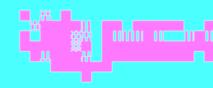
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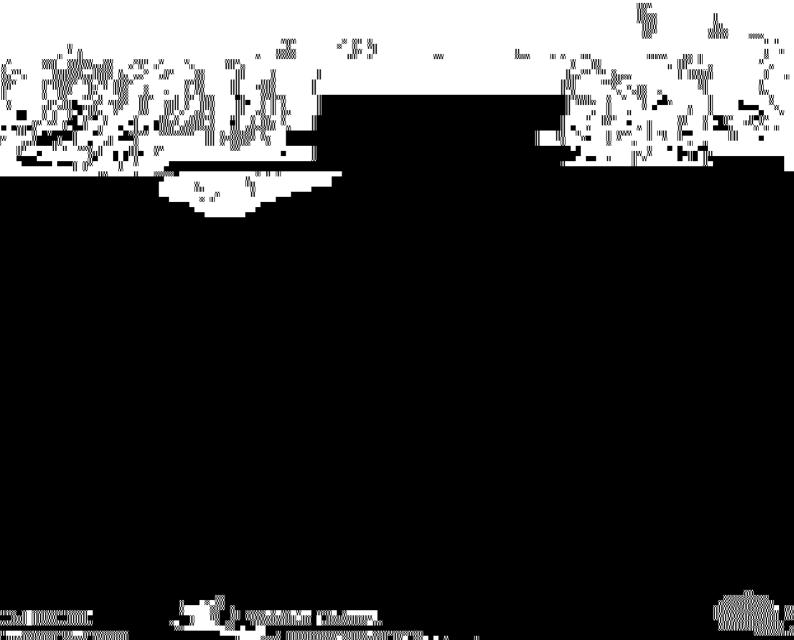
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FOREWORD

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FOREWORD BY GRO HARLEM BRUNDTLAND AND MIKE MOORE

As the world becomes increasingly integrated, it becomes less and less possible for different policy areas to be handled independently of each other. The linkage between trade and health has been the focus of much debate: real concerns should be dealt with and any misunderstandings should be clarified based on sound evidence and rigorous analysis.

We consider this joint study by the WHO and the WTO Secretariat a useful and timely initiative in this regard. It illustrates that there is much common ground between trade and health. Another important message is that health and trade policymakers can benefit from closer cooperation to ensure coherence between their different areas of responsibilities.

In both the WHO and the WTO questions of trade and public health feature high on the agenda, and significant advances have been made in the recent past. The endorsement by the international community of the Doha Declaration on the TRIPS Agreement and Public Health is a very visible expression of governments' commitment to ensuring that the rules-based trading system is compatible with public health interests.

The multilateral trading system has a lot to contribute to increase global welfare. In addition, the expertise and work of other organizations are needed to find effective solutions. In our common pursuit of sustainable human development, the WTO and the WHO are important partners. We are honoured to present this joint study on WTO Agreements and public health, the first of its kind. It is an encouraging testimony of our good and growing cooperation.



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ACKNOWLEDGEMENTS

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The principal coordinator for the WTO contribution was Deputy Director-General Miguel Rodríguez Mendoza with the assistance of Erik Wijkstrom and Alexander Keck. Inputs and comments were provided by Rolf Adlung, John Finn, David Hartridge, Marion Jansen, Pieter Jan Kuijper, Vivien Liu, João Magelhães, Hamid Mamdouh, Gabrielle Marceau, Doaa Abdel Motaal, Laoise Ni Bhriain, Adrian Otten, Gretchen Stanton, Thu-Lang Tran-Wasescha, Peter Ungphakorn, Jayashree Watal and Frank Wolter. With respect to the WTO, this study has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of WTO Members and to their rights and obligations under the WTO.

The opinions expressed in this report should be attributed to the authors and not to the institutions they represent.



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EXECUTIVE SUMMARY

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EXECUTIVE SUMMARY

1. This report deals with the relevant WTO Agreements and the way they may influence health and health policies. In undertaking this joint study, the WHO and WTO Secretariats seek to examine the linkages between trade and health policies, so as to enable both trade and health officials to better understand and monitor the effects of these linkages.

The WTO Agreements and public health

2. The first chapter of the report examines the main WTO Agreements related to health and health policies, namely the Agreements on Technical Barriers to Trade (TBT), Sanitary and Phytosanitary Measures (SPS), Trade-Related Intellectual Property Rights (TRIPS), and Trade in Services (GATS). It also refers to the fundamental WTO principles of non-discrimination and national treatment, which guide the actual implementation of the Agreements *inter alia* as they relate to health issues.

3. The basic WTO principle is non-discrimination: WTO Members cannot discriminate between their trading partners nor between imported and locally-produced goods that are otherwise similar. Since the inception of GATT more than 50 years ago, Article XX of GATT guarantees Members' right to take measures to restrict imports and export of products when those measures are necessary to protect the health of humans, animals and plants (Article XX(b)).

4. This and similar provisions in WTO Agreements recogni2men, 4t there are cases where Members may wish to subordinate trade-related considerations to other legitimate policy objectives and constraints, such as health. WTO jurisprudence, on several occasions, has confirmed t, 4t WTO Members have the right to determine the level of health protection they deem appropriate. Human health has been recogni2md by the WTO as being "important in the highest degree."

5. The above considerations inform the four WTO Agreements examined in this chapter. Both the TBT and SPS Agreements allow countries to restrain trade for legitimate reasons, including health, but they also requirmen, 4t such measures should not unnecessarily restrict trade. Of the two, the SPS Agreement deals with specific risks to health.



It contains specific rules for countries that want to restrict trade to ensure food safety and the protection of human life from plant- or animal-carried diseases (zoonoses).

6. While the aim of preventing unnecessary trade barriers is common to both the SPS and TBT Agreements, the rights and obligations they entail are somewhat different, for instance with regard to the assessment of health risks. The TBT Agreement has a broader scope of application, but only requires taking available scientific information into account, whereas in the SPS Agreement it is a fundamental requirement that Members have a scientific basis to justify trade measures aimed at mitigating a health risk. If available scientific evidence is not sufficient, the SPS Agreement permits the adoption of provisional measures.

7. The TRIPS Agreement also covers some areas that are relevant to health. The issue of patent protection for pharmaceutical products is particularly critical. This is an area where it is very important to find a proper balance between two complementary public health goals, that of providing incentives for future inventions of new drugs and that of





EXECUTIVE SUMMARY

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between WTO rules and the FCTC will depend on the direction taken by future negotiations on the FCTC, and the manner in which its rules are applied by governments.

