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TECHNICAL PAPER

GATT AGREEMENT—ITS IMPACT ON HEALTH
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EXECUTIVE SUMMARY

The World Trade Organization (WTO) was established on 1 January 1995 following the conclusion of the Uruguay Round of Multilateral Trade Negotiations in April 1994.

The fundamental principles of the multilateral trading system are:

- trade without discrimination
- predictable and growing access to markets
- promoting fair competition
- encouraging development and economic reform.

It is recognized that all the WTO agreements will have an impact on overall socioeconomic conditions at country level. The following agreements may have a direct or indirect impact on the health sector:

- Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
- Agreement on Technical Barriers to Trade
- General Agreement on Trade in Services
- Uruguay Round Protocol GATT 1994
- Agreement on Agriculture
- Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least-Developed and Net Food-Importing Developing Countries
- Agreement on Trade Related Aspects of Investment Measures
- Agreement on Implementation of Article VI (Anti-Dumping)
- Agreement on Rules of Origin
- Agreement on Safeguards.

The World Health Organization's Regional Office for the Eastern Mediterranean has alerted Member States to the possible impact of WTO agreements on the health sector. The Regional Office has participated in several national meetings discussing the impact of TRIPS on the local drug industry. One of the main recommendations of these meetings was the need to establish a joint expert group representing economists, lawyers and technical experts as well as policy-makers to discuss WTO agreements and develop national and regional plans for the coming years, to best prepare the health sector for the full implementation of WTO agreements. Of special importance is how we can strengthen national and regional contributions to technology development and benefit from TRIPS and other WTO agreements.

The impact of the WTO agreements was also discussed during the Twenty-first Meeting of the Eastern Mediterranean Regional Consultative Committee (RCC), held in the Syrian Arab Republic in May 1997. In addition, the Regional Office for the Eastern Mediterranean organized a consultation in September 1997 on the WTO agreements and their impact on health, in particular, the pharmaceutical sector.

It is clear that the implementation of various WTO agreements will have an impact on the health sector. The agreements strongly promote protection of intellectual property rights, free global trade and services, and harmonization of international standards. The agreements refer...
to encouraging development and economic reform. They also take into consideration protection of health and the environment. It seems that the interests of developing countries, in particular their social sectors including health services, were not taken into consideration during the negotiation phase.

It is also clear that more comprehensive studies are needed to investigate the impact of various aspects related to WTO agreements on the health sector. These studies must address the following:

• cost of health services, in particular, cost of drugs and other health technologies
• drug import/export and national drug policy
• transfer of health technology and health services providers
• the role of the government, in particular in health legislation
• standard-setting, both at national and international levels
• patency right of technological development in developing countries.

WHO should, therefore, take necessary steps to study the possible effects of the WTO Agreements on the health sector at both national and international levels. The role of WHO in setting international standards should be emphasized.

It is, therefore, important for WHO to take necessary steps to develop an official agreement with WTO to emphasize coordination and collaboration between them and ensure that WHO is the international standard-setting body in all aspects related to health.
1. INTRODUCTION

The World Trade Organization (WTO) was established on 1 January 1995 following the conclusion of the Uruguay Round of Multilateral Trade Negotiations in April 1994. The new Organization replaces the old administrative structure of the General Agreement on Tariffs and Trade (GATT) which organized international trade under a set of principles contained in the agreement originally adopted in 1947.

The fundamental principles of the multilateral trading system are:

- trade without discrimination
- predictable and growing access to markets
- promoting fair competition
- encouraging development and economic reform.

The Final Act comprises the Agreement Establishing the WTO, which constitutes an umbrella for all other agreements, understandings, ministerial decisions and so forth contained in the Act; there are thirteen multilateral agreements governing the conduct of international trade in goods, including GATT 1994 (the amended and updated version of GATT 1947), and a series of understandings on the interpretation of certain GATT articles, together with a multilateral agreement on trade in services, and another on trade-related aspects of intellectual property rights. The “package” also includes a number of ministerial decisions and declarations.

Following the conclusion of the Uruguay Round and the establishment of WTO, conflicting reactions to the various agreements establishing WTO were reported in various parts of the world. Of special concern was the impact of these agreements on the health and nutrition sectors, including impact on local drug industries and cost of essential health services, and availability of essential requirements for good nutrition. Of the 132 members who had accepted the WTO agreements as of 22 October 1997, 10 are from the Eastern Mediterranean Region (EMR). This is in addition to four EMR countries which have requested to join WTO.

2. AGREEMENTS HAVING DIRECT IMPLICATIONS FOR THE HEALTH SECTOR

While it is recognized that all the WTO agreements will have an impact on the overall socioeconomic conditions in various countries, some of these agreements will have a direct impact on the health sector. The Regional Office for the Eastern Mediterranean convened a consultation on the WTO agreements and their impact on health, in particular, the pharmaceutical sector, in Alexandria, on 21 September 1997. The Consultation concluded that the following agreements may have a direct or indirect impact on the health sector.

