The key administrative issues include:

- * Who should be designated the competent authority to consider licensing and other issues? Should multiple agencies within the government be so empowered? The manual recommends designating agencies other than the patent office as the competent authority.

- * TRIPS requires that compulsory licensing and government use decisions be made on the basis of an examination of the individual merits of each case. Yet, it is possible to include presumptions that compulsory licenses will be issued, given certain circumstances (for example, the patent holder has refused a reasonable request for a voluntary license).

- * TRIPS requires that there be prior negotiations for a voluntary license before a compulsory license is issued. The manual recommends clarifying this requirement by establishing in law how long is a

reasonable period for such negotiations (recommending 90 days) and reasonable terms (recommending reference to compensation guidelines established in law).

- * TRIPS requires that appeals must be available for compulsory licensing and government use provisions. The manual suggests considering administrative as opposed to judicial appeals. And it emphasizes the importance of not providing injunctive relief while a case is on appeal.

Part III of the manual also discusses how the TRIPS requirement that “adequate remuneration” should be paid to patent holders in case of government use or compulsory license. The key recommendation here is to

establish compensation guidelines, which would provide an administrative framework for determination of compensation in individual cases, and royalty guidelines that would establish the range of royalties that may be awarded. It recommends royalty rates ranging from 2 to 6 percent.

The Generics Industry

The Consultation was energized by the participation of representatives from generic companies from the region. The generics representatives made clear that there is a vibrant generics industry in many Asian countries; and that it is possible for governments to foster such industries, given the political will. The generics firms reported disparate experience, but all of those represented at the meeting are producing quality medicines at prices far below those offered by the brand-name multinationals.

Dr. Krisana Kraisintu reported on the achievements of Thailand's Government Pharmaceutical Organization (GPO), a state enterprise that supplies pharmaceuticals and medical products to support the Ministry of Health's health activities. It produces more than 300 drugs, employs 2200 people and has annual revenues of US\$100 million. About 1.6 percent of its revenues are devoted to R&D.

The GPO has been working on development of HIV/AIDS-related drugs since 1992. It began manufacturing its first product in 1995. By December 2001 the cost of triple therapy was reduced to \$53 a month. In April 2002, GPO introduced GPO-Vir, a triple therapy made up of lamivudine, stavudine and nevirapine, at a cost of \$27 per month. GPO now offers a broad range of ARVs and products for AIDS-related opportunistic infections. GPO products meet GMP standards, and GPO is now applying for certification in WHO's prequalification program. GPO manufactured ARVs are priced at from one-fifth to one-twentieth of the brand-name product.

Dr. Gopakuma G. Nair, Immediate Past President of the Indian Pharmaceutical Association, detailed the amazing growth of the Indian pharmaceutical industry. While the industry faces significant challenges, for 2004-2005, the industry is expected to secure total sales of US\$10 billion, and it is now a major force on the world market. More than 250 plants in the country meet GMP (good manufacturing practice) standards. Exports to regulated markets, especially the United States, are growing rapidly.

The industry's strength is traceable to the Indian Patent Act Amendment of 1970, which rolled back patent barriers to generic production. From that foundation, the industry evolved over time to become increasingly sophisticated, moving into production of bulk drugs, stepping up quality (at least at the top of the industry; quality problems remain at many smaller firms), and then expanding exports.

Indonesia has four government-owned pharmaceutical companies, and 163 private domestic companies. Overall, multinationals control about a third of the market, with the foreign market share declining slightly over the last four years. Approximately 250 generic products are on the market, with the government-owned companies maintaining a 60 percent market share of generics. Generic prices are government regulated. Use of generics is increasing in hospitals and for health insurance covered patients.

Zafrullah Chowdhury of Gonshasthra Kendraya described the remarkable health activist campaign in Bangladesh to innovate a 1982 National Drug Policy that imposed an Essential Drugs list, dramatically restricted the number of drugs permitted on the market, and required products to be made locally. Zafrullah recounted the significant opposition to the policy, from local doctors, the multinationals, and the multinationals' allies in foreign governments – and also the campaigning success that largely succeeded in defending the policy. Interestingly, the dollar value of the pharmaceutical market has expanded very

significantly since the National Drug Policy went into effect – with drugs more affordable, many more consumers have been able to purchase them, expanding the overall market.

Amy Guo of the Desano Biopharmaceutical Company in China described how this recent start-up (established in 1996) has moved rapidly into development and production of AIDS treatment active pharmaceutical ingredients (APIs), pharmaceutical intermediates and formulations. It also produces vitamins and nutraceuticals, as well as oncology and steroid pharmaceutical products. In 2002, the company had sales of \$60 million, with 1,700 employees, including 100 R&D employees. Desano is pursuing investment and technology transfer opportunities in Africa, and is cooperating with NGOs such as MSF.

Conclusion

In the latter phase of the Consultation, participants engaged in working groups that reviewed the status and situation in each country regarding patents, access to medicines and public health policies, obstacles to taking

measures like compulsory licensing and how these obstacles could be overcome, and proposals to improve the situation, including better regional coordination.

Country experience obviously varies considerably. But there were important commonalities. Most countries had provisions authorizing compulsory licensing and parallel importation, but these provisions are rarely if ever used. In most countries, they do not appear to be drafted to facilitate frequent use; they do not include specific provisions that presumptively favor such measures, nor have many countries articulated administrative procedures to make use of the policy tools simple and cheap.

No country reported utilization, or at least regular utilization, of government use provisions to procure drugs for the public health service.

Most countries maintain Essential Drug lists, though how they are used varies considerably.

The role of the state sector varies considerably. In some countries; public healthcare covers a significant portion of the population (60 percent in the Philippines); in others, a small portion (16 percent). Also varying considerably is the kind of care delivered by public health coverage.

In general, the extent of public access to essential medicines, and to basic health services, varies considerably between countries.

Participants pointed to common barriers to more effective use of TRIPS flexibilities. Identified problems and pressures include: bilateral pressure from the United States, free trade agreements with TRIPS-plus provisions, lack of political will, the limited role taken by or afforded to Ministries of Health in intellectual property debates, ignorance of policy options by governments, consumers and cooptation by industrialized countries of developing country government negotiators who fail to defend national interests in international negotiations and inadequate coordination among developing countries in international negotiations.

The state of local production varies considerably within the region. Countries such as India and China boast robust industries, including production of raw materials. Most of the countries in the region, have some kind of pharmaceutical production capacity, but especially in smaller and poorer countries, this may be limited to formulation or even packaging plants. The smaller and poorer countries are generally more reliant on imports.

In thinking about how to overcome obstacles to more effective use of TRIPS flexibilities, participants highlighted the importance of regional coordination, networking and capacity building.