Environment

17. The link between the environment, health and trade is a complex one. Removing trade barriers to modern "green" technologies and to suppliers of environmental goods and services can potentially benefit both the environment and health. For example, the removal of subsidies to polluting industries or to the energy and agricultural sectors could benefit both the environment and associated occupational health. Such efforts constitute a "win-win" situation for both trade and health advocates. However, trade in dangerous materials, such as hazardous wastes and unsafe chemicals, may also increase environmental and occupational health hazards, especially in developing countries, if appropriate handling or disposal cannot be guaranteed. Appropriate environmental policies remain essential. From the point of view of developing countries, where poverty is a major concern and an important obstacle to environmental protection, the opening up of world markets to their exports can be part of the solution. Trade liberalization for developing countries generate resources to protect the environment and work towards sustainable development.

18. Although the environment *per se* is not a WTO issue, several WTO Agreements and rules are relevant to environmental issues. There have been several environmental-related WTO disputes often centring on the issue of "like product". In making a determination of "likeness", WTO rules permit health risks to be taken into account. In a recent case on asbestos, the Appellate Body found the objective pursued, i.e. the preservation of human life and health, to be "both vital and important in the highest degree", and concluded that an import ban on asbestos was a "necessary" measure to protect human health.

19. Another important issue in this area is the relationship between WTO provisions and trade measures applied pursuant to multilateral environment agreements (MEAs). MEAs represent an important multilateral course of action to address specific environmental issues which may also be relevant to health, such as, for example, limiting the use of ozone-depleting substances. Although no disputes have thus far come to the WTO regarding the trade provisions contained in any MEA, there is scope for both controversy



and synergy. There are some 200 MEAs, of which at least 20 contain trade provisions. Some of them may violate the principle of non-discrimination, as they allow for trade with some countries but not with others in like products (a violation of the mostfavoured-nation principle), or for discrimination between like domestic and imported products (a violation of the national treatment principle). In the context of the Doha negotiations, countries will be looking more closely at the relationship between existing WTO rules and specific trade obligations set out in MEAs. Members will also be looking at, *inter alia*, procedures for regular information exchange between MEA Secretariats



possible while higher prices in rich countries continue to provide incentives for R&D. The TRIPS Agreement does not stand in the way of such arrangements.

23. Two cases relevant to the use of the flexibility in the TRIPS Agreement have arisen in the WTO so far. One was a dispute between Canada and the European Communities on the so-called "Bolar" exception allowing generic drug manufacturers to produce and/ or import and use quantities necessary of a patented product to conduct tests needed to obtain regulatory approval before the expiry of a patent.







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to give developing countries additional flexibilities to address their food security concerns, including flexibility to support their own production of essential food crops and for such assistance to be exempt from any reduction commitment. In general, increased market access is important for many, especially lower-income developing countries for which export agriculture remains the principal source of foreign exchange.

Emerging issues

34. There are two important technological advances that have the potential to revolutionize health care - biotechnology and information technology. A third emerging health issue is related, paradoxically, to the centuries-old use of herbal medicines and traditional knowledge for treating illnesses. The report examines the relationship between health and trade in these three cases.

35. Though the term covers a wide range of activities, *biotechnology* can be generally defined as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services" (OCDE, 1982). Biotechnology has already made enormous contributions to biomedical research and is beginning to translate into real-world applications in disease prevention and treatment. But as the scope of its application grows wider, from human and animals to genes and viruses to plants and trees, its impact on society and on economies is also widening. Biotechnology-related issues have been discussed in the WTO context. For example, the TRIPS Council has debated whether some biotechnological innovations are patentable, i.e. whether they meet the basic criteria of novelty, inventiveness and usefulness. There have also been some discussions in the TBT Committee regarding the GMO labelling requirements of various countries. And issues relating to food safety and to the potential spread of genetically modified seeds into the environment have been addressed by the SPS Committee in its discussions with respect to the Cartagena Biosafety Protocol. The SPS Committee has also discussed concerns raised with regard to some WTO Members' SPS notifications dealing with proposed GMO-related sanitary measures, as well as measures introduced without notification to the WTO.

36. *Information technology* is transforming societies and many economies, raising job productivity, creating new jobs, and speeding up communication and information flows, and the potential is still enormous. It has already stimulated changes in health care delivery, and has the potential to foster greater cross-border supply of health services.



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Doha Declaration on the TRIPS Agreements and Public Health and paragraph 6 of the Doha Ministerial Declaration made clear that WTO rules and health policies can go hand in hand, that public health considerations are important in implementing WTO rules, and that trade and health policies can be made mutually supportive. It was the intention of WHO and the WTO Secretariat in preparing this joint report to illustrate, for some key trade and health issues, that such coherence can be attained.



I. INTRODUCTION

1. Trade, the exchange of goods, services and information between individuals or groups, is as old as human history. Expanding trade is a central component of the increasing connectedness among countries.

2. Trade liberalization can affect health in multiple ways. Sometimes the impact is direct and the effect is obvious, as when a disease crosses a border together with a traded good. Other times the effects of trade liberalization are more indirect. For example, reducing tariffs may lead to lower prices for medical equipment and health-related products; changing international rules concerning patent protection may affect the prices of medicines and vaccines; importantly also, there is a positive link between freer trade and economic growth, which can lead to reduced poverty and higher standards of living, including better health.

3. The WHO defines health as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity". "Public health" refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life of the population as a whole. Good health for all populations is an accept-





THE WTO AGREEMENTS RELEVANT TO HEALTH

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II. THE WTO AGREEMENTS RELEVANT TO HEALTH



A. INTRODUCTION

(i) The institution

8. The World Trade Organization (WTO) is a relatively new international organization. However, it is responsible for a system that is over 50 years old. Established on 1 January 1995, the WTO replaced the General Agreement on Tariffs and Trade (GATT), which dated back to 1948. This was a consequence of a decision taken by governments after seven and a half years of negotiations (the "Uruguay Round"), which ended in 1994. With the WTO's creation, the rules were expanded to new areas. While the GATT dealt with trade in goods only, the WTO covers trade in services and intellectual property as well. There are also some areas, such as textiles, agriculture and sanitary and phytosanitary measures, where the WTO goes beyond the GATT by having established specific trade rules. Under the WTO, the procedure for settling trade disputes has also been strengthened.