2.1 Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS)

This Agreement has perhaps attracted the most attention in developing countries. Discussions and studies have been carried out to investigate the possible impact of TRIPS on the health sector, and in particular local drug industries.
It is important, therefore, to review this Agreement carefully. Professor William Hennessey, Professor of Law, Franklin Pierce Law Centre, United States of America, summarized the various views raised during the negotiations that resulted in the final formulation of TRIPS. The remainder of this section is a paraphrase of his remarks that are relevant to the developing world.

At the beginning of the Uruguay Round, the mandate of the negotiating group on TRIPS was to discuss the "trade-related aspects of intellectual property rights in the context of promotion of growth and development", a formula which seemed to leave both the developed nations of the North and the developing nations of the South plenty of room for manoeuvre. From the beginning, the focus of the developed nations in the negotiations was upon strengthening standards of legal protection for intellectual property, virtually across the board. That was not the view of the most articulate voices in the developing countries. For them, the key issue was the latter part of the mandate, providing them with "access to technology", not "intellectual property rights".

The stance of Brazil and India, among others, on intellectual property rights may be stated as follows:

• rigid intellectual property protection impedes access to the latest technological innovations, and therefore restricts the participation of developing countries in international trade;
• "abusive use" of intellectual property rights distorts international trade;
• what is "trade-related" about intellectual property rights is the "restrictive and anticompetitive behaviour of the owners of intellectual property" and not the behaviour of commercial interests in developing countries or that of their governments;
• patent systems can have adverse effects in critical sectors, such as food production, poverty alleviation, health care and disease prevention, and have a dampening effect on the promotion of research and development in developing countries and in improving their technological capabilities;
• systems for the protection of intellectual property rights are by nature "monopolistic", and sovereign nations should be free to tune their own systems of intellectual property protection to their own needs and conditions.

According to this view, a TRIPS agreement which was to be the "best of all possible worlds" for the developing nations would have been one in which barriers to market entry created by the "exclusive rights" granted to the owners of intellectual property would fall, the sacred principles of national sovereignty and freedom to adopt lower standards of intellectual property protection would be preserved, and the market to which entry would be afforded would now be a global one. That is not the way it worked out, however; and viewed from where the debate started, the negotiations ending in the TRIPS Agreement went very well for the developed countries of the North. The "minimum standards" for the protection of intellectual property eventually enacted into international law in the TRIPS Agreement are significantly higher than the norms of substantive protection in effect in many developing nations prior to its adoption. What, then, if anything, is there of advantage in TRIPS for a developing country attempting to "catch up" to the level of development of the rich nations of the North?
There are voices today in developing countries which are saying “we gained nothing from TRIPS, and we only signed it because we were forced to”.

From the perspective of multinationals, the TRIPS agreement is not perfect, but it is a vast improvement over the prior regime, or lack thereof. An adequate basis for protection of trademarks, including service marks, and of trade secrets is provided. Patents are to be available for both products and processes in virtually all fields of technology. Compulsory licensing of patented subject matter is sharply curtailed, and the minimum term of protection for patents is no less than 20 years from the filing date.

Obligations of the TRIPS Agreement

The TRIPS Agreement sets forth minimum standards to be met by all countries party to the GATT for the according of rights for the protection of intellectual property and for the enforcement of those rights. The underlying obligation for all countries is based on national treatment and most favoured nation treatment. The former requires countries to provide to nationals of other countries treatment no less favourable than that accorded its own nationals regarding the protection of intellectual property. The latter calls for equal treatment for the nationals of other countries.

The obligations define the protection that must be provided for copyright and related rights, trademarks, geographical indications, inventions (patents), layout-designs of integrated circuits, and undisclosed information (trade secrets). The obligations also define the nature of an enforcement regime for that protection. The obligations to protect inventions are again the areas that attracted most of the discussions in the pharmaceutical field.

TRIPS contains some significant benefits for inventors. TRIPS requires that product and process patents be available in all fields of technology. The only permissible exceptions to that broad obligation are a) diagnostic, therapeutic and surgical methods for treating humans or animals, and b) plants and animals, other than microorganisms, and essentially biological processes for producing plants or animals. Countries not providing patent protection for plant varieties must provide that protection through an effective sui generis system.

TRIPS specifies that patent owners must be given the right to prevent others from making, using, offering for sale, selling, or importing products covered by a product patent and from using a process claimed in a patent or using, offering for sale, selling, or importing at least the product obtained directly from use of the process. The right to assign or license rights under the patent is also assured. TRIPS members are permitted to maintain limited exceptions to patent rights so long as those exceptions do not unreasonably conflict with the normal exploitation of the patent by the patent owner, nor prejudice his legitimate interests.