Taking the reports of the discussion groups into account, the Consultation developed a series of recommendations, among them:

1. Each country should adopt national legislation to maximize the use of TRIPS flexibilities to protect and promote the health of its citizens and to provide affordable medicines for all. Key steps include:

(i) limiting the scope of approval of patent applications to patents that are genuinely novel or involve an inventive step, and

(ii) including in their national legislation effective provisions on government use, compulsory licensing and parallel imports in order to effect importation or production of medicines, including by adoption of practical and administrative measures required to make such provisions workable and efficacious.

2. A strengthened system of information sharing, communications and research should be established. Policy makers, NGOs, social movements, professionals, experts and generic drug producers should be part of this system. The organisers of the workshop (HAI AP, TWN, WHO) should discuss among themselves how to follow up on this proposal.

3. Generic drug producers should strive to strengthen their activities, to remain viable and to develop further. They should form an association or network among themselves to coordinate activities and urge policy makers to adopt appropriate measures to facilitate use and production of generics. They should also try their best to transfer technology and production know-how to all countries in the region.

4. Governments in the region should establish cooperation activities among themselves, not only to share information and best practices, but also to establish among themselves cooperation arrangements for production, technology-sharing, distribution, import and export of medicines, as well as the issuing of compulsory licences and other measures;

5. The WHO has an important role to play in bringing policy makers together to implement national and regional activities. The planned WHO activities in the region, such as Ministerial Conferences should include sessions on patents and medicines where experts and NGOs should also be invited to present their views.

Log onto our website on www.haiap.org for more details about the consultation

Network News

GLOBAL

HAI Briefing paper presented at the 56th World Health Assembly in May 2003

All four regions of the HAI network were represented at the 56th World Health Assembly held in Geneva May 2003. The HAI Network briefing paper concentrated on a number of issues including prequalification, competition and acceptance of generics, pricing and promotion of medicines and the WHO relations with civil society and NGOs.

On prequalification of generics HAI recommended that the WHO should continue and expand the Prequalification Project to include more medicines and expand to other disease categories without merely emphasizing on AIDS, Tuberculosis and Malaria. WHO should also ensure that the prequalification system and information about medicines are widely available at country level prioritizing its value to national medicines regulatory bodies and ministry staff. They must have the necessary quality assurance information to be able to register and procure needed medicines in the short term.

Acceptance of Generics

The inclusion of generic products on the WHO prequalification list for antiretrovirals (ARVs) has rapidly proved instrumental in improving acceptance of affordable high quality generic products around the world. HAI welcomes the indication by US President George Bush in his 2003 State of the Union speech that low cost quality medicines can help fight HIV/AIDS in developing countries. The quoted figure of US\$ 300 per person per year is an important recognition of the role of generics to increase access to medicines.

As it has effectively done in other areas of its work, WHO must invest at national, regional and global levels in confidence building measures in this regard. HAI believes that the commitment of WHO to work with generic manufacturers sends a clear, positive message.

Generic competition

Reports have shown that generic competition is the most effective way to ensure the greatest price reductions. The US Congressional Budget Office estimates that the generic competition saves the US between US\$8 billion and US\$10 billion a year. The market share of generics has accordingly risen from 19 percent to 43 percent in the last decade.¹ In the past five years, global prices of ARVs have decreased from approximately US\$10,000 per year to less than US\$300 per year for some combinations. This is primarily due to the price competition resulting from the introduction of generics in that time period. Generic competition is possible in some countries because of the lack of product patents and by the use of TRIPS safeguards in other countries. The Doha Declaration clearly acknowledged the explicit link between patent protection and access to medicines, stating:

We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices.

The Declaration further states:

We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Five months after the deadline to resolve Paragraph 6, Member States without manufacturing capacity still do not have a mechanism to introduce generic competition into their markets to respond to their public health crises. This problem will be exacerbated after 2005, when those middle-income countries that currently have the freedom to produce generics will be bound to more strict rules that adhere to the TRIPS agreement. Efforts to solve the Paragraph 6 problem have stalled, primarily due to the actions of one country that itself freely makes use of TRIPS safeguards. In the solution to Doha, there should be equal ability for all countries to address public health situations effectively. Why should the rich countries be able to invoke a compulsory license, when poor countries with little or no manufacturing capacity cannot? The Doha Declaration calls for a solution to this unfair

situation. HAI urges the WHO to engage in discussions with the WTO to solve this problem but urges WHO not to get involved in brokering any compromise to the Doha declaration. HAI rejects any interpretation of Doha and Paragraph 6 that limits disease scope. Rich countries are not limited in the public health crises where TRIPS safeguards may be used, and developing countries' options must not be limited either. WHO can play a more active role in discussions on trade and health at the international level. WHO can contribute significantly to health and trade issues at country level by reaffirming its commitments to provide technical support.

Affordable drug prices

In developing countries, medicine prices matter because most people have to buy medicines out of their own pocket and they have minimal incomes. Medicines save lives and improve well-being, but only if people can afford to purchase them.

Little is known about the prices people pay for medicines in developing countries. To address this issue, WHO and HAI have developed a robust and reliable method to collect and analyse:

- the prices that people have to pay for a selection of important medicines across local sectors (public, private-for-profit, private not-for-profit)
- the affordability and availability of medicines.
- price composition (duties, taxes, mark-ups, fees etc.)

Public Procurement Price

For generics, the most effective way to control purchase price is through an open-tender process. Pooled or bulk purchase nationally, regionally or globally is also effective but only in specific circumstances where multiple parties share similar goals and resources. The development of a country-level Essential Medicines List should be stressed and procurement should be rationalised to the EML process.

When generics of a specific medicine do not yet exist, a procurer needs to engage the manufacturer in a professional negotiation process, including using price evidence from other countries. Parallel importation, where possible, could reduce the procurement price because large international price differences for the same medicine are common. Other tools include voluntary and compulsory licensing.

Domestic Add-on Costs

The domestic distribution system also determines the price people pay for medicines. Tariffs, fees, mark-ups, taxes etc. all contribute to higher prices. Policies should be implemented to control these add-ons. Options include exempting essential medicines from tariffs and taxes, fee waivers for market approval of EML products, examining the competitiveness and efficiency of the distribution system, introducing capped generic-friendly policy on wholesale mark-ups, providing incentives to prescribers to support cost-effective practice and introducing fixed dispensing fees.

Efforts to curb unethical & inappropriate drug promotion

Unethical and inappropriate promotion by the pharmaceutical industry continues to contribute to irrational, wasteful and sometimes even dangerous medicines prescribing and consumption. The industry is gaining influence through the funding of patient groups, the setting of research agendas and the sponsoring of continuing medical education. Now, there is a move towards direct-to-consumer advertising, (e.g., the United States & New Zealand), or so-called disease-awareness campaigns that concentrate on lifestyle and emotive messages and prey on consumer insecurities and lack of knowledge. Furthermore, there is no evidence to show that direct-to-consumer advertising of prescription medicines leads to better health outcomes in spite of clear evidence that it increases health care costs.