9. The WTO is not a big institution. Like the WHO, it is based in Geneva but unlike the WHO it has no regional offices. It has a total staff of about 560 headed by a Director-General, and a limited budget.¹

(ii) Structure

10. The WTO's top decision-making body is the Ministerial Conference which meets at least once every two years (see Chart 1). The General Council, which is normally attended by ambassadors and other Geneva-based delegates, or capital-based officials (who may include health experts), meets several times a year in the Geneva headquarters. The General Council also meets as the Trade Policy Review Body and the Dispute Settlement Body (DSB). Delegates at the day-to-day meetings of the WTO are government representatives of all WTO Members and representatives of observer organizations. Both during negotiations and in the WTO committee work, decisions are made by consensus. Voting is possible but it has never been used in the WTO.



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(iii) Objective

11. The objective of the WTO is illustrated by the preamble to the Agreement Establishing the World Trade Organization (the WTO Agreement), signed in Marrakesh in April 1994:

"Recognizing that their relations in the field of trade and economic endeavour should be conducted with a view to <u>raising standards of living</u>, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of <u>sustainable</u> <u>development</u>, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development, ..." [emphasis added]

(iv) Basic function

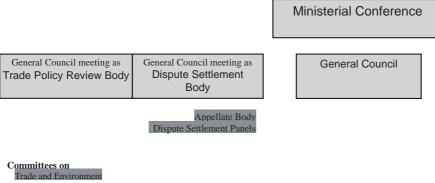
12. One of the key functions of the WTO is to serve as a forum for trade negotiations. The last round of multilateral trade negotiations was the Uruguay Round (1986-94). The WTO facilitates the implementation, administration and operation of the various covered agreements; however, the power of initiative in the context of the Organization rests not with the Secretariat but with Member governments whose representatives constitute and preside over the many councils and committees dealing with issues that arise in connection with the agreements.

13. The WTO is not a funding organization; it has no mandate to finance development projects. Nevertheless, the WTO does provide technical assistance to developing countries. The aim of this assistance is both to assist Members in the implementation of WTO agreements and to train officials so that they understand the system and its agreements, know how to administer them, and negotiate more effectively. Technical assistance is also extended to acceding countries. The training is often rather "legal" and is aimed at providing an understanding of rights and obligations Members have under the various agreements



THE WTO AGREEMENTS RELEVANT TO HEALTH

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Committees on Trade and Environment Trade and Development Subcommittee on Least-Developed Countries Regional Trade Agreements Balance of Payments Restrictions Budget, Finance and





quality and safety regulations. The GATS has several Annexes elaborating on the Agreement's coverage of, and application to, issues such as movements of natural persons and specific features of financial services (e.g. prudential standards) and telecommunications (e.g. access to and use of public networks and services). Both the GATT and the GATS are complemented by detailed and lengthy schedules (or lists) of commitments made by individual countries. In the goods area, these relate to tariff levels and, for agricultural products, also to subsidies. In services, the commitments specify the degree of foreign access which is guaranteed to foreign services and service providers in specific sectors, together with any limitations on market access and national treatment. It should be stressed that these are minimum conditions; nothing prevents a government from according better treatment than that guaranteed in its schedule. While treated differently in the GATT and the GATS, as well as in the specific agreements and Annexes, the key principles of most-favoured-nation (MFN) and national treatment are a common feature.

(i) Most-favoured-nation (MFN): treating other WTO Members equally

18. Under the WTO agreements, countries cannot normally discriminate between their trading partners. In simple terms, a special benefit granted to one country (such as a lower customs tariffs for one of their products) has to be granted to all other WTO Members. This principle, known as most-favoured-nation (MFN) treatment, is enshrined in Article I of the GATT, which governs trade in goods. MFN treatment is also one of core obligations of the GATS (Article II) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Article 4). Together, those three Agreements cover the main areas of trade covered by the WTO. In general, MFN means that every time a country lowers (or introduces) a trade barrier or opens up a market, it has to do so for the same goods or services or service suppliers from all its fellow WTO Members - whether rich or poor, weak or strong.

(ii) National treatment: treating foreigners and locals equally

19. The principle of national treatment requires that imported and locally-produced goods be treated equally, in terms of competitive opportunities in the importeftusq-le







(ii) Principles

28. The Agreement lays out a number of principles. The first is non-discrimination. With respect to technical requirements, non-discrimination means that if a Member applies certain requirements to imported products, it has to apply the same requirements to like domestic products (national treatment). If it applies a requirement to imports from one source, it has to apply it to like imports from all other sources as well (most-favoured-nation treatment).

29. Members should also seek to avoid unnecessary obstacles to trade. In practice, this means that Members must design technical requirements in the way that is not more trade restrictive than necessary to fulfill a legitimate objective, making them proportional to the objectives which they are trying to fulfil. Members are also encouraged to base their measures on international standards. The use of international standards helps to avoid the creation of multiple types of technical requirements and conformity assessment procedures at the national level, which can obstruct trade.

(iii) Examples as applied to health



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technical regulations, it should use them. Nevertheless, Members are free to set standards at a level they consider appropriate, but have to be able to justify their decisions if requested by another Member to do so. The Agreement also calls upon Members to play an active role in the process of international standardisation, particularly for any product for which it is developing a national requirement.

(v) Review of the TBT Agreement

32. Article 15.4 of the TBT Agreement states that "Not later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each of three-year period thereafter, the Committee shall review the operation and implementation of this Agreement." The Agreement has been reviewed under this provision twice, and the Second Triennial Review was concluded on 13 November 2000. The review examined the operation of the Agreement with respect to notifications, obligations and procedures for information exchange, the use of international standards, guides and recommendations, conformity assessment procedures the provision of technical assistance, and more.

33. One of the most relevant outcomes of the review was the adoption of a "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations." The Decision calls upon international standardizing bodies to observe a certain number of principles in their work, which include: transparency, openness, impartiality and consensus, effectiveness and relevance, and coherence. It also calls upon them to take the development dimension into account in the elaboration of their standards, guides and recommendations. International standardizing bodies that fulfil these criteria will be considered "international" within the meaning of the TBT Agreement. ⁵

2. The SPS Agreement

- (i) Rationale for the SPS Agreement
- 34. The SPS Agreement is linked to the Uruguay Round negotiations on the Agreement



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health as an excuse to restrict trade. Such measures could negate many of the benefits from reducing tariffs and subsidies. This led to the negotiation of the Agreement on the application of such types of measures, known as sanitary and phytosanitary measures (or "SPS measures").⁶

(ii) SPS directly relevant to health

35. The SPS Agreement contains specific rules for countries which want to restrict trade to ensure food safety and the protection of human life from plant- or animal-carried diseases (zoonoses). Its objective is two-fold. It aims to (i) recognize the sover-eign right of Members to determine the level of health protection they deem appropriate; and (ii) ensure that a sanitary or phytosanitary requirement does not represent an unnecessary, arbitrary, scientifically unjustifiable, or disguised restriction on international trade. In order to achieve its objective, the SPS Agreement encourages Members to use international standards, guidelines and recommendations where they exist. Members may adopt SPS measures which result in higher levels of health protection - or measures aimed at health concerns for which international standards do not exist - provided that they are scientifically justified.

