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World Trade Organization

Topic B: The new regulations to the World Trade Organization access to medical issues
President: Daniela Mendoza Polanco
Moderator: Georgina Bernardo Meza
Official Assistant: María Olimpia Toríz Salvador

INTRODUCTION:

All countries rely to varying degrees on imported goods to provide for the health care needs of their populations. In most countries, especially in smaller developing countries with little or no local production capacity in medical technologies, such imported goods make a unique contribution to these countries' national health systems.

As the world becomes increasingly integrated, it becomes less and less possible for different policy areas to be handled independently of each other. Three international organizations, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), are working together to provide new types of medicines and improve the way they are distributed. By working in this way, each of them can help another organization to fulfill its tasks in a more effective way and thus avoid repeating the tasks established to achieve the Sustainable Development Goal number three: Good health and well-being.

International efforts to promote access to medicines have increased since the beginning of the century. To ensure policy coherence, the three Secretariats have responded by strengthening their trilateral cooperation to achieve a better understanding of the linkage between public health and intellectual property policies and to enhance a mutually supportive implementation of those policies. Trade policy thus affects the way in which markets for medical technologies are opened to competition from imported goods and services.

Tariffs or customs duties on imported goods, are a traditional trade policy instrument and are preferred under WTO rules to quantitative

restrictions, such as quotas, which are generally prohibited. Tariffs are relatively transparent and, unlike quotas, do not impose rigid restrictions on volumes of imports.

WTO members have agreed to certain maximum levels for their respective tariffs on all or most imported products, including pharmaceuticals. These maximum levels are called "tariff bindings" and vary according to each country and product.

Tariffs make imported goods, including medicines, more expensive for consumers. Nevertheless, many countries apply tariffs to bolster the competitive position of locally based companies in the domestic market in an attempt to preserve employment or promote the development of the industry (e.g. the local production capacities of the pharmaceutical sector), or to maintain a certain level of independence from international markets. For consumers, tariff protection can result in costly outcomes. Tariffs also raise revenue for governments, although in the case of medicines, the revenue amounts raised are generally not significant.

the World trade Organization reports that the steady decrease of tariff rates through successive rounds of negotiations over the past 60 years has led to a shift in focus to other types of trade measures. Some experts argue that these other trade measures are increasingly used in place of tariffs to protect domestic industries. Non- tariff measures (NTMs) include, among others: sanitary measures; technical regulations; pre-shipment inspections; import licensing; price control measures; charges and taxes; restrictions on distribution and after-sales services. Several WTO agreements are dedicated to these types of NTMs. A basic objective of such agreements is to establish rules for the use of these measures so that they do not become unnecessary trade barriers. While all of these measures can affect trade in pharmaceuticals, the following two have a direct link to public health outcomes.

In developed countries, the tariffs applied on medicines are very low, if not zero. A number of WTO members, mainly developed countries, concluded the Pharmaceutical Tariff Elimination Agreement in 1994. Under this agreement, they eliminated tariffs on all finished pharmaceutical products as well as on designated active ingredients and manufacturing inputs. Since 1994, the parties have periodically updated the agreement's coverage.

For this topic, as mentioned beforehand, there is no country left out

since it is based on the premise of international cooperation, specially that among developed and developing countries.

In the matter of looking for key players in this scenario, the biggest exporting countries of pharmaceutical products, like Germany, Switzerland, Belgium, France and the United States, in 2016 according to The Observatory of Economic Complexity (chart below); are the ones. Developed countries with big pharmaceutical industries are the ones that hold some part of the stakes, in the cooperation negotiations in order to strengthen public health worldwide, especially in developing countries.

The real issues that this problem carries for the international community are:

1. For public health policies, key challenges include: the regulation of medicines to ensure they are of a high quality, without obstructing innovation and access.

2. The intellectual property system's rules, the way rights such as patents or trademarks are obtained and managed.

3. International trade and its rules. The way they are applied can determine whether medicines are available, and what prices patients have to pay. Competition policy can promote innovation, and improve access to medicines. Respecting transparent and non-discriminatory procurement procedures can help governments get the best deal for sustainable and affordable access.