The Ethical Criteria for Medicinal Drug Promotion was published in 1988 and provides guidance to Member States regarding ethical and appropriate promotion. HAI supports the Criteria but the fight against inappropriate promotion rages on. Given increased attempts to reach consumers directly and the mixed messages communicated to health care providers, governments should require pre-approval of promotional material and advertisements by regulatory authorities. Furthermore, direct-to-consumer advertising of prescription medicines should be banned entirely.

As a first step to raising awareness, WHO and HAI have coordinated the development of a database (www.drugpromo.info) of available information on medicines promotion. The website also contains information about what further research is needed. WHO and HAI are developing a tool, primarily for health science students

and health professionals, aimed for improving their ability to evaluate medicines promotion and to recognise and reject unethical promotional practices. Further work is needed by WHO and concerned NGOs to develop and disseminate information to improve consumers' ability to evaluate and monitor promotion and to pressure their governments to clamp down on unethical practices.

WHO relations with Civil Society and NGOs

In recent years, WHO has made substantive efforts to improve its working relations and collaboration with NGOs, for example setting up the WHO/EDM-public interest NGO Roundtable and launching the Civil Society Initiative.

The WHO review of NGO relations¹ pointed out a concern about the lack of guidance and clarity for WHO staff at all levels, but especially at regional to country levels, about how to interact with civil society. At headquarters, guidelines still need to be developed, especially concerning collaboration with NGOs. The Country Focus Initiative stresses the central role of country cooperation strategies in improving WHO effectiveness. Notably, these strategies are supposed to include ways to involve civil society. Yet regional offices and country-level staff remain unclear about their mandates and their means for improving interactions with NGOs and wider civil society.

A pressing need is to provide adequate guidance concerning relations with NGOs that represent commercial interests and to avoid at all times any conflict of interest. HAI notes with deep concern that draft guidelines for interactions with commercial enterprises, have never been finalised and publicly released. That document states that it is applicable "to a variety of other institutions, including ...associations representing commercial enterprises..." It is imperative, therefore, for WHO to address outstanding problems with the draft guidelines and finalize them without further delay. Revisions should address accountability and transparency issues and the need for independent monitoring that includes public health NGO representation.

HAI believes very strongly that health policies and interventions require the substantive involvement of civil society in the design and formulation, as well as implementation.

-HAI is concerned that changes to WHO relations with NGOs do not adequately address the current bias against relationships and collaboration in Geneva with Southern-based NGOs. These NGOs, which because of historical distortions in power, resources and purpose have not become international, have vital expertise and experience to contribute at headquarters level. The current list of NGOs due to be automatically accredited to WHO, is comprised almost totally of Northern-based, professional/technical NGOs. Effective WHO policy making and normative work needs to include a broader range of expertise and experience, WHO should not perpetrate a system whereby Southern NGO perspectives have to be filtered through Northern-based international NGOs to be heard in Geneva.

Latin America

Historical ARV negotiations of 10 Latin American countries

In June, 10 Latin American countries (Argentina, Bolivia, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay and Venezuela) reached a final agreement with ARV producers on pricing. It has taken one year of technical and political discussions to define the terms and conditions of the agreement.

The ten countries invited producers to help them respond to the HIV epidemic which is demanding more resources than available in each of these countries. ARV prices are not the only problem, but significant reductions in these prices are part of the solution.

The producers defined a "maximum reference price" for each ARV product, which will be valid for all ten countries. Individual countries are allowed to accept lower prices in tenders or purchases, but not higher ones. Producers also made price offers to the ten countries for each product. This price offer was fully independent of any future purchase, exclusivity, or minimal purchase volumes. Differential prices for quantities were also not allowed. Only the "maximum reference price" was agreed.

The results are spectacular. 37 drugs were negotiated, and in 15 of them the reference price is lower than the lowest price paid earlier in any one of the ten countries. For the first line treatment protocol (ZDV, LMVD, NVP) the price per year was reduced from US\$ 1100 (lowest) and US\$ 5000 (highest) to US\$ 365. The price of the second line protocol (with EFV) went down from US\$ 3000 to US\$ 1100.

If all savings would be used for first line treatment, some 150.000 extra People Living with HIV/AIDs could be treated. Negotiations also included test kits, for which price reductions from 9 – 90 percent have been achieved.

Except for Abbot, the multinational firms who participated in the "Accelerated Access Initiative" initially stuck to their policy of differential pricing based on per capita income and extent of the epidemic in each of the ten countries. Despite insistence of the

Ministries of Health, the multinationals refused to make a single pricing proposal. However, producers of India and Argentina, who have GMP certificates and had satisfactory bioequivalence studies carried out, made a large number of price offers for all ARVs. Thanks to the price offers of these firms, the results mentioned above were reached.

The agreement does not mean that these multinational firms will withdraw for the ten countries, or that governments and NGO's will not buy from them. It only means that they did not agree on a "maximum reference price", and hence did not accept the call of the Ministries of Health to fight together with them against the HIV epidemic. They will go on making their products available at the usual prices.

Source: E-drug listserv

EUROPE - Germany

Buko Pharma takes to the streets to ensure access to medicines

It is universally accepted that developing countries must have regular access to essential drugs at affordable costs. This was reiterated in the Doha Declaration on "TRIPS Agreement and Public Health: Paragraph 6 in the declaration specifically underscored the problems faced by developing countries without manufacturing capacities to use compulsory licenses to access lower priced generic drugs.

The WTO Ministerial Conference mandated the Council for TRIPS to find an expeditious solution to problems faced by developing countries without manufacturing capacities.

Unfortunately the US has blocked the solution to paragraph 6. Buko argues that Germany should influence the European Union so that they will retreat from its present position of *finding* a compromise solution based on the US position.

The safeguards provided in the TRIPS Agreement should enable developing countries to enact national patent laws which will enable these countries access to low priced drugs.

The US wants compulsory licenses issued only for drugs to treat a very limited number of diseases. The EU proposed a compromise with a slightly longer list of diseases. For drugs that are not in the second list, countries should seek assistance of the WHO.

BUKO Pharma-Kampagne together with a number of other organizations believe that the EU position cannot be accepted. It adds additional bureaucratic hurdles to countries when they want to import essential drugs under compulsory licenses.

The German government should be actively involved in finding a solution which respects the sovereignty of every nation in the world. Each country should have the right to decide on the drugs that are necessary to meet the health needs of its people and be able to use compulsory licenses, a safeguard allowed in TRIPS, to import the drugs.

BUKO Pharma-Kampagne performed street theatres in May and June 2003 to draw attention of the German public to the suffering faced by people in developing countries due to the actions of United States and the European Union. They collected signatures from the public to send an appeal to the German government to be actively involved to find a solution to paragraph 6 of the Doha Declaration and relieve the suffering people in developing countries.