(iii) Difference in coverage compared to TBT Agreement

36. To assess whether the SPS or TBT Agreement is relevant to any given technical barrier to trade, the fundamental question to be posed is: what is the purpose of the measure. In other words, whether a any given measure is an SPS measure will depend on whether its objective fits in any of the four categories set out in Box 1 below.



37. If the measure does not fit the definition in the above box, it is likely to be a TBT measure. While there is no overlap in coverage between the two Agreements, sometimes the same government regulation contains both SPS and TBT measures.⁷ Examples of SPS measures include the following: (i) requiring animals and animal products to come from disease-free areas; (ii) inspection of products for microbiological contaminants; (iii) mandating a specific fumigation treatment for products; and (iv) setting



39. The SPS Agreement applies to a narrowly defined range of health protection measures, but places quite strict requirements on these measures: for example, they have to be based on a scientific justification. The TBT Agreement, on the other hand, applies to a wide range of technical requirements, and solely notes that available scientific information may be one of the relevant elements of consideration in assessing risks. Some of these technical requirements are introduced for health or safety purposes, but others are introduced to standardize products, ensure quality or avoid consumer deception. In these cases scientific information might be less relevant in assessing risks than, for example, processing technology and intended end-uses.

40. If a trade dispute arises, the question of which of the two agreements applies can make a difference. While several disputes on SPS measures have arisen, and three have



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more objective risk assessment, and review the SPS measure within a reasonable period of time. Provisional measures could be taken, for example, as an emergency response to a sudden outbreak of an animal disease suspected of being linked to imports.

(vii) Review

43. The SPS Agreement was reviewed in 1998. At the Doha Ministerial Conference in November 2001, Ministers instructed the SPS Committee to review the operation of the Agreement at least once every four years. Any further review will be undertaken "as the need arises" (Article 12.7).⁹ WTO Members working through the SPS Committee may submit proposals to amend the text of this Agreement in light of further experience gained in its implementation, although this has not happened to date. "Food safety" is one issue on the table in the context of the on-going negotiations under the Agreement on Agriculture. It is too early in the negotiations to say how, if at all, this may affect the SPS Agreement.

INTELLECTUAL PROPERTY AND TRADE (TRIPS)

D. INTELLECTUAL PROPERTY AND TRADE (TRIPS)

44. The TRIPS Agreement requires WTO Members to establish minimum standards for protecting and enforcing intellectual property rights. Its objectives are set out in Article 7:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

45. The principles of the TRIPS Agreement are set out in its Article 8:

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.

^{9.} The revision of the SPS Agreement is contained in document G/SPS 12, available at www.wto.org. The matter of further reviews is currently one of the issues under consideration in the Implementation Review Mechanism under the auspices of the General Council.



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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.

46. Thus, the TRIPS Agreement attempts to strike a balance between the longer term objective of providing incentives for future inventions and creations, and the shorter term objective of allowing people to use existing inventions and creations. The Agreement covers a wide range of subjects, from copyright, patents and trademarks to integrated circuit designs and trade secrets.¹⁰

47. The TRIPS Agreement provides some flexibility for governments to fine-tune the basic balance provided for in the Agreement in the light of national social, developmental and other public policy objectives (see section III). While its rules require that national legislation embody certain minimum standards of protection, they afford considerable discretion in how these are implemented in practice. In each area of intellectual property, it allows governments to provide for exceptions, exclusions and limitations to rights, such as in the case of national emergencies, public non-commercial use, or remedying anti-competitive practices. This can be done, for example, in the form of compulsory licensing, exhaustion regimes and other types of exceptions, provided certain conditions are fulfilled.

What is relevant to health in the TRIPS Agreement?

48. The areas of intellectual property covered by the TRIPS Agreement that are relevant to health include: patents; trademarks including service marks, which are relevant, for example, to combating counterfeit drugs; and undisclosed information, including trade secrets and test data (see box 2). In respect of each of these areas, the Agreement sets out the minimum standards of protection that must be adopted by each Member. Each of the main elements of protection is defined, namely the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The standards build on those in the main pre-existing WIPO Conventions, substantive provisions of which are incorporated into the Agreement by reference. While the focus here is on patents, this is only one part of the TRIPS Agreement. One of the purposes of the TRIPS Agreement is, for

^{10.} Intellectual property protection is also covered by international treaties developed under the auspices of the World Intellectual Property Organization (WIPO). WIPO administers 11 treaties that set out internationally agreed rights and common standards for IPR protection, that the States which sign them agree to apply within their own territories. See WIPO's website, listed in the Annex, for further information.



(i) Provisions for public health protection

49. Patent protection for pharmaceutical products is an area where the problem of finding a proper balance is particularly acute - namely, between the goal of providing



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50. The patent system provides for, on the one hand, exclusive rights granted to inventors of new drugs, and, on the other hand, the requirement that for a new drug to benefit from such rights (to be patentable), it must be new, involve an inventive step, be industrially applicable and be fully disclosed, and further that after a term of protection the invention will fall into the public domain and become free and useable by all.

51. In addition, the TRIPS Agreement contains several other provisions enabling governments to implement their intellectual property regimes in a manner which takes account of immediate and longer-term public health considerations. Article 8 explicitly recognizes the right of WTO Members to "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." Furthermore, the TRIPS Agreement provides for certain exemptions from patentability, the possibility to make limited exceptions to patent owners' exclusive rights, compulsory licensing, and parallel importation. These are discussed in greater detail below.

(ii) What are Member governments' obligations with respect to pharmaceutical patents under TRIPS?