Of particular importance to patent owners are the restrictions that the TRIPS Agreement places on compulsory licensing. First, countries will no longer be allowed to grant compulsory licenses if a patentee does not manufacture the patented invention in the country. Importation will have to be treated as “working”, so only in circumstances in which a patentee makes no provision for marketing his product in a country would a compulsory license for “non-working” be consistent with TRIPS. TRIPS also imposes conditions on all compulsory licensing to ensure that voluntary licensing is encouraged, that payment for any compulsory
license is fair, that rights under a license are non-exclusive and can be transferred only under limited conditions, and that decisions regarding compulsory licenses are appealable. There are special provisions dealing with government use of patent rights and for use in national emergencies. Finally, dependent patent compulsory licenses may still be granted, but only if 1) the second invention represents an important technical advance over the first patent, and 2) the owner of the first patent receives a cross-license under the second patent. In addition, a dependent patent compulsory license is assignable only with the assignment of the second patent.

**Views**

The debate on TRIPS globally and in some Eastern Mediterranean Region countries is characterized by controversy. On one side are the views of multinationals and multinational subsidiaries in developing countries and on the other side are the views of public and private national drug industries. The interest of the public has also been expressed.

**Multinational views** are summarized in a document published by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and promoted by many representatives of multinationals in the Region. The views may be summarized as follows:

a) Rigid intellectual property rights will promote foreign investment and technology transfer.

b) Rigid intellectual property rights will encourage national industries to invest in research and development and make use of national resources, in particular national intellect and innovations for national drug industry development.

c) Strong intellectual property rights will be reflected in better quality locally produced drugs and thus greater confidence in them.

d) It is not expected that the implementation of TRIPS will have a serious impact on drug prices since most of drugs that are available in developing countries are generic and not protected by patent rights.

This view suggests that countries such as Egypt should implement TRIPS immediately and should not wait until the end of the transition period.

**The views of the public and private national drug industry** may be summarized as follows.

a) The claim that TRIPS implementation will attract foreign investment is not always true. Representatives of this sector argue that stronger global protection of intellectual property is beneficial to the developed countries of the North whose economic interests are affected by economic activity in the South. If stronger intellectual property protection is intrinsically good for developing nations themselves, it is surely only one among many factors: cost conditions, market size, human capital (both in terms of cultural cohesiveness and education), political stability and macroeconomic conditions all affect decisions to invest in a developing nation.

According to the International Monetary Fund, 40% of direct foreign investment in 1993 (US$ 70 billion out of US$ 175 billion) flowed into developing countries; and the ratio of
such investment is growing. Much of the investment into markets with “inadequate” intellectual property protection such as those of Mexico (over US$ 20 billion in 1993), south-east Asia (US$ 20 billion in 1993) and China (US$ 27 billion in 1993), are primarily due to factors other than “stronger intellectual property protection”.

A 1994 World Bank survey of business executives in the United States makes the point that, at least with regard to advanced technologies which are easily replicated, such as those in the chemical and pharmaceutical industries, those business executives polled subjectively believed that weak intellectual property protection was an “important factor” in investment decisions—particularly with regard to the transfer of advanced technologies or for establishment of research and development facilities. Coming to a different conclusion, a 1993 United Nations study of the same issue asserted, with no empirical basis, that United States companies invested in research and development only in developing countries which also invested in research and development—particularly in countries of south-east Asia—with little regard to the present state of their intellectual property protection. Strong intellectual property standards and enforcement are only a single factor among many in the decision of a firm to invest in a particular developing country.

b) It is expected that implementation of TRIPS will be accompanied by a large increase in prices. The extension of patent protection to cover both processes and products for 20 years will be accompanied by price increase and production of more costly products.

c) TRIPS has made it more difficult for developing countries to make use of compulsory licensing. This will be accompanied by high cost burdens on their health systems, which will result in denying developing countries access to the benefit of new developments in the field of health. Reports indicate that elimination of Canada’s system of compulsory licensing could cost the health sector in Canada between US$ 4 billion and US$ 7 billion over the next 15–20 years.

d) The increase in cost of locally produced drugs will make it more difficult for local drug industries to compete in the world drug market.