Source: Buko Pharma press release

Switzerland

WTO DECISION-MAKING SYSTEM CRITICISED AT WTO SYMPOSIUM

The World Trade Organisation's nontransparent decision-making system and the controversial push by developed countries to begin negotiating new issues at the Cancun Ministerial conference became the main focus of debate as the WTO's three-day public symposium got underway in June 2003.

Opening the symposium on "Challenges ahead on the road to Cancun," WTO Director-General Dr Supachai Pantichpakdi stated that although deadlines on many issues had been missed, constructive discussions continue.

In reply to questions at the opening session about the nontransparent and non-participatory decision-making process surrounding WTO Ministerial Conferences, Supachai said he was trying to find ways for all WTO members to be involved.

He said that he and the chairman of the WTO General Council, Ambassador Carlos Perez del Castillo are "highly concerned to learn from the past experience of previous Ministerial Conferences and are willing to engage with their Members to find the best solution to get everyone involved.

Supachai added that there should be a situation in which everyone can respond properly.

At question time earlier, Aileen Kwa from Focus on the Global South said that rules should not be imposed on developing countries through an unfair process. She said that the Indian Commerce Minister Mr. Maran had complained that at the Doha Ministerial conference, drafts of texts had been pulled out at the eleventh hour for delegations to consider. She remarked that any system that imposes drafts at the last minute on its Members cannot be a fair system.

Kwa added that 15 developing countries had asked the WTO to adopt clear procedures; in fact many Mini Ministerial meetings had been held in the past few months. There had also been a proliferation of Chairman's texts being used, instead of texts from members, as the basis for negotiations, and this is not in line with procedures of international organizations. She said the Chairs should facilitate and not rule over the negotiations, and asked whether we can expect transparency in the WTO that befits the title of a democratic organization.

Martin Khor of the Third World Network said the main reason why the WTO had failed to reflect development concerns despite the rhetoric in the Doha Declaration was the continuation of the non-participatory decision-making

process in which Ministers, officials, Ambassadors and diplomats from developing countries were not given the opportunity to take part in the key decisions, especially during Ministerial conferences and their preparatory process.

He further referred to the process which had operated at the Doha Ministerial where drafts had been produced in a nontransparent way. Developing countries had complained that their views were not reflected.

He added that the proposal by many developing countries for the WTO to adopt rules and procedures on how Ministerials should be run was astonishing as it revealed how the WTO did not practice even the most basic principles such as the positions of different members' be included in drafts, and that Ministers and delegations be informed if a meeting is called or extended.

He said such disregard for procedures and rules was ironic in an organization that prided itself to be a "multilateral rules-based organization." As long as the WTO did not reform this decision-making system, its legitimacy would be questioned by the public and be opened to criticisms.

Prof. John Jackson of Georgetown University in the US, also responded on the issue of better rules at Ministerials. "I don't think you can do everything with 146 Ministers, there should be a more efficient process, and the work must be divided". He suggested that countries could be divided into groups, and representatives of the groups could meet with the assistance of the Secretariat, and the website could be used better to provide information to delegations.

He warned that basic concerns remain, and the missed datelines in TRIPS and health, agriculture, non-agriculture market access, implementation and Special and Differential treatment were setbacks that had entailed a cost. Failure to reach agreement on these issues had postponed the preparation of work for Cancun. "If understanding on these issues is not reached, Ministers will have an unmanageable task in Cancun."

A panelist, Dr Claude Martin, Director General of WWF International, said the WTO cannot take on all issues and "to think of the WTO as a place for negotiating a ragtag of new issues is wrong headed. The WTO has no expertise to deal with the proposed new issues.

"Investment is one such new issue that should be dropped from the WTO agenda," said Dr Martin. To grant foreign investors the right to enter and establish in countries, or to deny host countries the ability to regulate foreign investment flies in the face of sustainable development goals, he added.

Stating that the proposal for a WTO investment agreement was just a watered down version of the failed OECD multilateral agreement on investment (MAI), he said such an agreement would damage the development options for developing countries and would affect their integrity.

The WTO had an opportunity to use trade policy for sustainable development. The credibility of the WTO rested on its being able to solve existing problems, not on its hopping onto new issues before it could deliver on its core issues, he concluded.

A representative from the EC in Brussels said it was a myth that the aim of negotiating the new issues was only to open up markets. He said there was a deep concern that TNCs have too much power and that states have too little. Competition rules in the WTO would balance this perceived imbalance.

A representative from German industry disagreed that the proposed WTO investment agreement would be the same as the failed OECD-MAI.

Shelley Chaderton, a diplomat from St Kitts and Nevis, proposed that the decision scheduled to be made at Cancun on the starting of negotiations "be postponed indefinitely."

Criticising the proposals being discussed at the WTO for reducing tariffs in industrial products in developing countries, she said that almost half the revenue from her country was derived from customs duty, and any agreement to reduce import duties will have serious effects such as social disruption.

Panellist Prof. Jackson said there was a tension on what the WTO is and what it should become. He posed the issue of whether the WTO is a place for nation states to talk and take actions on issues addressed for the longterm, or is it a regulatory body for new rules for new issues that can balance the need for nation states to meet the goals of its constituents but also have international coordination as nation states cannot cope with problems arising from globalisation.

There was also the question of internal governance or how to administer the WTO since its Green Room process had broken down, said Jackson. What can replace this process, and have transparency and increase the knowledge base of Missions whose capacity needed to be built. Although he supported the consensus rule in WTO, Jackson said its use by some countries to "hold an issue hostage" was not wise, and therefore the consensus rule should be amended.

Mr. Aftab from ActionAid Pakistan and the Pakistan WTO Watchgroup, said the WTO practice of reaching consensus was of little use if it did not produce deliverables for developing countries.

Source: TWN Info Service: Geneva 16 June 2003

AFRICA

Ugandan MPs learn more about IP and access to Essential Medicines

The Uganda Access to Essential Medicines Coalition (UAEMC), of which HAI Africa is a founding member and key partner, held a one-day briefing in May for Ugandan members of parliament (MPs) so that they could increase their understanding of the impact of intellectual property (IP) laws on access to affordable essential medicines.

The Ugandan parliament is likely to receive an IP bill later in 2003. Even though Uganda has until the end of 2005 to adapt its domestic legislation to ensure it complies with the WTO TRIPS, the new bill has been prepared by the Uganda Law Reform Commission, with the help of legal consultants funded by USAID.

The draft revised IP act does not contain basic public health safeguards permitted under TRIPS and reiterated by the Doha declaration. For example, Uganda, as a least-developed country, could exempt patents on pharmaceuticals until 2016. And the licensing sections are more restrictive than TRIPS (TRIPS-plus) and even US and Canadian law.

As NGOs learned in Kenya in 2001, to get an IP bill that can be used to increase access to essential medicines, MPs have to understand and support making substantive changes to the draft bill. In Kenya, the original bill that

went to parliament was substantively deficient in all key public safeguard areas. By working with MPs and by providing solid analysis and well-grounded alternative language, NGOs were able to convince a majority of MPs of the value of taking full advantage of legal flexibilities provided for in the TRIPS Agreement.