52. International conventions before TRIPS did not usually specify the minimum standards for patents. Over 40 countries provided no product patent protection for pharmaceuticals prior to the launching of the negotiation of the TRIPS Agreement and some 20 WTO Members still did not do so by the time of the conclusion of the TRIPS negotiations. A few of these countries did not provide process protection in this area as well. The duration of patents was less than 20 years in many countries. TRIPS rules require WTO Members to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. Patent protection has to last at least 20 years from the date the patent application was filed.¹¹

^{11.} In the case of pharmaceutical products, which are subjected to lengthy procedures that verify safety and efficacy, the effective patent life remaining out of the 20 years once the product has received marketing approval is generally considerably shorter. For example, in the WTO dispute between the European Communities and Canada regarding Patent Protection of Pharmaceutical Products (WT/ DS114/ R, para. 7.3), it was accepted by the parties to this dispute that the effective patent life was typically in the region of 8 to 12 years. Most industrial-ized countries allow patent term extension for pharmaceuticals to compensate for such regulatory approval delays but this is not a requirement under TRIPS



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(b) diagnostic, therapeutic and surgical methods for treating humans or animals;(c) plant and animal inventions other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes.

(iii) A patent is not a permit to put a product on a market

58. Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions. It is not, however, a permit to put a product on the market. A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe or therapeutic for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

(iv) Research exception and "Bolar" provisions

59. Under the TRIPS Agreement, governments can make limited exceptions to patent rights provided certain conditions are met. These exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interest of third parties (Article 30). A range of exceptions may be covered by this provision. For example, many countries provide for a "research" or "experimental use" exception to allow researchers to use a patented invention for research, in order to understand the invention more fully. In addition, Article 30 permits countries to allow manufacturers of generic drugs to use the patented invention, without the patent owner's permission and before the patent protection expires, for the purpose of obtaining marketing approval from public health authorities. Generic producers are thus able to market their versions almost as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision, and has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling: in a report adopted on 7 April 2000, a WTO dispute settlement panel stated that Canadian law was consistent with the TRIPS Agreement in allowing manufacturers to do so.¹²



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(v) Compulsory licensing and government use

60. Compulsory licensing takes place when a government allows a third party to produce a patented product or use a patented process without the consent of the patent owner. Most developed and developing countries provide for compulsory licensing in their national legislation. The term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the practice falls under "other use without authorization of the right holder" (Article 31), of which compulsory licensing is only part, since "other use" also includes use by governments for their own purposes. In current public discussion, compulsory licenses are usually associated with pharmaceuticals but could apply to patents in any field.

61. The TRIPS Agreement does not limit the reasons for which governments may grant compulsory licences. However, compulsory licensing or government use of a patent without the authorization of the right holder can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder. Article 31 lists a number of provisions that should be respected in such cases. For example, the person or company applying for a licence must have first attempted unsuccessfully to obtain a voluntary licence from the right holder on reasonable commercial terms. However, for "national emergencies", "other circumstances of extreme urgency", "public noncommercial use" or remedying anti-competitive practices, there is no need to try for a voluntary licence. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder, taking into account the economic value of the authorization (Article 31(h)). Compulsory licensing must meet several other requirements listed in the same Article. In particular, it cannot take the form of an exclusive licence, and "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use" (Article 31(f)). This condition need not be applied where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive (Article 31(k)).

(vi) Parallel imports and "exhaustion" of rights

62. Parallel importation is importation of a patented or trademarked product from a country where it is marketed either by the right holder or with his consent. In the TRIPS Agreement, this matter is regulated by the concept of the "exhaustion" of intellectual property rights. The TRIPS Agreement simply says (Article 6) that none of its provisions, except those dealing with non-discrimination on the basis of nationality



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(national treatment and most-favoured-nation treatment), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute.

(vii) Developing countries' transition periods - Year 2000 for most

63. In general, developing countries and economies in transition from central planning did not have to implement most provisions of the TRIPS Agreement until 1 January 2000. Least-developed countries have at least until 1 January 2006, but this deadline may be extended. Developed countries had until 1 January 1996, one year after the TRIPS Agreement took effect, to apply it. Most new Members who joined after the WTO was created in 1995 have agreed to apply the TRIPS Agreement as soon as they joined. This question is determined by each new Member's terms of accession. The TRIPS Agreement specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries, and therefore provides the possibility for further extension of the transitional period. The recent Doha Declaration on the TRIPS Agreement and Public Health allows least-developed countries until 1 January 2016 to meet the TRIPS provisions on the protection of patents and undisclosed information with respect to pharmaceutical products, without prejudice to their right to seek other extensions of the transition periods (see below, section III, Box 18).

64. Some developing countries may delay patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005, under provisions stating that a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on 1 January 1995) has up to 10 years to introduce the protection. However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide such protection on 1 January 1995) have two obligations:

(a) They must allow inventors to file patent applications from 1 January 1995, even though the actual decision on whether or not to grant any patent need not be taken until the end of the transition period. (This is sometimes called the "mailbox" provision). This provision was established because the date of filing is significant, as it is used for assessing whether the application meets the criteria for patenting, including novelty ("newness" criterion).



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(b) Second, if the government allows the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it must - subject to certain conditions - provide the patent applicant an exclusive marketing right for the product for five years, or until a decision on a product patent is taken, whichever is shorter.

65. Fewer than 20 developing countries were affected by the provisions referred to in the previous paragraph, most having had product patent protection for pharmaceutical products all along or having introduced it prior to the entry into force of the TRIPS Agreement.¹³

SERVICES (GATS)

E. SERVICES (GATS)

66. In the past, most services were not considered to be tradable across borders. Much has occurred to alter the tradability of services, including health services. Advances in communications technology, including the development of e-commerce, as well as regulatory changes in many parts of the world have made it easier to deliver services across borders. In many countries, changes in government policy have left greater room for the private sector - domestic as well as foreign - to provide services. Partly as a result, services have become the fastest-growing segment of the world economy, providing more than 60 per cent of global output and employment.

67. Such changes led governments to include services in trade negotiations, resulting in the General Agreement on Trade in Services (GATS) at the end of the Uruguay Round. GATS takes a gradual approach to trade liberalization. So far, the liberalizing effects have remained limited as most WTO Members have made relatively few commitments that go beyond existing levels of access.

68. GATS recognizes the special nature of services compared to goods by defining four modes of service delivery. Box 4 describes each mode and gives health services examples.

^{13.} To the best knowledge of the WTO Secretariat, these countries were Angola, Argentina, Bangladesh, Brazil, Cuba, Egypt, Guatemala, India, Kuwait, Madagascar, Morocco, Pakistan, Paraguay, Qatar, Tunisia, Turkey, United Arab Emirates and Uruguay. A number of these countries, including Argentina, Brazil, Guatemala, Morocco, Paraguay, Turkey and Uruguay, are not using the full transition period available to them, having already introduced product patent protection for pharmaceuticals or indicated their intention to do so prior to 1 January 2005.



