Minutes

Formulating and Implementing Governance on Health: The Case of Access to Medicines in the Developing and Least-Developed Countries

Session organized by the Centre for Socio-Economic Development (CSEND)[1] during the WTO Public Forum on the 30th of October 2009

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Speakers:

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Abstract:

The objective of this session was to address the institutional issues surrounding the implementation of the Doha Declaration on TRIPS Agreement. While the Doha Declaration was a major breakthrough in the adoption of the Doha Development Agenda, its' policies have yet to achieve full and effective implementation, especially in the beneficiary developing and least developed countries. Furthermore, the discussion focused on the impact of provisions related to intellectual property rights and standards in regional agreements on access to medicines. In examining trade agreements, the session analyzed offensive and defensive interests of developing (DCs) and the least-developed countries (LDCs) in the health sector in relation with investments and technology transfers in the sector. The session addressed the issues from four levels, the national level, the regional level, the multilateral level, and the strategic level. The national level focused on identifying and addressing the institutional barriers to successful implementation of the Doha Declaration. The issue was addressed from the regional level through empirical evidence of current regional schemes and an assessment of their progress to date. The multilateral level focused on which trade-related technical assistance and capacity building activities will provide a better

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implementation of the legal framework on access to medicines. Lastly, the strategic level focused on the way forward and how to assist beneficiary countries in implementing the legal multilateral framework in order to ensure effective use of the flexibilities on access to medicines. Each of these levels helped to address how a new perspective on governance in health could assist the developing and least developed countries in the implementation of the Doha Declaration on TRIPS and Public Health in the WTO context.

Presentation by the Panelists:

Ms. Silke Trommer: Impact of provisions related to intellectual property standards in regional agreements on access to medicines

- Regrettably, most FTAs involving medicines include clauses that favor the rights of the inventor and obstruct developing countries from receiving affordable generic drugs.
- Access to less expensive medicines is greatly hindered by the presence of patents, which are used to compensate the inventor of the medicine. Extended patent terms, second use patents, and the creation of additional patentability criteria have all decreased access to affordable medicines for developing countries. Additionally, the creation of test data exclusivity, the link between the patent term and marketing approval procedures, and regulation on generic drug imports each create pressure on the production of affordable generic drugs.
- Furthermore, tightened enforcement laws on imports and exports have reduced developing countries' abilities to import generic drugs.
- This increasingly obstructs South to South trade of generic medication, which is completely lawful under public international law
- In order to combat the issue of expensive brand drugs, it is important that countries are able to use the flexibilities in the TRIPS agreement, which were guaranteed by the Doha Declaration in 2001.
- Unfortunately, there are various clauses which restrict existing TRIPS flexibilities and others which introduce TRIPS+ obligations that are to the sole benefit of the patent holder.
- Suggestions to move forward include: sticking to TRIPS flexibilities, committing to Doha declaration in FTAs, avoiding all clauses that extend patent protection, and making sure that countries know their defensive and offensive interests when making trade agreements.
- Including public health experts and interest groups in the policy formulation will reintroduce a voice that defends the societal interest over the interests of the inventor.

Mr. David Vivas-Eugui (ICTSD): Assesing the impact of TRIPS-plus provisions on Public Healh: Lessons from case studies in Latin America

- The assessment of the impact of TRIPS+ project focused on how TRIPS+ provisions would impact public health and access to medicines in a particular market at the macro level. The project was implemented through the development of an impact assessment methodology and case-studies of several countries including: Costa Rica, Guatemala, Thailand, Jordan, Bolivia, Colombia, Uruguay, and the Dominican Republic. The objective of the project was to develop methodological tools, through national assessments, which will assist developing countries to better understand the costs and benefits of FTAs for negotiation and implementation purposes
- The studies were undertaken with a partial equilibrium model at the macro level. The model measured the level of exclusivity, impact over average prices, impact on public and private spending on medicines, and impact on consumption and competition.
- There are some limitations to the model. For example the model does not measure the impact over innovation or the market and government failures.
- An in-depth look at the examples of Costa Rica and Dominican Republic revealed important differences on the impact over prices and market structures of the countries.
- Background information on the case-study for Costa Rica: TRIPS and CAFTA have already been implemented, there is universal health care coverage (almost inelastic demand), and it is applicable only to the institutional market.
- The findings in Costa Rica revealed that by 2030, the price of all drugs will increase between 18% and 40% yearly and there will be a need for increased public spending from about 2.008 to 3.357 million USD. If the public budget is not increased, consumption will decrease by 24% in the worst case scenario. Furthermore, the concentration in the supply is putting at risk the sustainability of the universal access and procurement system.
- Background information on the case-study for the Dominican Republic: TRIPS has been implemented, CAFTA is in the process of being implemented and the study is applicable to both the institutional market and the private market.
- The findings in the Dominican Republic study show that there will be a modest price increase of 9% to 17%. Since consumers already pay a very high price in the health care market, about 80% of the purchases today are out-of-pocket, the private sector price will not greatly increase due to TRIPS+ obligations. If the public budget does not increase, consumption will decrease by 8% in the worst-case scenario.
- Some lessons gained from these studies are:
    - TRIPS plus can have important impact over public spending and social security systems;
    - The use of TRIPS flexibilities can mitigate the impact;
    - It is important to not underestimate the effect of information asymmetries and market and government imperfections on prices, demand needs to be higher in order to negotiate prices
- Recommendations to mitigate impact include using TRIPS and US/CAFTA-DR flexibilities, exploring the value of regional procurement, increasing consumer subsidies, expanding the coverage of social security systems, and improving institutional capacity in the offices of: IP, sanitary regulation, procurement system, and social security.

