AWPII Programme Area II.1:
Joint Action to Increase Access to Affordable Drugs and Testing Reagents
AWPII Activity II.1.1. and II.1.5.
Policy Review and Capacity Building

Project Title:
Policy Review and Capacity Building Activities on Increasing Access to Affordable Drugs and Test Reagents

Present Situation/Problem to be addressed:

All ASEAN member countries are either members or observers of the WTO. As such they are, or will soon be, committed to follow the rules laid down in its Agreements, including the TRIPS Agreement. However, there is a growing concern worldwide that the TRIPS standards for intellectual property rights may have negative implications with regard to access to medicines, notably in developing countries. In fact, this concern has led to discussion in several international fora, including the WTO TRIPS Council.

Within ASEAN, two workshops on the TRIPS Agreement have been conducted; the first one in May 2000 (with a focus on pharmaceuticals) and the second one in February 2001 (focusing on implications for traditional medicine). Thus, in the ASEAN region, there is a general awareness within Ministries of Health and Drug Regulatory Authorities with regard to the potential implications or intellectual property rights (IPR), and more specifically TRIPS, with regard to access to medicines. Similarly, Health Authorities are aware of the importance of ensuring that allowable safeguards -notably workable provisions for compulsory licensing, parallel importation and/or a 'Bolar- provision'- are incorporated in national patent legislation. However, most Ministries of Health and Drug Regulatory Authorities lack the expertise to carry out an in-depth assessment of national IPR legislation; in fact, such an assessment should be carried out by an IPR expert with a good understanding of the public health issues, and, preferably, of the licensing practices of pharmaceutical companies.

At the same time, an increasing awareness regarding HIV-infections, and, unfortunately, increasing numbers of HIV infected people have led to an increasing number of NGOs being active in the area of promoting access to medicines, treatment and care. However, many of these NGOs do not have the capacity to analyze the national laws of their own country, in order to determine if there are valid legal options available to them to initiate small scale pilot treatment projects, and/or to advocate for viable solutions.

This lack of clarity on potential mechanisms that can actually be used to enhance access to affordable treatment, without running afoul of the law, is becoming an obstacle to action, and, thus, to access and treatment, both within governments and NGOs. Unfortunately, in most if not all ASEAN countries, there is a shortage of experts with extensive knowledge on both intellectual property rights and public health.

Objective:

1. To review countries' IPR laws (or pending bills, if any) from a public health perspective, in order to identify options available for enhancing access to medicines; and
2. To build local, legal capacity in ASEAN countries with regard to intellectual property rights and public health/access to medicines.

Proposed Strategies

Review of national intellectual property legislation (notably patent legislation) by a renowned international legal expert, who is well aware of public health issues, in order to analyze the law from a public health/access to medicine perspective, and to identify options that can actually be used in order to increase access to medicines (notably, though not exclusively, HIV/AIDS medicines). The international expert will work together with 2 or 3 selected national IPR experts, using the review partly as a means to update the knowledge of national experts.

It is envisaged that the analysis of national IPR laws can be used, among other activities, as a means of building capacity, by having outside experts work together with local experts while carrying out the review, and by using those reviews as 'real-life' examples in workshops (see below for more details).

Expected Outputs:

1. Study completed reviewing IPR laws, assessing varied issues, including but not limited to legal, ethical, social and economic, and recommendations related to opportunities for regional or inter-country cooperation with a view to undertake a) bulk purchasing, b) differential pricing, c) parallel importing, and/or d) compulsory licensing; and

2. Two or three ASEAN workshops, bringing together the same national (ASEAN) experts and international legal experts, plus public health experts, in order to share information, and increase capacity among national (ASEAN) IPR experts and lawyer with regard to public health implications of IPR legislation, and with regard to the importance of public health safeguards such as compulsory licensing. These workshops may use examples from the before mentioned reviews of national legislation as training materials.

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