69. Technological or practical constraints may render some modes of trade unfeasible, for example, crolog0 Gborsome upply (M of 1)tradnursing services. Nevertheless, rapid improvementary in telecommun cotiral infraintucturestru crd with falling cosay have allowrd examthee upply radservicese uch ay red constlaimsctiocessing and red con recordsde unscriptira ra alog0 Gborsomeble, s.



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pharmaceutical firms have invested in service providers as part of broader disease management strategies.

72. Presence of natural persons (Mode 4), although accounting for only a limited share in total trade flows, is the most visible of the four modes of supply in health services. The movement of health professionals from less developed to more developed countries is the most prominent example of this mode of health service trade.

(i) GATS general obligations

73. Certain obligations apply across all service sectors, regardless of whether they have been included in a Member's Schedule of Commitments. These unconditional obligations, include most-favored nation treatment (MFN), certain transparency and notification obligations, and certain competition principles.

74. The MFN obligation in GATS requires Members to treat equally services and suppliers of services from all other WTO Members (GATS, Article II). If a Member permits trade in services in a sector, then all suppliers from other Members must be treated on equal terms, regardless of country of ownership or origin. By the same token, any trade restriction must be applied vis-à-vis all other Members. These provisions do not prevent Members from entering into Economic Integration Agreements or recognizing the standards and regulations of one or more trading partners, subject to certain conditions. Furthermore, signatories could have sought exemptions from the MFN obligation at the time the GATS came into effect in 1995, and some 400 such exemptions were listed. In principle, these exemptions should not last more than 10 years; they will be subject to negotiation in any subsequent rounds.

75. Any services supplied in the exercise of governmental authority are excluded from GATS. Article I:3 establishes two criteria defining such services: they must be "supplied neither on a commercial basis, nor in competition with one or more service suppliers". There are some services to which these criteria clearly apply, such as free medical treatment in public facilities. Since governmental services do not fall under the Agreement, these services are not covered by the negotiations, and commitments on market access and national treatment do not apply to them. This is a principle to which all Member Governments attach great importance and which none has sought to reopen. So far, Members have not expressed the need to adopt an authoritative inter-



pretation of the criteria in Article I:3(c). They could obviously do so whenever they deem it desirable or appropriate. Also, the issue could arise if a specific measure which had been challenged in dispute settlement proceedings were to be defended on the ground that it applied only to services supplied in the exercise of governmental authority. There is no requirement to notify such services.

76. Under Article XIV of GATS, Members are entitled to take any measure necessary to protect human, animal or plant life or health, regardless of their obligations under the Agreement. The same proviso applies as under Article XX of the GATT: application of a measure must not discriminate arbitrarily or unjustifiably between countries where like conditions prevail, it must not constitute a disguised restriction on trade in services. Like any other trade measure, action under Article XIV may be challenged by affected countries under the WTO dispute settlement mechanism if they feel that the relevant provisions have not been respected.

(ii) Country options for GATS commitments in health services

77. GATS allows WTO Members to choose which service sectors to open up to trade and foreign competition and which modes of service to liberalize. Since GATS, 40 per cent of WTO Members (over 50 countries) have made some type of commitment on health services, compared with 70 per cent on financial and/ or telecommunications services. Well over 100 Members have made commitments in financial services, which may have implications for health systems to the extent that health insurance has been included in that context.

78. Sectors in which WTO Members choose to make commitments are inscribed in



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market access in their Schedules. Members making market access commitments still retain substantial scope for national policy making. For example, a requirement that hospitals devote 25 per cent of beds to care for the uninsured, if applied to all suppliers, does not constitute a market access limitation: it would rather be a matter of domestic regulation. If it were applied only to foreign-owned hospitals, it would still be permitted under GATS provided it was scheduled as a national treatment limitation.

80. In GATS, an unqualified national treatment requires Members to treat all services and service suppliers of any other Member no less favourably than its own like services and service suppliers. However, GATS regards national treatment as a conditional (and negotiable) obligation which may be made subject to conditions or qualifications that Members inscribe in their schedules (GATS Article XVII). Together with the market-access commitments, these conditions or qualifications represent the minimum treatment of a foreign service or supplier to which the country binds itself; countries may offer better treatment in practice.

81. Market access and national treatment commitments must be specified for each mode of supply within each scheduled sector: There are three principal options (i) full commitments, that is commitments without limitations, (ii) limited (or partial) commitments, which are subject to some restrictions or qualifications and (iii) no commitments ("unbound"), where the Member remains free to introduce restrictions on trade in that mode at any time. Commitments must not necessarily be implemented at the end of the negotiations concerned, but can be postponed to a later date specified in the Member's schedule. Such "pre-commitments" provide time for the authorities concerned to undertake any domestic regulatory and institutional changes that may be necessary to ensure compliance.

82. Governments may make commitments for various reasons: to encourage suppliers to enter the market; improve the volume, range and quality of the services available; attract foreign direct investment (FDI) and the related flows of skills and expertise; promote efficiency, and/ or stimulate competition in a service sector. As noted elsewhere, the GATS commitments undertaken in the Uruguay Round have served mainly to maintain the status quo regarding market access and national treatment for foreign suppliers. It should be stressed that the absence of a commitment does not mean that trade is prohibited; trade may occur, depending on the regime in place, but foreign suppliers have no guarantee of market access or national treatment.¹⁴

83. Although a commitment is legally binding, it is not cast in stone. Governments may modify or withdraw it at any time three years after its entry into force. However, where the proposed



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withdrawal or modification affects another country, the country proposing the change may be asked by trading partners to offer equivalent commitments in compensation.

F. SOLVING DISPUTES

84. Formal dispute settlement at the WTO is a last-resort option. As stated in the conclusions of this report, it is preferable that countries should solve their differences among themselves, whether bilaterally, plurilaterally or multilaterally (see paragraph 307). Many differences between Members are unlikely ever to become an issue at the WTO, and even if they do, they will not necessarily trigger formal dispute settlement procedures. Some issues are settled at the committee level or defused in that context. Nevertheless, in the case where two or more Members of the WTO have a dispute over a health-related trade measure and are unable to come to a solution among themselves (or in other fora), they have the right to bring the dispute to the WTO.

85. The WTO Secretariat cannot challenge any Member. It has no right to prosecute. It is up to governments to decide whether or not to bring a dispute against another government to the WTO. And it is also entirely up to the complainant to argue its case. The dispute is only between governments, and only about alleged failures to comply with WTO agreements or commitments. So, for example, a government cannot complain about another government's health policy as such. It can only complain if it believes a particular measure breaks an agreement or commitment that the other government has made in the WTO. Companies, organizations or private individuals cannot complain directly to the WTO, but can do so through their governments.

