

Regional Consultation on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses

Colombo, Sri Lanka, 17-19 April 2003

The “Regional Consultation on the WTO/TRIPS Agreement and Access to Medicines: Appropriate Policy Responses” was held in Colombo on 17-19th April 2003. It was hosted by the Ministry of Health, Sri Lanka, organized jointly by the Health Action International Asia - Pacific (HAIAP), Third World Network (TWN) and co-sponsored by the Department of Essential Drugs and Medicines Policy, Drug Action Programme, (EDM/DAP), World Health Organization (WHO), Geneva and the South-East Asian Regional office of WHO, New Delhi. Among the 70 participants were senior health and trade officials and representatives of health-related NGOs and social movements from 18 Asian and Pacific countries, as well as international experts and resource persons. The following is a statement of Conclusions and Recommendations of the Consultation, which was presented at the Closing Ceremony on 19 April, to the Minister of Health of Sri Lanka, who officiated at the Ceremony.

CONCLUSIONS AND RECOMMENDATIONS

Participants at the Regional Consultation gathered together to analyse the effects of the TRIPS Agreement on access to medicines, and to discuss appropriate policy and legal responses at national, regional and international levels. Participants noted that the traditional issues taken up by those involved in promoting essential drugs (i.e., drug efficacy, safety of drugs, saving of health expenditure through the focus on essential drugs) have been overtaken in recent years by the problem of public access to medicines caused by patents, especially after the WTO's TRIPS Agreement came into force.

TRIPS has placed constraints on WTO Members; for example, they no longer have flexible policy space to exempt food and drugs or other sectors from patentability (as they had before), and the minimum period of protection for patents has been mandatorily fixed at longer terms than existed in most countries. TRIPS has tilted the balance between the IPR holder and the public interest in favour of the IPR holder, vis-à-vis consumers and producers that are not IP holders. As a result, prices of drugs and other items, and the cost of production, have escalated.

Despite this adverse recent situation, participants of the Consultation confirmed that TRIPS does contain several types and degrees of flexibilities that allow WTO Members to take certain measures to override patent holders' exclusive rights. The Consultation extensively discussed these flexibilities and measures, especially compulsory licensing, parallel importing and government use of patents. Legal experts at the workshop illustrated how many developed countries (such as the US, the UK, etc.) have for years been making use of these measures for the public purpose.

In relation to health, the Consultation analysed the Doha Declaration on the TRIPS Agreement and Public Health (November 2001) and noted that this Declaration has reaffirmed the rights of WTO Members to make use of measures like compulsory licensing and parallel imports. It has also politically and legally strengthened the ability and attitude of developing countries to make use of these measures aimed at providing access to affordable medicines for all

The Consultation agreed that with the assistance of the Doha Declaration, it is now vital for developing countries to make maximum use of the flexibilities in TRIPS with the aim of promoting public health. National

implementation through formulating appropriate measures, policies and legal provision and laws on patents is now the most important step.

In this context the Consultation heard the presentation on the Manual on Good Practices in Public Health Sensitive Policy Measures and Patent Laws, which was developed by the Third World Network and a group of legal and trade experts. The participants expressed appreciation for the Manual and recommended that it be widely distributed and used as an important reference and model and guide for the formulation of national policies and laws on patents and medicines.

The Consultation also heard and discussed presentations by legal and trade experts who explained the present situation regarding trade rules, TRIPS and the use of compulsory licences, parallel imports and government use of patents.

The Consultation also heard from a panel of national generic drug producers in the region and discussed the benefits of generic medicines in terms of the low prices and good quality of such medicines. It was agreed that generic drug production in the region is a viable and beneficial enterprise and should be spread to many countries.

During the Consultation, the participants also took part in small working group discussions that covered the following issues: the status and situation in each country regarding patents and 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 the better regional coordination.

Taking the reports of these working group discussion into account, the Consultation has come up with the following recommendations:

1. Each country in the region should give the highest priority to formulating appropriate policies, policy measures and laws or legal provisions regarding patents and access to medicines.
2. In doing so, each country should maximize the use of the rights that the country has to protect and promote the health of its citizens and to provide affordable medicines for all.