Hence, the UAEMC has started on a campaign to ensure that key MPs are well-versed about IP and access issues in good time before the bill goes forward.

Patrick Mubangizi, a pharmacist and Vice-Chairperson of HEPS Uganda gave an overview of the main problems affecting access to essential medicines in Uganda. The majority of people live more than one hour's walk from the nearest health facility, and the drugs in these health facilities are often priced out of reach.

Dr Peter Mugenyi, Director of the Joint Clinical Research Centre (one of the facilities in Uganda providing ARV treatment) focussed on the AIDS pandemic in Uganda and how Ugandan 'success story' may be overrated. Infection rates are levelling off, but at an unacceptably high level, and the social impact of the pandemic is only really starting to hit the country now. As the cost of ARVs has been lowered due to increased competition from generic medicines, the numbers being treated in Uganda have increased. However, of the estimated 200,000 people needing ARVs, only an estimated 10,000 to 15,000 are receiving treatment. And for almost all Ugandans, the price, even at the all-time low of US\$300 per year, is still totally unaffordable.

Silver Ojakol, WTO desk officer at the Ministry of Trade explained that many factors contribute to why Africa accounts for only 1 per cent of the world pharmaceutical market, despite having the highest disease burden. They include poverty, poor infrastructure, inadequate finance, weak policies and legislation and the high price of pharmaceuticals bestowed by the international patent system and World Trade Organisation rules. "One can say that trade in pharmaceuticals is effected by several factors but most importantly by patents. These severely limit access to new technologies". Ojakol stated.

Currently Uganda produces few drugs locally and two-thirds of the drugs it imports are generics. When the countries producing these drugs and Uganda start to comply with the TRIPS agreement, much of this trade in generics is likely to be made much harder, if not prevented. Twenty-year patents on pharmaceutical products and processes will greatly raise the prices for new medicines.

Ojakol affirmed that relying on donations is not sustainable, and that Uganda needed to ensure that all legally, available means provided under the TRIPS Agreement should be adequately reflected in Uganda's reform of its IP law.

Arthur Mpeirwe, Legal Counsel for the coalition, stated that "through good legislation, Uganda can harness the benefits of the patent system while at the same time minimizing its potential negative effects. To do this, the country must first identify its strategic interests and set national priorities while resisting foreign pressure." He explained what TRIPS requirements will be new for Uganda. Mpeirwe pointed out that, while Uganda had to comply with TRIPS by January 2006, as a least-developed country, it could exempt pharmaceuticals products from patent protection until 2016.

Sean Flynn from the Washington-based NGO, Consumer Projects on Technology, gave a presentation on compulsory licensing, one of the most powerful public health safeguards concerning medicines that should be in all national IP legislation. This important safeguard was also affirmed by the WTO itself in its 2001 Doha Declaration on TRIPS and Public Health. He explained how countries such as Canada, France and the US have invoked such agreements and how laws in the EU and Argentina are written to encourage compulsory licensing.

Participants included members of the Parliamentary Committees on Parliamentary Legal and Parliamentary Affairs, HIV/AIDS, Trade and Social Services and other key legislators. MPs were able to see more clearly the

connection between IP and prices of essential medicines. Moreover, they also understood better the need to have full compulsory and other licensing, parallel importation and other flexibilities built into IP law as a means for increasing access to affordable medicines. Neither the existing law nor the current draft IP bill provide these needed safeguards.

The coalition, HAI Africa and others are organising activities and generating information on an ongoing basis on the understanding that the new draft IP bill will be sent to parliament later in 2003.

Main funding for the workshop was provided by the DFID country office, with additional resources provided by HAI Africa, Oxfam Uganda and Panos East Africa.

Reported by Beryl Leach, based on a draft workshop summary prepared by HEPS Uganda.

Journal Scan

India agrees to help Nigeria tackle the import of fake drugs

India, one of the largest exporters of fake and substandard drugs to Nigeria, has agreed to take measures to

tackle the problem. It is concerned about Nigeria's threat to ban the import of all drugs from countries that export fake drugs to its shores.

"India is one of the largest exporters of pharmaceuticals into Nigeria and Indian pharmaceutical companies are constantly in touch with Nigeria's National Agency for Food and Drugs Administration and Control [NAFDAC] and have institutionalised pre-export inspection in India to control export of substandard drugs to Nigeria." stated the Indian Minister of State for Commerce and industry, Mr Shri Rajiv Pratap Rudy, during his visit to Nigeria

He continued: "We have taken note of the quality of pharmaceuticals, and inspection agencies have taken steps to ensure that substandard products do not get out of the country. We are working with NAFDAC to ensure that these products are not exported out of India. A check has been put in place."

India also promised to send the agency a list of blacklisted Indian drug manufacturers and companies involved in fake products.

The Pharmaceutical Society of Nigeria said that at least 70 per cent of the drugs in circulation in Nigeria are fake and that most imported fake and substandard drugs in Nigeria come from India, China, Pakistan, Egypt and Indonesia.

Nigerian health experts say that fake and substandard drugs in the country have been endangering health and have resulted in several deaths.

Source 7 June, 2003, BMJ/ 2003;326:1234 , Lagos, Abiodun Raufu

Death Penalty Prescribed for Makers of Fake Medicine

Every day in the warrens that make up Bhagirath Palace and the surrounding markets of Chandni Chowk (Moonlight Square), deals worth millions of dollars are struck for consignments of drugs as ranitidine, used for ulcers, and paracetamol at a fraction of what chemists would sell them across the country.

But tired of complaints from patients who have suffered the ill effects of consuming chalk instead of medicines, the Indian government announced plans to usher in laws that include the death penalty for people caught dealing in fake drugs.

India's existing Drugs and Cosmetics Act of 1940 does not use the word 'counterfeit', which is commonly used to describe spurious drugs across the world. According to the World Health Organisation (WHO), counterfeit medicine is that which is deliberately or fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, with insufficient active ingredients or fake packaging.

"The death penalty is certainly not too great for people who are interested only in profiteering, the result of which is mass murder," Union Health Minister Sushma Swaraj told IPS.

According to P V Unnikrishnan, campaigner for the People's Health Assembly (PHA), what has really got the big names of the industry going is the fact that the purveyors of fake drugs were now getting sophisticated enough to enter the lucrative sector for lifestyle drugs.

"The point is that the fake drug industry has been growing steadily even if we have been campaigning against it. This could not have happened except for poor enforcement and the outright corruption of the inspector of the Drug Control Authority (DCA)," Unnikrishnan said.

In Unnikrishnan's opinion, the death penalty will not make any dent on the Indian drug market, which has some 90,000 brand names floating around.

"In the end, the major pharma companies are creating artificial demands with their lifestyle drugs and the competition (spurious drugs) is taking a bite out of this new market -- while nobody gives a hoot about affordable medicines for ordinary illnesses that afflict ordinary people," he said.