86. Settling disputes is the responsibility of the Dispute Settlement Body (the "DSB"), which is the WTO General Council in another guise (See above, Chart 1). The DSB has sole authority to establish "panels" of experts to consider the case, and to adopt the panels' findings or the results of an appeal. It monitors the implementation of the rulings and recommendations of panels and the Appellate Body, and has the power to authorise retaliation when a country does not comply with a ruling.

How are disputes settled?

87. One of the most profound changes introduced by the transition from GATT to the WTO in 1995 was the agreement to implement a dispute settlement process that would be speedier and more "automatic", with fixed deadlines (see below, Chart 2). This





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and then, the final report, which is first submitted to the parties and then later circulated to all WTO Members. Subsequently, the final report is passed to the DSB, which can only reject the report by consensus. The report becomes the DSB's ruling or recommendation within 60 days and is posted on the WTO website.

91. Panel reports can be appealed. The Appellate Body can hear on appeal only points of law decided by panels. Generally, the Appellate Body is not allowed to review facts of the case, as determined by the panel, or examine any evidence. Each appeal is heard by three members of a quasi-permanent seven-member Appellate Body set up by the DSB. Members of the Appellate Body have four-year terms and may be reappointed once. They have to be individuals with recognized standing in the field of law and international trade, and not affiliated with any government. The Appellate Body can uphold, modify or reverse the panel's legal findings and conclusions, and proceedings should normally not last more than 90 days. When a case has been appealed, the DSB has to adopt the reports of the Appellate Body and of the panel (as amended, reversed or upheld) within 30 days from the circulation of the Appellate Body report; rejection is only possible by consensus.

92. The Dispute Settlement Understanding stresses that "prompt compliance with recommendations or rulings of the DSB is essential in order to ensure effective resolution of disputes to the benefit of all Members". If a country is found to be at fault with the rules, it is expected to promptly correct the measure at issue. Moreover, it must state its intention to do so at a DSB meeting held within 30 days of the report's adoption. If immediate compliance with the recommendation proves impractical, the country will be allowed a "reasonable period of time". If it fails to act within this period, it has to enter into negotiations with the complaining country (or countries) in order to determine temporary compensation - for instance, tariff reductions in areas of particular interest to the complaining side. There is no financial compensation. If no satisfactory compensation is agreed, the complaining side may ask the DSB for permission to impose limited trade sanctions ("suspend concessions or obligations") against the other side. If requested the DSB must grant this authorization. WTO Arbitration on the level of such sanctions can also be requested if the parties do not agree.

93. The DSB monitors how adopted rulings are implemented, and any outstanding case remains on its agenda until the issue is resolved. There have been a several disputes relevant to health, a number of which are described in the next Chapter.



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Consultations (Art. 4)

Panel established by Dispute Settlement Body (DSB) (Art. 6)

> Terms of reference (Art. 7) Composition (Art. 8)

Panel examination Normally 2 meetings with parties (Art. 12), 1 meeting with third parties (Art. 10)



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III. SPECIFIC HEALTH ISSUES AND WTO AGREEMENTS



A. INTRODUCTION

94. As noted in the preceding Chapter, several WTO agreements are relevant to health policy. Generally, the positive growth and income effects of more open and predictable trade regimes can provide the resources, as well as goods, services and information, for effective health systems.¹⁶ The WTO agreements explicitly allow governments, in pursuing national health and other policy objectives, to take measures to restrict trade in order to protect health. This is legitimate as a matter of principle. The emphasis in WTO rules is on *how* policies are pursued without questioning the underlying objective. For example, is a measure applied or enforced in a way that discriminates between trading partners or between imported products and products produced domestically? Are there ways of implementing policy that would be less restrictive on trade? Thus, it is the manner in which government pursue specific health policies in practice which might have trade-related implications, which are examined in this Chapter.

95. Putting WTO rules into practice can raise difficult questions for health policy makers. For example, what happens when, for a given hazard, there is uncertainty about the risk? This poses a challenge for regulatory action, and responses to uncertainty and risk are likely to be different in different countries. Among the factors to be considered may be the trade-restrictiveness and efficacy of the measure to achieve the level of health protection sought.

96. This Chapter does not provide definitive answers to these questions. In the end, these are matters for decision-makers in national governments. The discussion of how different countries have addressed such questions sheds light on how health and trade policies can promote synergies in some cases, and how they continue to give rise to tensions in others.

97. The Chapter is organized around eight important health issues facing national policy makers which relate to one or more of the WTO agreements. For each of the eight issues, the trade relevance is explained and applicable WTO agreements are discussed.

^{16.} For more information on inputs for effective health systems see WHO World Health Report, 2000.



99. The variety of transmission methods and the increase in volume of trade of all kinds means that to effectively control disease outbreaks in today's world, public health officials need to collect and disseminate information quickly. Likewise, trade officials who negotiate and implement trade agreements need to be aware of health risks. In most cases, sound public health practice will focus on the mode of transmission-for



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102. However, much will depend on how this health objective is enforced in practice at the border. WTO rules require, for example, that the measure used should be properly balanced between the importance of the health interests protected, the efficacy of the measure and the impact of the law on imports and exports - to the extent that this is feasible without compromising the intended health objective (see paragraph 23). If it is possible to enforce the health objective through checks or sampling rather than an outright ban, that would be preferable as it is the measure which would least interfere with trade while guaranteeing the level of health protection chosen by that Member. Since quarantines and trade embargoes are associated with substantial economic losses, these restrictions run the risk of being challenged unless they are unquestionably justified by the severity of the health risk. Likewise WTO rules on non-discrimination apply. If a country's sanitary measure addresses a risk in products coming from one country but ignores similar risks in products originating from another country, the measure might be challenged as discriminatory. Such discriminatory action could flag, or serve as a warning signal, that the objective behind the measure at issue may not solely be concerned with protecting health.

Box 6 Safety of imported fish during a cholera outbreak

In early 1998, Tanzania complained in a SPS Committee meeting that the European Communities (EC) was unfairly blocking imports of fish from certain African countries. In response, the EC told the WTO SPS Committee that it had indeed banned imports of fruit, vegetables and fish products in light of a cholera outbreak in Tanzania, Kenya, Uganda and Mozambique. EC inspection procedures in these countries had uncovered deficiencies, and the EC sought to put in effect proper hygiene requirements. EC Member States, meanwhile, were trying to develop a joint cholera policy based on risk assessment.

