

Conclusions of the Asian Workshop on TRIPS and Access to Medicines: Appropriate National Responses

Kuala Lumpur, Malaysia, 28-30 November 2004

General

1. The Asian Regional Workshop on the WTO TRIPS Agreement and Access to Medicines: Appropriate National Policy Responses was held in Kuala Lumpur on 28-30 November 2004. It was co-organised by the Third World Network and Health Action International (Asia Pacific) with the cooperation of the UNDP, WHO, Medicine Sans Frontier and Consumer Project on Technology.

2. The workshop was attended by 90 participants who are policy makers, and representatives and experts from health movements, NGOs, and international agencies, from countries in the region: Bangladesh, Cambodia, China, Fiji, Hong Kong, India, Indonesia, Laos, Malaysia, Papua New Guinea, Myanmar, Pakistan, Philippines, South Korea, Sri Lanka, Thailand, Vietnam. Other participants came from Ghana, Australia, France and Switzerland.

3. The workshop was organized in several plenary sessions, working groups to consider country reports, and panel discussions, on a wide range of topics. The following are some of the significant conclusions.

Main Conclusions

4. Participants stressed that access to medicines and health services are vital for the Asian region, especially since this region has the largest share of the world's people. They also noted that the globalization process has had an impact on health care.

5. The workshop heard presentations and discussed the relationship between patents, prices and access to medicines. Data on prices of various products within and across Asian countries were presented by resource persons showing that prices of branded products are significantly (and

often greatly) higher than similar generic products, and also that the presence of generics brings down the prices of branded products in the same country. Countries that do not have access to generics pay much higher prices than those that do have such access for the same products. It is therefore essential that patented drugs do not enjoy monopoly and that competition from generics should be enabled, so that the patients have more choice and prices can be brought down. Many participants also called for price controls to be placed by governments on medicines since these are essential items.

6. The Workshop also discussed how the TRIPS Agreement by requiring patentability of medicines under certain minimum standards has constrained the ability of governments to institute pro-health policies, such as exclusion of medicines from patentability, which some Asian countries had done prior to the coming into force of TRIPS. The Doha Declaration has clarified that there are some flexibilities and safeguards such as the ability of governments to implement measures such as compulsory licensing, government use/rights and parallel importing, to offset the monopoly of patents.

7. Many participants asked that governments undertake a serious review process of TRIPS so as to expand the policy flexibilities in TRIPS, for example to consider that countries are enabled to exclude patents on medicines and food. Several speakers pointed out that before TRIPS, countries had excluded medicines from patentability, for example in the India patent law 1970.

8. In the immediate term, governments are urged to urgently review their patent laws and amending them to bring them in line with the best options and provisions possible, especially in light of the Doha Declaration on TRIPS and Public Health. The patent laws should enable

the country to provide compulsory licences, government use orders and parallel importing in simple and effective ways. The governments in the region should then exercise their rights by taking these measures required to treat ailments. The workshop recommended that the Manual on Good Practices in Public Health Oriented Patent Policies and Laws and its supplement (published by TWN) be used as a key reference point for review of policies and laws.

9. The participants expressed concern and also anxiety whether there will be continued and expanded supply of medicines to countries that have no or inadequate manufacturing capacity. This arises from a constraint in TRIPS Article 31(f) that production under compulsory license have to supply predominantly for the domestic market, thus limiting export supply. The “interim solution” to this through the WTO’s 30 August 2003 decision was found by participants to be impractical for dealing with this problem. Many participants pointed out that the measures required, such as notification of amounts of drugs and special labeling and packaging, on top of the issuing of compulsory licences, will most likely deter generic drug producers from making use of this mechanism. They called for a more appropriate permanent solution that revises TRIPS and that removes the Article 31(f) constraint without placing new constraints so that the export and import of generic drugs can be smoothly facilitated.

10. The participants were concerned about the post-2005 situation since an important generic-producing country, India, has to start allowing drug product patent applications, under its TRIPS obligation. Participants urged that the proposed amendments to the India patents act 1970 should be made in ways that take full advantage of the rights and flexibilities of the TRIPS agreement and the Doha Declaration, and that obligations that are not required by TRIPS (that are, i.e., TRIPS-plus) need not be included. Many participants signed a joint letter drafted during the workshop to the President and Prime Minister of India to this effect. The participants also hope and expect that the relevant Indian authorities will establish systems that enable applications for compulsory licences to be rapidly processed and acted on. It was emphasized that it is critical that the supply of generic drugs from India should not be reduced or hampered, including to African countries, in the new post-2005 situation.