(WTO, n.d: https://www.wto.org/english/tratop_e/trips_e/trilat_5feb13_e.htm)

HISTORICAL BACKGROUND

When it comes to international trade in medicines, this specific market grew exponentially between the years 1980 and 1999, however this specific trade was mostly dominated by the imports and exports of the countries with more economic and industrial power, those with higher incomes.

This heavily industrialized countries are what represented the biggest

10 exporting countries accounted for 80% of world exports, and the biggest 10 importers accounted for over 60% of all imports in 1999. This concentration grew between 1980 and 1999, with low- and middle-income countries losing their combined share of both exports and imports. However, several individual low-income countries, including India, Pakistan and Indonesia, expanded their export share during this period. Low-income countries manufacturing medicines produce predominantly for the home market. Major exporters among low- and middle-income countries export to other low- and middle-income countries. However China's exports are mainly to industrialized countries. Imports by low- and middle-income countries come mainly from industrialized countries.

WHO recommends that medicines on a country's essential medicines list should not be subject to tariffs. However, in the 10 developing countries with the highest tariffs on imported medicines, the average tariff adds almost 23% to the price of active ingredients and over 12% to the price of finished medicaments.

When the Uruguay Round trade negotiations was finalized in 1994 there were some agreements included, among them was the Technical Barriers to Trade (TBT), which consisted in applying regulations and standards such as those of quality, etc., the Application of Sanitary and Phytosanitary Measures (SPS), which consisted in certain rules for the safety of the food that was imported or exported to ensure the health of those that consumed them; the General Agreement on Trade Services (GATS), set the standards of trade when it comes to services; and the Trade Related Aspects of Intellectual Property Rights (TRIPS), this one dealt with rules that countries had to follow when it came to intellectual property.

In 1994, Canada, the European Communities, Japan, Norway, Switzerland and the United States concluded the WTO Pharmaceutical Agreement. The "zero-for-zero initiative" cutting tariffs on pharmaceutical products and chemical intermediates used for their production. Also during the Uruguay Round, some WTO members reached an agreement called he "Chemical Harmonization" initiative in order to harmonize tariffs on chemical products, bringing them to zero. In 2006, in the context of the Doha Round negotiations on Non-Agricultural Market Access, some WTO members have put forward a proposal on "Open access to enhanced healthcare". In order to reduce or eliminate tariffs and nontariff barriers on a wide range of health-related products. The list of products to be covered includes chemical and pharmaceutical products. (WTO,WIPO, WHO, 2013)

To ensure the best of efforts when it comes to the fight for all countries, especially those that doesn't have such strong economies, to have a better and faster access to medicines and health services; There's been an union of the top three organizations in this specific subject to ensure a relevant improvement. The World Health Organization (WHO) is the directing authority of the UN in charge of international health issues, it helps to lead on crisis and also acts on its own agenda for research, setting standards, monitoring health trends, etc. The World Intellectual Property Organization (WIPO) is an UN specialized agency that works for the development of a more accessible Intellectual Property system and in that way to contribute to a growth in economy. The World Trade Organization (WTO) works to ensure fair trade.

The WTO had already worked with both of these organizations although separately in the Uruguay Round of negotiations in the period of 1987 to 1994, with the WIPO they developed the Trade Related Aspects of Intellectual Property Rights (TRIPS) and with the WHO they developed the Sanitary and Phytosanitary Measures (SPS). With this agencies and organization there's been a joint agreement so that they can share their information and make several activities to help their member countries such as joint studies, capacity building and technical cooperation, technical symposiums, etc., in this way the innovation and promotion of access to medical issues has an order and an structure that countries can use.

CURRENT RELEVANCE

The influence of WTO in medical issues is very important and can affect at a worldwide level, because the agreements allow the governments to pursue national health and other policies to restrict trade in order to protect health. A clear example of a situation where the WTO rules are used is when the authorities in a country decide to restrict the level of pesticides on fruit because of the risk that represents for health, this will affect trade because the imported fruit does not meet the sanitary requirements so it could be banned from the market. No matter where the problem originates, the regulations would apply in order to protect the costumer.