The views of those representing the public interest have not been thoroughly taken into consideration. These views can be summarized as follows.

a) Multinationals exaggerate the cost of research and development for two main purposes:
   - to make it difficult for industry in the developing world to consider investing in this field.
   - to justify their requests for very high prices. Multinationals claim that the cost of developing a new drug is about US$ 400 million. Data do not support this figure.

b) So-called new developments are not always real breakthroughs in drug development. Some studies indicate that only one-third of new drugs can be considered of significant advantage. It seems, therefore, reasonable to assume that patients are paying for industrial failures in research and development.

c) Patent claims need more careful analysis. Scientific achievements can only be considered as a result of the accumulation of knowledge and work of hundreds of scientists from various
parts of the world and could have their basis in the culture of ancient civilization. The claim of patency is usually the tip of the iceberg. The efforts of all those who actually contributed are not usually considered. If we add to this the brain drain from developing countries to developed countries, this makes it difficult to accept such a rigid patency right.

d) Rigid intellectual property rights and abuse of such rights by multinationals will deny developing countries and poor patients access to urgently needed scientific advances.

e) The nature of the health sector necessitates a humanitarian approach with the understanding that diseases, in particular communicable diseases, and health problems do not recognize borders and sectoral divisions.

f) Rigid intellectual property rights and lack of ethical promotional practices will place a huge burden on poor patients and health care systems in developing countries, contributing to existing socioeconomic problems.

This view emphasizes the importance of transparency in the field of patency rights, in particular the real cost. It would have been in the public interest also if TRIPS had addressed compulsory licensing of drugs in a completely different way, taking into consideration the special characteristics of the health sector.

There is a need to elaborate on the dimensions and practical implementation of principles referred to in article 8 of the TRIPS agreement, which states:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The ongoing discussion has, therefore, been concluded in some debates in the need for the establishment of national/regional committees including representatives from various sectors, such as multinationals, public/private drug industries, professional associations, non-governmental organizations, consumer associations, health economists, legal experts, politicians and public health leaders to develop appropriate national and regional plans to deal with TRIPS and its implementation.

2.2 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

This Agreement concerns the application of sanitary and phytosanitary measures, i.e. food safety and animal and plant health regulations. The Agreement recognizes that governments have the right to take sanitary and phytosanitary measures but that they should be applied only to the extent necessary to protect human, animal or plant life or health and should not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail.
In order to harmonize sanitary and phytosanitary measures on as wide a basis as possible, members are encouraged to base their measures on international standards, guidelines and recommendations where they exist. However, members may maintain or introduce measures which result in higher standards if there is scientific justification, or as a consequence of consistent risk decisions based on an appropriate risk assessment. The Agreement spells out procedures and criteria for the assessment of risk and the determination of appropriate levels of sanitary or phytosanitary protection.

It is expected that members will accept the sanitary and phytosanitary measures of others as equivalent if the exporting country demonstrates to the importing country that its measures achieve the importing country’s appropriate level of health protection. The agreement includes provisions on control, inspection and approval procedures.

The Committee on Sanitary and Phytosanitary Measures, established under the SPS, is developing a procedure to monitor members' use of international sanitary and phytosanitary standards and has been considering some proposals in this regard. The Committee has also begun work on the development of guidelines to facilitate governments' implementation of obligations related to decisions taken on what constitutes an appropriate level of health protection.

Article 3 of this Agreement addresses an important issue of harmonization. Paragraph 1 in this article states that “To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3 of Article 2”. This states: “Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade”.

Reference to international standards is also made in other paragraphs of these articles. Reference is made to international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the Office international des épidémies, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

Paragraph 2 of Article 3 states that “Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and GATT 1994”.

All these statements clearly show the importance of setting international standards as part of this Agreement. This issue will be discussed in detail in section 4.
2.3 Agreement on Technical Barriers to Trade

This Agreement is intended to extend and clarify the Agreement on Technical Barriers to Trade reached in the Tokyo Round. It seeks to ensure that technical regulations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. However, it recognizes that countries have the right to establish protection, at levels they consider appropriate, for example for human, animal or plant life or health or the environment, and should not be prevented from taking measures necessary to ensure that those levels of protection are met. The Agreement therefore, encourages countries to use international standards where these are appropriate, but it does not require them to change their levels of protection as a result of standardization.

Innovative features of the revised Agreement are that it covers processing and production methods related to the characteristics of the product itself. The coverage of conformity assessment procedures is enlarged and the disciplines made more precise. Notification provisions applying to local government and nongovernmental bodies are elaborated in more detail than in the Tokyo Round agreement. A Code of Good Practice for the Preparation, Adoption and Application of Standards by standard-setting bodies, which is open to acceptance by private bodies as well as the public sector, is included as an annex to the agreement.

Article 2.6 of the Agreement on Technical Barriers to Trade, states: “With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations”.

This article refers to appropriate international standard-setting bodies. It is, therefore, important to take the initiative, so that WHO is recognized as the international standard-setting body in issues related to health.

2.4 General Agreement on Trade in Services

The Services Agreement which forms part of the Final Act rests on three pillars. The first is a Framework Agreement containing basic obligations which apply to all member countries. The second concerns national schedules of commitments containing specific further national commitments, which will be the subject of a continuing process of liberalization. The third is a number of annexes addressing the special situations of individual services sectors.