Source: Ranjit Devraj, 14 August 2003, Inter Press Service

Drug company secretly briefed medical societies on HRT

Pharmaceutical giant Wyeth has admitted that it secretly briefed a number of medical societies about the results of a study into hormone replacement therapy (HRT) and dementia before they were published.

JAMA published the study, funded by Wyeth, which shows that the company's combined oestrogen and progestogen pill doubled the risk of dementia among elderly women from about 1 to 2 per cent over five years. The latest data on dementia comes after findings last year which showed that long term use of the drug slightly increases the risks of breast cancer, heart attacks, and strokes in healthy women aged over 50 years

The company's briefings of outside bodies have caused grave concern in the research community, including the researchers who conducted the study, although Wyeth is standing by its actions.

With top quality randomised controlled trials showing that its HRT causes harm, Wyeth has been forced to concede that its product increases the long term risks of blood clots, strokes, heart attacks, and breast cancer, while fighting hard to maintain mass markets for short term relief of symptoms.

Source: 31 May 2003, BMJ 326:1161. The article is by Ray Moynihan Washington, DC

This year's WHA sees rich and poor nations attempt to trash out a deal to improve access to essential drugs

Faced with deep and bitter divisions at the World Health Assembly (WHA) between the USA and developing countries over patents, WHO's incoming Director-General Jong-Wook Lee said he would try to steer a middle ground on access to essential medicines. At a press conference after he was confirmed in office, Lee said he wanted to avoid a divisive policy between research and development-based pharmaceutical companies and generics manufacturers. "The objective is to make these drugs available to the people at affordable cost. That's the goal. I don't mind which way it comes from."

The debate on access to medicines and intellectual property rights was one of the most heated at the WHA this year.

The delegates were trying to reach an agreement on a resolution which represented a compromise between US demands for strong emphasis on patent protection and insistence by developing countries that health should take priority.

The compromise text pointed out that, of the 1400 new products developed by the pharmaceutical industry between 1975 and 1999, only 13 were for tropical diseases and three were for tuberculosis. It said that developed countries accounted for nearly 90 per cent of global pharmaceutical sales, whereas developing countries accounted for 90 per cent of the 14 million deaths from infectious disease.

It recognized the importance of intellectual property rights in fostering research and development in innovative and essential medicines, while urging member states to reaffirm that public-health interests should be paramount in pharmaceutical and health policy. It also urged governments to make use of the flexibilities in the

World Trade Organisation's TRIPS agreement and the related Doha declaration to meet the needs of developing countries.

Meanwhile in Brussels, the EU approved a plan on May 26 to encourage drug firms to sell cut-price AIDS, tuberculosis, and malaria drugs to least developed countries by reducing worries the medicines will end up on the black market back in Europe.

Under the plan, drug companies that agree to sell their products at a 75 per cent discount from European prices, or a 15 percent markup over the cost of production--whichever is cheaper--will qualify to use a special logo on their packaging. That will help customs officials identify them to prevent illegal reimports back into Europe. The programme applies to 76 countries, mostly in Sub-Saharan Africa.

In a separate move, WHO joined forces with Health Action International to produce a computer-assisted guide to enable procurers of medicines to compare the price and availability of 30 widely-used medicines. It proposes a price survey methodology, and identifies broad policy options to achieve more affordable prices.

The manual also brings to light the difference between procurement price and consumer prices. The latter includes mark-ups, taxes, tariffs, and other charges.

Source: *The Lancet* May 31 2003. The article was by Clare Kapp

Silver screen is now a smokescreen

The World Health Organization (WHO) has urged the film and fashion industries to stop promoting tobacco use, warning that smoking is set to become the single biggest cause of disease in the Asia-Pacific region.

WHO said that these two industries were both significantly fostering the use of tobacco, either directly or indirectly, through stars smoking on films, sponsorships of fashion shows and fashion accessories bearing tobacco names. Moreover, some tobacco companies pay for product placement in movies.

Studies show that the likelihood of young people trying out cigarettes more than doubles with frequent exposure to seeing smoking on screen. Every day, some 40,000 to 50,000 Asian teens take up smoking.

According to the University of California, San Francisco nine out of ten Hollywood movies dramatize tobacco. Also 28 percent of films and one in five children's movies show a cigarette logo or brand name. A recent WHO study of Indian films showed 80 percent depicted tobacco use.

Smoking has gained a more positive image through film in some areas. Once in Indian films, only "bad guys" smoked; now the heroes smoke just as much.

Currently WHO's Western Pacific Region has the highest smoking rate in the world, with nearly two-thirds of men smoking. With growing restrictions on tobacco advertising, tobacco companies now have few settings to promote their products.

WHO has called on the film industry to: Certify that no one involved with film production receives any payoffs for depicting smoking; Run strong anti-tobacco advertising before films with tobacco use; Stop identifying tobacco brands in movie scenes; and Implement a rating system for films that depict smoking

Source: Press Release 28 May 2003, World Health Organization Regional Office for the Western Pacific

WHO to adopt Brazilian model to fight AIDS/HIV

Brazil's policy for combating AIDS will become the foundation for the new policy of the World Health Organization (WHO), to be adopted for the next five years.

Jong Wook Lee, Director-elect of the WHO, has asked the Brazilian Health Minister Humberto Costa that the head of the administration's AIDS programme, Paulo Teixeira, be released to formulate the new policy for combating AIDS throughout the world, based on Brazil's experience.

The invitation surprised the Brazilian delegation, which was in Geneva for the World Health Assembly. Teixeira will be released to work on the WHO transition team. "This is one of the highest recognitions of Brazil's work in this area", Costa said.

There has been criticism that the WHO has stuck to the line of some developed countries - that poorer governments do not have the means to treat their sick, and therefore, they should focus their energy and resources on prevention.

"The WHO has been little involved with treatment over the past 10 years and Brazil has proven that you do not have to be a developed country to have an effective treatment programme," said Teixeira. He believes Lee is signalling that he will push for a revolution in this regard.

In Teixeira's opinion, applying the Brazilian programme throughout the world will not be an impossible task. "Brazil's experience has shown that even in poor regions there is a way to make treatment viable," said the expert.

What impressed Lee was that Brazil - despite being a developing country - has adopted, since the early days of the Fernando Henrique Cardoso administration, a policy which guarantees free access to treatment for all patients

infected with the AIDS virus. The country has also managed to prevent the disease from spreading, which has obligated the WHO to lower its projections on the number of AIDS victims in Brazil.

Teixeira stresses that the WHO will not be the first to adopt the Brazilian programme. In the last three years, 31 developing countries have adopted Brazil's guidelines and both the Kenyan and South African governments are working with medicines donated by Brazil.

Source: BBC Monitoring International via NewsEdge Corporation : Estado, 21 May 2003

Daschle, McCain and Kennedy letter requesting GAO study drug costs.