In regards to the medicine industry, the regulations are also very important due to volume of the market, as it is shown in an investigation made by the Observatory of Economic Complexity. Showing up next is a map, where it can be observed the exports on pharmaceutical products made by different countries in 2016 and the volume of each of them.

Quantity of exports made by different countries (Simoes, 2016)

The WTO does not only work with prevention of diseases, but also with the matters that concern patents. An example of this was presented on May 2010, between India and the European Union, when India requested consultations regarding the repeated seizures on patent infringement grounds of generic drugs originating in India but transiting through ports and airports in the Netherlands to third country destinations, including Brazil, who also requested a consultation alleging that the EU and Dutch measures against the situation were inconsistent. More countries joined the request until the European Union accepted the Dispute Settlement Body.

Another case respects to Cambodia, who was the first least-developed country (LDC) to conclude WTO accession negotiations (many LDCs were original WTO members on its formation in 1995). Its Working Party was established in 1994 and met from 2001 until 2003, and Cambodia acceded to the WTO in 2004. In its terms of accession, Cambodia made a commitment to implement the TRIPS Agreement no later than 1 January 2007 – although an extension had been agreed for LDC members in the Doha Declaration until 1 January 2016 for patents and test data protection with respect to pharmaceutical products, and a general extension was later agreed for LDC members until 1 July 2013.

Cambodia's commitment to implement the TRIPS Agreement beginning in 2007 was made on the understanding that during the transition period it would, among other things, grant exclusive rights to test data for five years and provide for patent linkage to marketing approvals (WTO document WT/ACC/KHM/21, paras. 204-206 and 224). Cambodia thus accepted demands from existing members that went beyond the express obligations set out in the TRIPS Agreement. By doing so, Cambodia in its accession agreement appeared to have given away a number of the flexibilities under the Agreement that it would otherwise have benefited from under current transition periods.

However, immediately prior to adoption of the decision on Cambodia's accession, the WTO Deputy Director-General, speaking on behalf of the Chairman of the Working Party on the Accession of Cambodia, clarified that: "The results achieved in the case of Cambodia speak for themselves, and in this context I should also add that the terms of this accession do not preclude access to the benefits under the Doha Declaration on the TRIPS Agreement and Public Health to Cambodia as a (least developed country)".

INTERNATIONAL ACTIONS

Health. Material from WHO and elsewhere is brought together with references so readers can delve deeper. The study tracks new trends in the global disease burden. It examines the importance of regulation for innovation and access to quality medical products, and the challenge of innovation to address neglected diseases. It includes a summary of the work of various agencies.

Intellectual property. The book explains intellectual property, what it means and how it is used for innovation in health technologies and for access to treatments. It looks at a number of current issues, including the role of information about patents in public health policy and how to obtain it, the impact of protecting test data and trade agreements on public health, trends in voluntary and compulsory licensing, and traditional medical knowledge. It covers WIPO's current work related to public health, and the contribution to tackling neglected diseases.

UN ACTIONS

Public health is a global challenge, and therefore international co-operation has a high priority. The World Health Organization (WHO) is the global authority for health. But a range of other issues are involved in achieving health objectives, requiring WHO to join forces with counterparts. Two of these are the World Intellectual Property Organization (WIPO) and World Trade Organization (WTO)

The World Trade Organization's negotiations launched in 2000 to further liberalise trade in services under the General Agreement on Trade in Services (GATS) could increase the organisation's influence on financing and delivery of health care. In contrast with other agreements, GATS gives countries considerable flexibility to decide which service sectors to open to foreign competition and to set limits on access to markets. About 60 members of the organisation have already made commitments related to market access in health services. Few of these represent any loosening of existing national policy. But that could change, as the intent of the current GATS negotiations is to "deepen and widen" sectoral commitments.

POINTS TO DISCUSS

Access and availability to medical resources

· How the activities of the three organizations (WTO, WHO, WIPO) can reinforce each other, in order to achieve objectives such as the right of health

· Sustainable financing

· How rules on services are related to access to medical technologies

· Business models in the pharmaceutical sector

· How can developed countries help developing countries in their medical issues?

· How is the economy of each country affected by this regulation?

· How is the easy access to medical technologies and innovation in each country?

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Other Useful Links

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