Prof. Raymond Saner (CSEND): Offensive and defensive interests of developing (DCs) and the least-developed countries (LDCs) in the health sector in relation with investments and technology transfers in the sector

- The Health Sector is one of most rapidly growing sectors of the world economy with 4 Trillion USD/year (Chanda, 2001) but the gap between developed and developing countries is very significant. Healthcare expenditures in OECD countries counted in 1998 for 3'500.- USD/capita/year while in comparison, it counted only for 5.- USD/capita in the LDCs (UNCTAD/WHO, 1998).

- Trade in Health Services is still small as it represents only 0.4% total health expenditure of OECD countries (Lautier, 2005). However cross border trade and investment in this sector are growing considerably due to numerous factors (aging societies in Europe and Japan leading to increased health expenditures, increase of spending on health services, technological application of Health Services to remote areas, continued FDI liberalisation and a high and increasing demand for skilled medical personnel).

- By 2008, 88 WTO Member Countries had committed to one or several agreements related to trade in Health Services accordingly to the WTO modes of trade (M1-Cross border Supply, M2-Consumption abroad, M3-Commercial presence, M4-Movement of natural persons). Like any other tradable service, a country can have Offensive Interests (e.g. requesting expansion of the scope of activities committed by other WTO member countries, and ensure their commitment towards greater market access and stringent national treatment,) as well as Defensive Interests (e.g. protecting national service providers and consumers) in Health Services
- As an example, prior to joining the EC, Hungary had primarily no restriction in term of market access and national treatment when considering its health related specific commitment with Mode 1, 2 and 3 which list "none" in the schedule. Hungary did not take any specific mode 4 commitments on health services (unbound). Certain commitments were however taken horizontally to provide for the entry and temporary stay of natural persons under various categories. In terms of commercial presence, while there were no sector-specific restrictions on market access and national treatment, a number of horizontal limitations require the establishment of a limited liability company, joint stock company or representative office apply. The acquisition of state-owned properties is excluded from the scope of the commitments

- The main offensive interest of a country like Hungary should be to push in the EU for the full implementation of the free movement of doctors complementing the free movement of patients.[2] On the defensive side, Hungary could request foreign health providers moving to Hungary to learn Hungarian and to spend X days in sharing know-how with Hungarian health

[2] European Commission. 2001. "The internal market and health services. Report of the High Level Committee on Health" http://ec.europa.eu/health/ph_overview/Documents/key06_en.pdf, page11.

professionals.

- Question to Prof Saner: Hungary's GATS/Health sector commitments predated entry into the EC and are higher than the EC commitments. How to reconcile the difference?
- Response (RS)

  The process of harmonization of the EC health sector has not been completed yet. Once completed, the EC and Hungary might have to negotiate compensation for non-EU WTO member countries holding offensive interests for the Hungarian health sector. Meanwhile, The Hungarian government should do its best to restructure its health sector and build up competitiveness[i].

Questions and Comments from the Audience:

1) Question for Silke Trommer: How would you respond to the fact that trade negotiations are very skewed between countries, even between medium sized countries and more powerful countries?

-Response (ST): From my personal research I have found that in West Africa, some NGOs with particular technical knowledge of development-related legal and economic issues have been able to help the region negotiate better trade agreements. This shows that medical personnel and outside groups can help to make negotiations fairer between two countries.

2) Question for Silke Trommer: Why is it a problem if developing countries exchange concessions on intellectual property for market access other areas?

-Response (ST): Many LDCs expose structural problems such as economic vulnerability which make it difficult for them to reap trade benefits despite market access opportunities. Furthermore, market access concessions are subject to preference erosion, whereas intellectual property concessions in FTAs are not. The feasibility of the bargain deserves thorough prior econometric analysis to which institutional capacity problems present a true obstacle.

2) Question for David Vivas: Why were the Dominican Republic results so different from the Costa Rican results?

-Response (DV): These differences were also surprising to the researchers. The main reason for price impact differential in the case of the Dominican Republic were a) the inclusion of future mitigation policies in the model (i.e. expansion of the social security system from 20% to 80% coverage by 2012), and b) the existence of already high prices at the consumer level in this country (i.e. most of the purchases are out of the pocket at the pharmacy level).

3) Comment by Raymond Saner: The main export for LDCs are usually agricultural and when they sign trade agreements, they are locked into an agreement in which they are bound to trading agricultural goods even if they are beyond that level of development and have the potential to export other goods and services. In this case, we must determine if the LDC should be able to renegotiate their trade agreement.

4) Comment: FTAs are drastically different depending on whom the agreement is between. It is up to each and every country to decide how to use or not use the flexibilities of the agreements, especially considering how vague most of the flexibilities are in FTAs.

-Response to comment above: the flexibility is very hard to implement, especially for the smaller, less developed country who is easily pressured by the richer country.

5) Comment by Raymond Saner: We must determine how far we should go in allowing countries to take back the commitments they have made. If a country has been persuaded by an institution such as the IMF or a powerful country into an agreement that does not benefit their country, should we allow them to take back their agreements? Why not talk about bringing back plurilateral agreements, such as the DOHA rounds?

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[i] See : Saner, Raymond, "Offensive and defensive interests of developing (DCs) and the least-developed countries (LDCs) in the health sector in relation with investments and technology transfers in the sector, 2009, CSEND.occasional papers.