The following is a letter by US Senators Daschle, McCain and Kennedy to Hon. David Walker, Controller General of the United States.

June 13 2003

The Honourable David Walker
Controller General of the United States
441 G Street, NW
Washington, DC 20548

Dear Mr Controller General,

We are writing to request the assistance of General Accounting Office (GAO) to analyze the cost of manufacturing drugs to treat persons with HIV/AIDS, and the price paid for those drugs by US government agencies for use in the developing world.

In May 2003, the President signed into law H.R.1298, which authorizes the appropriation of \$15 billion for Fiscal Year (FY 2004 through FY 2008 for the global HIV/AIDS fight, including to purchase drugs to treat persons with HIV/AIDS in developing countries. We feel strongly that these funds should be used to purchase products of assured quality at the lowest reasonable price, so that taxpayers will receive the greatest value for this urgently needed investment to stop the HIV/AIDS epidemic.

President Bush has also expressed an interest in purchasing drugs to treat persons with HIV/AIDS at an economical cost. To ensure efficient use of taxpayer resources, we wish to obtain accurate information about the cost of manufacturing these drugs and the prices that will be paid for them in resource-poor countries. We request, therefore, that GAO study and issue a report as expeditiously as possible to:

- Detail the actual costs to manufacture the anti-retroviral and anti-viral drugs used to treat HIV/AIDS, as well as drugs to treat the opportunistic infections associated with HIV/AIDS, both for brand pharmaceutical companies and for generic manufacturers, including those manufacturers in India and Brazil and elsewhere. Such drugs include nevirapine, didanosine, zalcitabine, stavudine, lamivudine, abacavir, saquinavir, ritonavir, nelfinavir, amprenavir, acyclovir, gancyclovir and combinations of these and other drugs used to treat opportunistic infections, such as pentamidine, azithromycin and ciprofloxacin
- Detail components or the costs of manufacturing these drugs, such as the cost of the raw ingredients, the cost of manufacturing and packaging the products, and other costs
- Identify the factors, such as limited supplies of raw materials or active ingredients, limited manufacturing capacity, and/or the costs associated with increasing manufacturing capacity, that may affect the cost to manufacture these products
- Identify the lowest price for drugs that are approved by the Food and Drug Administration, authorized for marketing by the European Commission, or included in the most recent edition of the list of HIV-related

medicines pre-qualified for procurement by the World Health Organization's Pilot Procurement Quality and Sourcing Project

- Identify the various prices at which these drugs have actually been procured in the past year, and the lowest reasonable prices at which they could be procured using funds under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 and
- Identify procurement methods, existing and proposed, such as bulk procurement, that would reduce costs to the U.S. government.

Thank you very much for considering this request. We would be pleased to discuss it with you in greater detail, and we look forward to your report.

With best wishes, I am

Tom Daschle

John McCain

Edward M. Kennedy
Source: IP-health listserv

Resources

The International Drug Price Indicator Guide - 2002

The International Drug Price Indicator Guide provides what the name implies—an indication of drug prices on the international market. It provides a spectrum of prices from nonprofit drug suppliers and commercial procurement agencies, based on their current catalogues or price lists. It also contains prices obtained from international development organizations and from government agencies.

The International Drug Price Indicator Guide helps supply officers determine the probable cost of pharmaceutical products for their programs. It can be used as a reference list to compare current prices paid for products available on the international market. It can also be used to assess the potential financial impact of changes to a drug list.

This edition of the Guide includes nearly 90 new items (for a total of more than 750 items) and prices from 17 different sources. The therapeutic classes with the most new entries this year are antibacterials, including antituberculosis drugs; anticonvulsants; cardiovascular drugs; and drugs used in psychotic disorders. Also included the ATC code for each product.

Management Sciences for Health produced the 2002 edition of the Guide in collaboration with the World Health Organization. Development and publication of the Guide were supported by the Strategies for Enhancing Access to Medicines (SEAM) Program, which is funded by the Bill & Melinda Gates Foundation.

The electronic version of the 2002 edition is posted on the Manager's Electronic Resource Center (<http://erc.msh.org>), along with data since 1996.

If you would like to receive a print copy of the 2002 International Drug Price Indicator Guide, please contact the MSH Bookstore at bookstore@msh.org.

"Behind the Scenes at the WTO: the Real World of International Trade Negotiations". Zed Books, London.

It is an immensely important book on the politics of the WTO, which takes the lid off on how the WTO really works, and what really happened before, at, and after the Fourth WTO Ministerial Conference in Doha in 2001, on the basis of interviews with 33 Geneva-based delegates to the WTO and 10 Secretariat staff members.

This is the ammunition the critics of the WTO have been waiting for. It reveals the systematic subversion of an ostensibly democratic system to ensure that the "agreements" that are reached are those the major powers primarily the US and the European Union - want, irrespective of the views of interests of most developing countries, who form the great majority of the membership.

The authors summarise:

"Crucial meetings are held behind closed doors, excluding participants with critical interests at stake, with no formal record of the discussion. When delegates are, in principle, entitled to attend meetings, they are not informed when or where they are to be held. Meetings are held without translations, with documents only in English, which have been issued only hours before, or even at the meeting itself. Those most familiar with the issues are sometimes discouraged or prevented from speaking in at Ministerial meetings. 'Consultations' with Members on key decisions are held one-to-one, in private, with no written record, and the interpretation left to an individual who has a stake in the outcome.

Chairs of committees and facilitators are selected by a small clique, and often have an interest in the issues for

which the committee is responsible. The established principle of decision-making by consensus is routinely overridden, and the views of decision-makers are 'interpreted' rather than a formal vote being taken, even in such key decisions as the selection of Mike Moore as Director General and the chairmanship of the Trade Negotiations Committee. Rules are ignored when they are inconvenient, and a blind eye is turned to blackmail and inducements. The list is endless. "Any country whose political system operated as the WTO did before, during and after the Doha Ministerial - where procedures were interpreted with such 'flexibility', rules were routinely ignored, and people or interested groups routinely used bribery and blackmail to achieve their political ends -

would not only be rightly condemned by the international community as undemocratic and corrupt, it would also face a real and constant threat of revolution.

No developed country would contemplate running its government in this way; and yet they are happy both to exploit the system and to defend it against pressure for democratic reform at the international level." This book is a "must-read", not only for anyone engaged in campaigning and advocacy on the WTO and international trade issues, but also for anyone who wants to know how our world is really run, what's going on behind the headlines, and how international structures are being abused to impose globalisation on an unwilling world.

ON-LINE ORDERING INFORMATION: Go to: <http://www.zedbooks.demon.co.uk> Or Please e-mail Farouk Sohawon (Farouk.Z@zedbooks.demon.co.uk)

Price (paperback UK£12.99/US\$19.95; hardback UK£36.95/US\$59.99).