3. In particular, policy makers in each country should take the following steps:

- (i) limit the scope of approval of patent applications to patents that are genuinely novel or involve an inventive step, and to reject applications that are not novel or do not satisfy the criteria of an invention, or that involve only minor developments (such as slightly different dosage form or formulation);
- (ii) examine existing legislation and determine whether there are inadequacies and weaknesses, and if so, to amend these laws and introduce provisions that maximize the rights and policy options of the country to be able to take policy measures such as compulsory licence, parallel imports and government use;
- (iii) examine the national situation regarding patents and prices of medicine in relation to the diseases in the country, and devise measures such as government use, compulsory licensing and parallel imports in order to effect importation or production of medicines;
- (iv) examine and resolve the practical and administrative measures required, such as establishing institutions or competent authorities or an inter-agency committee, appropriate appeal procedures and appropriate systems and rates of compensation for the patent holder;
- (v) establish institutional arrangements for coordination of policies and measures between different government departments involved in the issue (e.g., Ministry of Health, Ministry of Industry and Trade, the Patent Office, Attorney-General's office or the Ministry of Law);
- (vi) governments should also establish consultative mechanisms with NGOs, social movements and private sector national generic drug producers or potential producers so that a coordinated national response can be effectively made.

4. NGOs and social movements should take steps to monitor and analyse the developments in TRIPS (including the on-going discussions on the Paragraph 6 issue of the Doha Declaration) and to analyse the national status and situation regarding patents and medi-

cines, and to actively communicate their views and proposals to the policy makers, other NGOs, the media, parliamentarians, etc.

5. 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 Consultation (HAI AP, TWN, and WHO) should discuss among themselves how to follow up on this proposal.

6. The Consultation participants also encouraged generic drug producers to strengthen their activities, to remain viable and to develop further. They should aim to expand the production of essential and needed medicines and to make these available at the lowest possible prices. The producers should also form an association or network among themselves and make known to the public and to policy makers the capacity, expertise and services that they possess. They should also try their best to transfer technology and production know-how to all countries in the region. They should also try to make practical arrangements among the companies and with policy makers, to produce, import and export generic medicines.

7. 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.

8. 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. WHO should play an active and expanded role in this region and also internationally.

9. We encourage and mandate the co-organisers of the Consultation (HAI AP, TWN and WHO) to plan follow up mechanisms, arrangements and activities. They should consult health groups in the region, including the Peoples' Health Movement. These mechanisms and activities should include:

(i) an information-sharing and communications system;

(ii) making available a pool or team of experts on patents, trade rules and public health, with the perspective of health and public interest; and encouraging policy makers and the WHO to make use of these experts to advise on national patent laws, TRIPS negotiations, policy measures such as compulsory licensing and practical actions such as generic drug production;

(iii) establishing a coordinating and networking mechanism that can bring about better cooperation and activity of NGOs, policy makers and generic drug producers.

10. The Consultation also calls on policy makers in the region to strengthen their capacity and effectiveness in the TRIPS negotiations, including in the Paragraph 6 issue on TRIPS and public health, on the review of Article 27.3b (on biodiversity) as well as the overall review of TRIPS (under Article 71.1 of TRIPS). We also call on NGOs to be active in influencing the reform of TRIPS. We also appreciate the endeavour of NGOs that seek to examine whether intellectual property issues should remain in the WTO and if not, then what mechanisms exist for the issues to be transferred to another venue. We also appreciate the attempts by NGOs to seek alternative systems that reduce the claimed rationale for monopoly and exclusive rights of patent holders (such as alternative sources of financing R&D and rewarding genuine innovation without having to rely on IPRs).

11. Whilst this Consultation has mainly focussed on the effects and challenges posed by TRIPS, we are also concerned about the implications for public health of the process and substance of bilateral and regional trade agreements as well as developments in WIPO. NGOs and the generic drug producers should actively monitor these developments and communicate their views to the government.

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