11. The workshop participants also heard presentations

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

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

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

14. The workshop discussed issues and processes related

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

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

16. Three working groups were convened to discuss the situation of individual countries with regard to their policy on access to medicines, patent law and patent law amendment, safeguard measures and generic production. A plenary session to receive reports from these groups heard the present status of the countries, and many suggestions on what can and should be done. A session was also held on "the way forward" for Asian countries on making progress on providing access to medicines.

Further proposals

17. Besides the suggestions mentioned earlier, the workshop participants also made many other proposals. These include the following:

1. Governments are urged to initiate or continue review of patent laws and amend these to take full advantage of flexibilities in TRIPS and the Doha Declaration
1. A committee or group of experts should be made available to the governments and NGOs to assist in the law review and amendments.
1. National patent laws should set appropriate scope and criteria for patentability and patents so that frivolous and ineligible applications are not entertained.
1. The review of TRIPS should be taken seriously by Asian governments which should advocate reforms so that flexibilities can be expanded in relation to access to medicines, including consideration to allow exclusion of medicines from patentability.
1. Policy makers should seriously consider taking safeguard measures such as compulsory license, government use and parallel importation, to facilitate access to affordable medicines to the public.
1. Best practices in legislation and policies on safeguard measures should be shared among countries in the region.
1. The TWN Manual on Good Practices in Public Health Sensitive Patent Policies and Laws are adopted by the workshop as a valuable resource and reference material.
1. There should be closer collaboration among relevant departments and Ministries (health ministry, trade ministry, patent office, attorney general office, etc.,) on the basis of protecting and promoting public health interests.
1. Fast track registration mechanism should be established for generic drugs that are required to treat serious ailments.
1. There should be priority to activities to sensitise policy makers so that there will be strong political will to establish health-sensitive laws and policies regarding patents and access to medicines and safeguard measures.
1. Pool procurement for essential drugs in the region should be explored.
1. It was also agreed that regional patent pools among groups of states should be explored, aimed at sharing patents and licenses through international agreements to provide essential medicines at affordable costs to citizens.
1. National databases on patents and patent applications for pharmaceutical products should be set up and made available to the public to enable appropriate responses if needed.
1. A regional centre or network for collection of information on drug patents should be set up, from where people can access the information.
1. Guidelines for procurement of medicines should be drawn up.
1. The organizers (TWN, HAI) and WHO, etc., should

set up a stronger system to assist developing countries to understand international IP regimes (e.g., TRIPS), and options for patent laws, so that countries can choose the appropriate options.

1 Awareness for the public and policy makers on patents and access to medicines should be raised through national workshops and seminars which raise the problems and increase knowledge about options in patent laws and safeguard measures, etc.

1 Information dissemination on these issues should be expanded.

1 Technical support and technical assistance should be provided to policy makers and NGOs that would like to act on these issues.

1 Policy makers in Asia should be on the alert and reject proposals in free trade agreements that introduce TRIPS-plus obligations such as data exclusivity, extension of patent term, linking drug registration to patents and limiting the grounds for compulsory license, etc. NGOs and health movements should strengthen their work to raise awareness and prevent these types of provisions. Regional cooperation among policy makers and NGOs/social movements on this issue is urgently required.

1 Urgent measures must be taken to ensure that in the post 2005 situation, that there should not be a break or reduction or disruption to the supply of required drugs from generic producers in exporting countries to importing countries in Asia as well as Africa and other developing regions.

1 International agencies especially WHO and UNDP should expand their capacity to assist countries in the region in a wide range of issues and activities, including information, analysis and assistance on issues relating to patents and access to medicines.

1 The co-organisers, TWN and HAI (AP) are requested to review the proposals put forward in the workshop and to initiate work programme and activities to implement as many of them as possible.

1 Similar regional workshops should be organized every one or two years so that policy makers and health movements can share information and experiences and improve laws, policies and practices.

1 Participants agreed that: We reaffirm our commitment to provide essential medicines and health services so as to protect and promote public health. There is a crucial need to make medicines affordable and accessible to all the people. We call on policy makers, parliamentarians, international and regional organizations, and all other organizations to act urgently as lives and health of people in the region are at stake.

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