Services are defined in the Agreement according to the way in which they are supplied:

- across a national border (telemedicine services, for example);
- through consumption abroad (for instance, a patient travelling to another country for treatment);
- through a commercial presence, i.e. establishment of a foreign enterprise in a country (such as a health maintenance organization);
• through the presence of people who are service suppliers (foreign health professionals, for example).

With regard to the movement of people supplying services under the Agreement, an annex stipulates that provisions apply only to those who are service suppliers or employed by a service supplier in accordance with the terms of a specific commitment. They do not apply to people seeking access to a foreign labour market.

Of particular interest to the health sector is the provision in the Agreement which excludes services supplied in “the exercise of governmental authority”, understood as provided neither on a commercial basis nor in competition with other service suppliers.

The extent to which governments might wish to open their health sector to foreign service suppliers is a policy choice. They might be reluctant to take this step without prior experience either of national private provision of health services or, and perhaps more important, of managing contracts for those services. Where the private sector is already involved, the question would be whether to take this option a step further and permit foreign private sector involvement, a decision likely to be taken in the context of a country’s development strategy as a whole.

To face this potentially radical change, ministries of health in developing countries need strong analytical and managerial capability. The effect of the new Agreement on the health sector is limited at present, although a trend towards foreign private sector participation in national health services might develop in the future. For WHO, the foremost objective is to ensure that change makes health systems more equitable and accessible to all the population.

The sections of the agreement dealing with the “Movement of Natural Persons” are a good indication of just how difficult it is to write rules for services trades and to negotiate their liberalization. The issue is one of four services topics whose negotiations remained uncompleted after the Uruguay Round. (The other three were market access negotiations in financial services, basic telecommunications and maritime transportation.) The purpose of the negotiations that resumed in May 1994, one month after the Uruguay Round agreements were signed in Marrakesh, was to improve upon those initial commitments. The negotiations ended in July 1995. The package of new commitments was attached to the Third Protocol of the General Agreement on Trade in Services. The protocol, which took effect in 1996, represented a modest improvement over the Uruguay Round package.

2.5 Uruguay Round Protocol—GATT 1994

Participants in this protocol have made commitments to eliminate or reduce tariff rates and non-tariff measures applicable to trade in goods that are recorded in national schedules of concessions annexed to the Uruguay Round Protocol that forms an integral part of the Final Act.

The Protocol has five appendices: Appendix I Section A: Agricultural Products—Tariff concessions on a Most-Favoured Nation Basis; Appendix I Section B: Agricultural Products—Tariff Quotas; Appendix II: Tariff Concessions on a Most-Favoured Nation Basis on Other Products, Appendix III: Preferential Tariff—Part II of Schedules (if applicable); Appendix IV:

A related Decision on Measures in Favour of Least-Developed Countries establishes, among other things, that these countries will not be required to undertake any commitments and concessions which are inconsistent with their individual development, financial and trade needs.

2.6 Agreement on Agriculture

The negotiations resulted in four main portions of the Agreement; the Agreement on Agriculture itself; the concessions and commitments members are to undertake on market access, domestic support and export subsidies; the Agreement on Sanitary and Phytosanitary Measures; and the Ministerial Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least Developed and Net Food-Importing Developing Countries.

In the area of market access, non-tariff border measures are replaced by tariffs that provide substantially the same level of protection. Tariffs resulting from this “tarification” process, as well as other tariffs on agricultural products, are to be reduced by an average 36% in the case of developed countries and 24% in the case of developing countries, with minimum reductions for each tariff line being required. Reductions are to be undertaken over six years in the case of developed countries and over ten years in the case of developing countries. Least developed countries are not required to reduce their tariffs.

The package is conceived as part of a continuing process, with the long-term objective of securing substantial progressive reductions in support and protection. In this light, it calls for further negotiations in the fifth year of implementation which, along with an assessment of the first five years, would take into account non-trade concerns, special and differential treatment for developing countries, the objective to establish a fair and market-oriented agricultural trading system and other concerns and objectives.

2.7 Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least Developed and Net Food-Importing Developing Countries

It is recognized that during the reform programme the least developed and net food-importing developing countries may experience negative effects with respect to supplies of food imports on reasonable terms and conditions. Therefore, a special Decision sets out objectives with regard to the provision of food aid, the provision of basic foodstuffs in full grant form and aid for agricultural development. It also refers to the possibility of assistance from the International Monetary Fund and the World Bank with respect to the short-term financing of commercial food imports. The Committee of Agriculture, set up under the Agreement on Agriculture, monitors the follow-up to the Decision.
2.8 Agreement on Trade-Related Aspects of Investment Measures

The Agreement recognizes that certain investment measures restrict and distort trade. It provides that no contracting party shall apply any trade-related investment measure inconsistent with Articles III (national treatment) and XI (prohibition of quantitative restrictions) of the GATT. To this end, an illustrative list of trade-related investment measures agreed to be inconsistent with these articles is appended to the Agreement. The list includes measures which require particular levels of local procurement by an enterprise ("local content requirements") or which restrict the volume or value of imports such an enterprise can purchase or use to an amount related to the level of products it exports ("trade balancing requirements").