BULK ORDERS AND SALES TO NGOs: Prices include postage where applicable. Courier costs, if required, are extra. Northern NGOs: up to 5 copies: UK£10.72/US\$16.46 (25% discount plus postage) 6 to 20 copies: UK£9.57/US\$14.70 (33% discount plus postage) 21 to 50 copies: UK£8.57/US\$13.17 (40% discount plus postage) 51 to 100 copies: UK£7.79/US\$11.97 (40% discount, postage free) more than 100 copies, negotiable. Southern NGOs: up to 10 copies: UK£7.79/US\$11.97 (40% discount, postage free) 11 to 50 copies: UK£6.50/US\$9.98 (50% discount, postage free) more than 50 copies: negotiable.

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If you are able to review the book for a newspaper, journal, newsletter, etc, please request a review copy from Farouk Sohawon (Farouk.Z@zedbooks.demon.co.uk). Suggestions for possible reviewers are very welcome (with e-mail address if possible). If you write a review, please send a copy or web-link) to David Woodward (woodwarddavid@hotmail.com).

LEAFLETS: If you require leaflets for distribution, please contact Farouk Sohawon (Farouk.Z@zedbooks.demon.co.uk).

EVENTS:

If your organisation is interested in holding an event related to this book (eg a local press launch or press briefing, workshop, etc), please e-mail David Woodward (woodwarddavid@hotmail.com). NB we are unable to offer financial or logistical support for such events, but we MAY be able to provide other resources (eg advance copies for pre-Cancun events; leaflets and possibly a video of the launch). We hope such events will form the basis of a global debate on the legitimacy of the WTO. If you would like to be informed of any planned events in your country, please send an e-mail specifying the country to David Woodward (woodwarddavid@hotmail.com).

The Therapeutic Guidelines – Antibiotic – Version 12

The Therapeutic Guidelines are booklets with clear and concise recommendations for the most cost-effective choice of drugs. Published by Therapeutic Guidelines, a non-profit, independent, national organization, these publications cover all therapeutic areas. Over the years they have become extremely popular among prescribers as a source of independent and expert advice.

The Therapeutic Guidelines Antibiotic 12, announced as the silver anniversary edition (it has been 25 years since the writers sat down to writing a small 31 page booklet called the Therapeutic Guidelines) makes available in print the experience, insight and opinions of Australian experts who have based this updated text on the best available scientific evidence. It provides best independent advice to help you tackle the continuous problems of antibiotic use and microbial resistance and covers all organ systems and systematic infections. The publication also includes special reference to infections found in tropical and remote countries. While being extensively revised with major changes in the following areas:

- * lower respiratory tract infections with new algorithms for the management of community-acquired pneumonia
- * upper respiratory tract infections
- * genital tract infections
- * intra-abdominal infections including viral hepatitis and pancreatitis

* skin and soft tissue infections

it also carries the most up-to-date information about:

* how to minimize antimicrobial resistance; intravenous administration of antimicrobials; outpatient intravenous therapy; adverse reactions with antimicrobials; paediatric dosing; dosing in patients with renal impairment and blood level monitoring.

Prepared to face disasters?

“Emergencies and disasters can occur affecting human health, people’s lives and the infrastructure built to support them. Environmental health problems arising from emergencies and disasters are connected to their effects on the physical, biological and social environment that pose a threat to human health, well-being and survival: shelter, water, sanitation, disease vectors, pollution etc. This book deals with the management of such problems...” sums up the first paragraph to the Introduction of Environmental Health in Emergencies and Disasters, a practical guide published by the World Health Organization with the UN Refugee Agency, The International Strategy for disaster reduction, International Federation of Red Cross and the Red Crescent Societies.

During 1999-2000 an average of 211 million people have been affected by environmental disasters. This publication therefore is concerned with reducing the vulnerability of communities to hazards and thereby increasing their ability to disruption and rapid recovery; minimizing the health effects of emergencies and disasters by strengthening routine services; preparing appropriate health activities like water, sanitation to respond to emergency disasters. Its fundamental objective is to provide a structure to think ahead and plan for disasters and emergencies and to give an overview of the technical aspects of environmental health management. The publication consists of two parts and sixteen chapters. Part one deals with the general aspects or answers the questions what, where, when, why and who while part two is on the technical aspects and answers the question who in environmental health during the disaster management cycle.

According to the publication, the blame for great suffering due to disasters cannot be put entirely on nature being violent. Socioeconomic and political factors such as environmental pollution, mass migration and war have contributed to people becoming more vulnerable. Global climate has changed due to hazardous human activities and in return is affecting human well-being and health. Floods, hurricanes, wildfires and droughts are frequent and contribute to hazardous living. Poverty, the deadliest disease is however interrelated to the misuse of natural resources causing land degradation, deforestation and decreasing food security. Industrialization invariably leaves habitants to find shelter in dangerous places like slopes and flood plains and technology like nuclear power have been components of health disasters.

“ From each country experience the world has been learning its lessons. Therefore now it is possible to summarize these experiences and draw lessons for environmental health management of emergencies” states the publication. However, new management processes have been created and scientific and technological advances have begun to aid emergency management (for instance satellite images). Work done by the UN towards disaster management is appreciated yet policy commitment and implementation are different. The support provided for preventing disaster is not adequate.

Targeted at emergency planners and administrators, environmental technical staff, activists, public health officers, community workers and employees of water and sanitation companies it attempts to provide measures designed to reduce the impact of disasters on environmental health infrastructure and focuses on strengthening the ability of people to withstand the disruption of their infrastructure and system for environmental health.

Contact WHO Marketing and Dissemination, CH-1211, Geneva 27, Switzerland. Tel: 41 22 791 24 76/Fax: 41 22 791 48 57 Email: bookorders@who.int

Cardiovascular Version 4, 2003

An easy-to-use resource that provides an agreed interpretation of the best available evidence from the current world literature, by Australia's most eminent and respected experts.

New information deals with:

- Syncope - a common and sometimes very difficult problem
- Pulmonary hypertension – a serious condition, especially in its primary form, but for which there are promising new drug treatments.

Major revisions cover:

- Primary and secondary prevention of atheromatous disease
- A list of cardiovascular risk assessment tools
- An increased emphasis on preventing and dealing with the decline of renal function (with or without diabetes)
- Treatment of heart failure, with the emphasis on improving prognosis
- Coronary pain syndromes including newer drugs for managing the acute phase and the increasing use of early revascularisation for high-risk patients
- Pre-eclampsia including the significant therapeutic findings from a recent large study
- Uncomplicated benign hypertension - endorsement from a review of trial evidence for diuretics as the most cost-effective initial treatment
- Assessment and treatment of smoking

Also:

- Updated information on dyslipidaemia; hypertension; hypertension and cardiovascular disease in pregnancy; arrhythmias; peripheral vascular and cerebrovascular disease; venous thrombosis and pulmonary embolism
- Appendices on cardiovascular drug interactions, etc.

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