United Nations Secretary-General's High-Level Panel on Access to Medicines

Additional Information for C46, Achieving policy coherence between trade and health

Burcu Kilic, Public Citizen

In the era of multilateral mega free trade agreements (FTAs), a key challenge is establishing policy coherence between FTA commitments and national health objectives. This requires formulating policy measures and mechanisms for positioning health more centrally in trade as well as creating and sustaining coordination among key policymakers and experts.

There is no time to lose but so much to gain. The Trans-Pacific Partnership Agreement (TPP) has concluded but has not been implemented. There is opportunity to assist countries to introduce strong public health exceptions to protect their people. The Regional Comprehensive Economic Partnership (RCEP) negotiations are ongoing; negotiating countries would appreciate assistance and policy dialogue.

The High-Level Panel has a critical leadership role to play in engaging effectively with trade and health policies and can be a catalyst for policy coherence.

The High-Level Panel should convene a 'permanent mechanism' or 'expert group' to help countries mitigate the negative consequences of FTAs & TRIPs-plus rules. This mechanism/expert group can serve governments at the national and international level in trade-related policy making and implementation.

The group or mechanism would provide an ongoing forum linking national trade and health policy makers and negotiators to the kinds of networks of expertise that they will need to engage most effectively in trade related policy making and implementation.

The United Nations Development Program (UNDP) can be the primary delivery vehicle for this permanent mechanism/expert group. The UNDP is an efficient and knowledgeable institution in delivering multilateral technical assistance.

Activities of this mechanism/expert group would include:

- *Detailed reviews* of provisions in concluded trade agreements and their effects on access to medicines and innovation, because effective engagement requires a grasp of technical detail.

- *Development of policy measures and mechanisms* that are designed to promote a trade-health coherence agenda, putting in place appropriate public interest policies that promote public health.

- *Analysis of policy options* to achieve better health outcomes where FTAs have already been implemented.

- *Design of complementary policies* aimed at smoothing negative effects of FTA provisions to maximize public health outcomes (e.g. model law provisions for implementation)

Example: Public Health Safeguards for Data/Market Exclusivity

One such policy option would be a well-articulated public health safeguard to deal with data and marketing exclusivity.

Pharmaceutical companies are increasingly intent on using data/marketing exclusivities as their most effective monopoly tool, because, unlike patents, these exclusivities take effect from the time a medicine is actually introduced into a market. The trend has been to lengthen these drug registration-related monopolies both in the EU and the U.S. and to export these via trade agreements.

These exclusivity rules are separate from patents, and governments have limited experience overriding them in order to protect health. Patents have well-established flexibilities, such as compulsory licensing, to protect health. Exceptions to data and marketing exclusivity are not as well established – they are unvoiced.

The recently concluded TPP includes a specific provision on biologic exclusivity. Biologic medicines are the next generation of life-saving medicines. For biologics, data and marketing exclusivities may be more important, and more frequently used, than patents. Therefore, the lack of well-articulated public health safeguards to deal with data and marketing exclusivity becomes a more serious problem for biologics.

There is a need for a clear and explicit public health exception to address data/market exclusivity obstacles for access to medicines. This issue unfortunately has not been adequately addressed in the TPP. The expert group should identify this problem and provide countries with options to solve it as a matter of policy and law.

Working Groups

Discrete groups can be set up in support of the activities of the group:

- A *Steering Committee* with representatives from the FTA negotiating/implementing governments as well as from intergovernmental regimes (the World Health Organization (WHO), the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Industrial Development Organization (UNIDO)), regional trade-related bodies such as the Association of Southeast Asian Nations (ASEAN), Asia-Pacific Economic Cooperation (APEC) and Alianza del

Pacifico, and important stakeholders, such as non-governmental organizations (NGOs), industry representatives and academics.

• A *Working Group on Implementation*, dealing with the implementation of FTAs (particularly the TPP) in least harmful ways and making recommendations for most appropriate options for consideration in the work program. The Working Group also, where appropriate, drafts model law clauses to provide guidance to governments implementing the FTAs.

• A *Working Group on Negotiations*, available to provide technical assistance on trade and health, including in the context of ongoing FTA negotiations, and establishing policy dialogue between trade, health and human rights officials.

It's not too late to develop a coherent agenda putting in place appropriate public health and public interest policies to achieve realization of the right to health. Opportunity still exists and the High-Level Panel can make this happen.