2.9 Agreement on Implementation of Article VI (Anti-Dumping)

Article VI of the GATT provides for the right of contracting parties to apply anti-dumping measures, i.e. measures against imports of a product at an export price below its "normal value" (usually the price of the product in the domestic market of the exporting country) if such dumped imports cause injury to a domestic industry in the territory of the importing contracting party. More detailed rules governing the application of such measures are currently provided in an Anti-Dumping Agreement concluded at the end of the Tokyo Round. Negotiations in the Uruguay Round have resulted in a revision of this Agreement.

In particular, the revised Agreement provides for greater clarity and more detailed rules in relation to the method of determining that a product is dumped, the criteria to be taken into account in a determination that dumped imports cause injury to a domestic industry, the procedures to be followed in initiating and conducting anti-dumping investigations, and the implementation and duration of anti-dumping measures. In addition, the new Agreement clarifies the role of dispute settlement panels in disputes relating to anti-dumping actions taken by domestic authorities.

The Agreement strengthens the requirement for the importing country to establish a clear causal relationship between dumped imports and injury to the domestic industry. Clear-cut procedures have been established on how anti-dumping cases are to be initiated and how such investigations are to be conducted. Conditions for ensuring that all interested parties are given an opportunity to present evidence are set out.

2.10 Agreement on Rules of Origin

The Agreement aims at long-term harmonization of rules of origin, other than rules of origin relating to the granting of tariff preferences, and to ensure that such rules do not themselves create unnecessary obstacles to trade.

The Agreement sets up a harmonization programme, to be initiated as soon as possible after the completion of the Uruguay Round and to be completed within three years of initiation.
Until the completion of the harmonization programme, contracting parties would be expected to ensure that their rules of origin are transparent; that they do not have restricting, distorting or disruptive effects on international trade; that they are administered in a consistent, uniform, impartial and reasonable manner, and that they are based on a positive standard (in other words, they should state what does confer origin rather than what does not).

2.11 Agreement on Safeguards

Article XIX of the General Agreement allows a GATT member to take a “safeguard” action to protect a specific domestic industry from an unforeseen increase of imports of any product which is causing, or which is likely to cause, serious injury to the industry.

The Agreement sets out requirements for safeguard investigation which include public notice for hearings and other appropriate means for interested parties to present evidence, including on whether a measure would be in the public interest. In the event of critical circumstances, a provisional safeguard measure may be imposed based upon a preliminary determination of serious injury. The duration of such a provisional measure would not exceed 200 days.

The Agreement sets out the criteria for “serious injury” and the factors which must be considered in determining the impact of imports. The safeguard measure should be applied only to the extent necessary to prevent or remedy serious injury and to facilitate adjustment.

3. WHO RESPONSE TO THE ESTABLISHMENT OF WTO

3.1 At headquarters level

It is a curious fact that WHO was not actually involved in the negotiations of the various agreements that led to the establishment of the WTO. The Regional Office for the Eastern Mediterranean was the first to raise the question of what would be the possible impact of these agreements on the health sector. These are questions to which WHO—in view of its responsibility to provide information and counsel to Member States in the field of health—started to provide answers as soon as the Final Act was signed.

The Director-General immediately advised ministries of health of the likely effects on food standards and food safety of the Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures. In June 1994, eminent persons forming WHO's Task Force on Health in Development examined in their first meeting some of the consequences of the new trade agreements on health in developing countries, identifying certain areas where effects may be adverse. The following month a number of WHO technical staff met for a brainstorming session on implications of the agreements for WHO's work. It concluded that the Organization, as an advocate for the health sector, could enter into partnerships with other international organizations to help ensure that health was taken into account when trade policies were framed, without prejudice, naturally, to WTO's role as the legal and institutional basis of the multilateral trading-system.
Based on these discussions the WHO Task Force on Health Economics published a document on WTO entitled *Health economics. WTO: what's in it for WHO?* The document addresses important aspects related to the possible impact of WTO agreements on health sectors. The Director-General has also established a task force, the WHO Coordinating Group for WHO/WTO Cooperation, to elaborate on the best approaches for cooperating with WTO. The terms of reference of this task force are as follows:

1. To identify issues in the Agreements and associated instruments annexed to the Agreement Establishing the World Trade Organization (the “WTO Agreements”) that are of relevance to health and health policies and programmes, including issues that could be subject to WHO/WTO cooperation;

2. To promote the analysis of the identified issues and the study of their implications for the health sector, the work of WHO or any cooperation between WHO and WTO, as well as the dissemination of relevant information to all Member States;

3. To develop WHO policy, position papers and contractual arrangements, as appropriate, in respect of relevant identified health issues and contribute, in WHO’s field of competence and expertise, to formulation of new trade agreements and to any future amendment of the WTO Agreements;

4. To facilitate coordination and exchange of information between Divisions/Units as well as between headquarters and Regions in respect of issues related to the WTO Agreements and any cooperation between WHO and WTO.

WTO staff were invited to the meeting of the headquarters task force to brief them on WTO activities and discuss ways of collaboration between the two organizations.

Recently WHO headquarters has published three documents related to the impact of certain WTO agreements, namely SPS and TRIPS, on the health sector. The first document, *Food safety and globalization of trade in food: a challenge to the public health sector*, was prepared by WHO headquarters in collaboration with the World Trade Organization to assist government decision-makers in developing policies to improve national food safety programmes while at the same time complying with the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization. The document emphasizes the importance of information exchange and international harmonization. The document also emphasizes the reference to technical assistance to be provided to developing countries by bilateral or international organizations to strengthen their national food control systems.

The second document, *Globalization and access to drugs: implications of the WTO/TRIPS agreement*, discusses the following:

- issues in the WTO agreements relating to access to essential drugs and pharmaceutical policies, and informing Member States about them;
- the implications of globalization for innovation, and for the development, production, marketing and pricing of drugs, so as to identify the possible effects of the TRIPS agreement and other trade agreements on access to essential drugs;
- the importance of informing Member States about the need to take steps to protect public health in parallel with the implementation of the new trade agreements.
This document, which provides some practical recommendations to ensure that the implementation of TRIPS will not adversely affect the access of developing countries to essential drugs at affordable prices, has been vigorously criticized by multinationals. This shows the importance of developing countries establishing a joint position founded on the demand for a balance between the rights and duties of the patent holders vis-à-vis the country. The declaration of the VIII Summit of the Heads of State and Government of the Group of Fifteen, Cairo, Egypt, 11–13 May 1998, called for a similar position. The Joint Communiqué emphasized that the future work of the WTO should be among the priorities of developing countries. It seeks to ensure that the interests of developing countries are fully taken into account in the agenda of future negotiations of WTO agreements. It is of great importance in this context for developing countries to identify their interests and develop a proactive role.

The third document, Health economics: technical briefing note, measuring trade liberalization against public health objectives: the case of health services, is intended to complement the commercial viewpoint of trade in health services with a qualitative public health dimension. It analyses systematically the four modes of trade identified in the General Agreement on Trade in Services from the standpoint of health systems in developing countries. In order to make a preliminary appraisal of the potential impact of this trade, three health policy objectives are taken as a yardstick: equity of access, quality of services and efficient use of resources.

3.2 At regional level

The Regional Office for the Eastern Mediterranean has raised awareness among Member States of the possible impact of WTO agreements on the health and health-related sectors. The issue was discussed in intercountry meetings and in the Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC III). The Regional Office has participated in several national meetings discussing the impact of TRIPS on local drug industries, and will also participate in a project funded by the European Union on the impact of TRIPS on the pharmaceutical sector in north African countries. One of the main recommendations of these meetings was the need to establish a joint expert group representing economists, lawyers and technical experts as well as policy makers to discuss WTO agreements and develop national and regional plans for the coming years, to best prepare the health sector for the full implementation of WTO agreements. Of special importance, is what the Regional Office can do to strengthen national and regional contributions to technology development and allow countries to benefit from TRIPS and other WTO agreements.

The impact of the WTO agreements was also discussed during the twenty-first meeting of the Eastern Mediterranean Regional Consultative Committee, held in Damascus, Syrian Arab Republic, from 28 to 29 May 1997. The committee made the following recommendations.

- WHO/EMRO should form a small multidisciplinary team to review the available documents and studies and to prepare a concise and clear fact paper on WTO and the health sector, the paper to be presented to a future Regional Committee meeting and later used to promote awareness about this topic among decision-makers.
- The regional expert group and national expert multidisciplinary teams should conduct further in-depth analysis and, if necessary, research studies to advise on the best
approaches to make use of the transition period and how WHO may contribute to future negotiations.

- Efforts should be made to establish at regional and national levels a regional code of ethics to deal with these issues.
- WHO headquarters should be requested to initiate negotiations with WTO to reaffirm WHO as the international body for standard-setting in the health field.

Accordingly, EMRO organized a consultation on 21 September 1997 on WTO agreements and their impact on health, in particular, the pharmaceutical sector. The present paper is based on the outcome of discussions held during this consultation.

4. INTERNATIONAL HEALTH STANDARDS

It is evident from analysis of the WTO agreements that international standard-setting is of crucial importance. The role of WHO in this respect is of utmost importance. It is important to emphasize that the first function of WHO, as indicated in Article 2 of the WHO Constitution is “to act as the directing and coordinating authority on international health work”.

This is elaborated upon under the same article in reference to specific areas:

- to establish and revise as necessary international nomenclatures of diseases, of causes of death and of public health practices;
- to standardize diagnostic procedures as necessary, and
- to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products.

These functions clearly demonstrate the normative role of WHO.

The recent WHO document Health economics. WTO: what’s in it for WHO? discusses “standard-setting: safeguarding health, facilitating trade”. It emphasizes that the area of standard-setting is of particular interest for WHO, which constitutionally has the function of developing, establishing and promoting international standards within its field of competence.

WHO is responsible for setting standards for pharmaceutical, biological and similar products, and for food. Such standards are designed to provide the basis for national legislation and are of particular value to countries that cannot afford to establish their own standard-setting agencies.

The document also reviews WHO activities in setting standards in the areas of drugs, biologicals and food: international pharmacopoeia, WHO good manufacturing practices guidelines, WHO Certification Scheme, international nonproprietary names for pharmaceutical substances, biological standardization, the Joint FAO/WHO Food Standards Programme, and Codex Alimentarius.

Work on international biological standardization was taken over by WHO from the Health Organization of the League of Nations in 1948, and the first Expert Committee on Biological Standardization met in 1951. WHO’s responsibility is to establish primary international standards against which others can be calibrated worldwide. WHO also produces guidelines
and requirements for the production and control of biological medicines. Its Expert Committee serves as the international focal point for discussing requirements, evaluating candidate preparations and establishing international standards for the activity and identity of biological products. As a result of its work, along with that of WHO's International Laboratories for Biological Standardization, both biological standards and reference reagents are now universally used.

These activities, however, do not cover other important sectors, such as medical equipment, new biotechnological products and diagnostics, drug delivery systems, and new health services, such as telemedicine and health maintenance organizations.

In the area of pharmaceuticals, the issue of harmonization is globally discussed in an international forum known as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which came about in 1990 as a result of tripartite consultations between the Secretariat of the European Community (now the European Union), the Ministry of Health and Welfare of Japan and the United States Food and Drugs Administration (USFDA). The subsequent discussions with the pharmaceutical industry resulted in a proposal to hold an international conference.

The objectives of the conference are:

- to provide a forum for dialogue between regulatory agencies in the European Union, USA and Japan, and the pharmaceutical industry on the real differences and obstacles in the requirements for registration of pharmaceutical products; and
- to identify areas of possible harmonization in drug registration requirements in order to rationalize the use of human, animal and material resources.

WHO is invited to attend the discussions of the International Conference on Harmonisation as an observer. This limiting of negotiations to developed countries with WHO participating as an observer only was the concern of the seventh International Conference of Drug Regulatory Authorities (ICDRA VII), held in the Netherlands in 1994. A more active role for developing countries and WHO should be considered.

WHO should, however, take into consideration the interests of developing countries in setting these international standards. WHO should not be influenced by the trend in multinational industry towards very high standards that cannot be met by local drug industry and national drug regulatory authorities.

Conclusion

From the discussion, it is clear that the implementation of various WTO agreements will have an impact on the health sector. The agreements strongly promote protection of intellectual property rights, free global trade and services, and harmonization of international standards. The agreements refer to encouraging development and economic reform. They also take into consideration protection of health and the environment. The interests of developing countries, in particular the social sector including health, do not appear to have been taken into consideration during the negotiation phase.
It is also clear that more comprehensive studies are needed to investigate the impact of various aspects of WTO agreements on the health sector, in particular the following:

- cost of health services, in particular, the cost of drugs and other health technologies,
- drug import/export and national drug policy,
- transfer of health technology and health services providers;
- the role of the government, in particular, health legislation;
- standard-setting, both at national and international level; and
- patency rights of technological development in developing countries.

WHO should, therefore, take necessary steps to study the possible impact of WTO agreements on the health sector at both national and international levels. WHO should develop the necessary expertise to be able to advise Member States on the best approach to dealing with the transitional phase of implementing WTO agreements. The role of WHO in setting international standards should be emphasized.

It is, therefore, important for WHO to take the necessary steps to develop an official agreement with WTO to emphasize coordination and collaboration between them and to ensure that WHO is the international standard-setting body in all aspects related to health. Such an agreement may be jointly developed with FAO in order to recognize WHO as the international standard-setting body in issues related to nutrition and food safety.
BIBLIOGRAPHY