A WHO investigator had told the EC that she did not consider the ban on fish imports necessary, since fish products were not consumed in raw form in Europe. She cited the WHO Guidance on Formulation of National Policy on the Control of Cholera: "Although there is a theoretical risk of cholera transmission associated with some food commodities moving in international trade, this has rarely proved significant and authorities should seek means of dealing with it other than by applying an embargo on importation".



(iv) Revising the IHR to cope with new threats to health

103. Cholera is a long-standing, endemic disease with well-known control measures. But the modern era has witnessed the emergence of new global health security threats, for which control measures are still evolving. HIV/ AIDS was unknown until about 20 years ago and new pathogens have come to light, such as the Ebola and Marburg viruses. In addition, many "older" diseases (such as tuberculosis, malaria and sexually transmitted diseases) have become a greater threat because they have developed resistance to the drugs commonly used to treat them.¹⁸

104. These developments prompted WHO in 1995 to call for a revision of the IHR. It had become less useful as a tool to control the global spread of disease for several rea-



105. Revision of the IHR will focus on three areas. One involves expansion of the scope



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suffers from food-borne disease every year, and out of these maybe up to 20 per million die. Considering that these figures only relate to microbiological problems, the addition of chemical contamination of food makes the situation extremely serious. The epidemic nature of outbreaks of food-borne disease varies from localised and self-limiting outbreaks - which would not be relevant to international trade - to rapidly spreading epidemics that can quickly cross international borders via trade.¹⁹

(ii) ... and the link to trade

108. Several new sources of food-borne illness are of increasing relevance to international trade. In the past few years, chemical hazards in food-related products have been the source of several limited, but highly publicized health crises, for example the contamination of animal feed by dioxin in Belgium that affected food products throughout Europe. Changing patterns of farming and animal husbandry can also affect food safety, illustrated by the spread of mad cow disease (BSE) and its onward transmission to people which manifests as vCJD, a fatal neurological disease. The widespread use of antibiotics in animal husbandry has contributed to increased levels of antibiotic-resistant bacteria in humans. In addition, the safety for human consumption of certain genetically modified foods is a matter of concern to some.

109. All of these food safety concerns come into play in the context of international trade in foods, which has grown substantially over the past 10 years. Agriculture and food exports are essential to most developing countries as many have a comparative advantage in agricultural production. Furthermore, the trend towards the export of more and more processed foods is increasing the importance of sanitary and phytosanitary measures and the SPS Agreement.²⁰ Also, as was noted in Chapter II, as tariffs and other classical barriers to trade are likely to fall further in the context of further agricultural reform - including support to agricultural production in the richer countries - the relative importance of non-tariff measures is likely to increase.

^{19.} A big burden of food-borne disease also lies in the sporadic cases, which are not linked to outbreaks, and therefore typically are not recognized or reported.



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Box 7 SPS and Codex¹

The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Codex Alimentarius Commission (Codex) was established in 1962 to establish standards for food safety. The Commission currently has 165 member governments who, with the advice of independent technical experts selected by FAO and WHO, develop food standards, guidelines and recommendations for the protection of consumer health. Codex recognizes the importance of minimizing the effect of such regulations on food trade. Member states formally endorse Codex standards, after thorough reviews of scientific papers based on widely accepted risk assessment procedures. While it remains voluntary for governments to apply Codex standards, there are strong incentives to do so, as food production that meets Codex standards can facilitate trade by creating greater export opportunities.

Many new ideas are being integrated into Codex recommendations and standards. Codex now recommends using a risk-based preventive approach in achieving food safety, and promotes the use of formalized Risk analysis. An example of a approach is the implementation of the Hazard Analysis and Critical Control Point (HACCP) system. HACCP encourages the food industry and governments to target limited resources to the most critical steps of food production and distribution, rather than having to comply with a long list of product and procedure specifications as has been traditionally prescribed. HACCP often requires reorientation of food safety authorities towards audit and training functions, rather than on physical inspection and laboratory analysis. Although HACCP does not completely eliminate the necessity for final product inspection, the concept of process control is central to HACCP national food safety programmes.

Another important trend in Codex is its horizontal approach. Codex is in the process of elaborating general standards covering food additives, contaminants and toxins to provide a wider basis for protecting consumers' health. Countries can better adapt themselves to this approach by implementing a generic regulation applicable to a wide range of products rather than maintaining an inventory of registered foods with specifications for each.

^{1.} For further information about food safety and trade issues, see the WHO publication, Food Safety and Globalization of Trade in Food, 1998 (revised), visit WHO's website on Food Safety: http://www.who.int/fsf, or go directly to the Codex website: http://www.fao.org/es/esn/codex/



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(iii) The SPS Agreement is perhaps the closest "match" between a health issue (in this case food safety) and trade

110. Unlike some other "health issues" in this report, food safety has one WTO Agreement which is specifically relevant: the SPS Agreement (for an overview see pages 34-38). It applies to any trade-related measure taken to protect human life or health from risks arising from additives, contaminants, toxins, veterinary drug and pesticide residues, or other disease-causing organisms in foods or beverages. The SPS Agreement clearly gives governments the right to restrict trade to achieve health objectives, but the measures applied must be based on scientific evidence.

111. The SPS Agreement formally recognizes the food safety standards, guidelines and recommendations established by the FAO/ WHO Codex Alimentarius Commission (Codex for short). The recognition of Codex standards eliminates the need for each country individually to do its own risk assessment for any given hazard for which a standard, recommendation or guideline exists. If countries adopt national food safety standards that are not more stringent than the Codex standards, and have mechanisms for monitoring compliance among food producers and exporters with these standards, then their food safety measures are presumed to be consistent with SPS provisions. Recognizing that many global food safety issues lie beyond the reach of international trade agreements, WHO together with FAO and national governments are stepping up efforts to ensure that consumers across the globe are protected from threats to food safety from a wide range of sources.

(iv) How is the WTO "used" to address food safety concerns?

112. Since the WTO SPS Agreement came into force in 1995, more than 100 specific trade concerns have been raised in the SPS Committee, of which about 30 are directly relevant to food safety. The remaining trade concerns have dealt with animal and plant health issues which are equally relevant to the SPS Agreement. The food safety issues range from discussions on restrictions on imports of hard cheeses made from non-pasteurised milk to labelling requirements on shelled eggs, or shelf-life requirements for canned food products.

113. The number of specific trade concerns related to food safety is not limited to issues actually raised in the SPS Committee. Many concerns regarding food safety meas-



ures are solved bilaterally before they come to the WTO, or around the edges of the SPS Committee meetings without actually having been raised at the meeting itself.



(v) The use of "precaution" in food safety



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116. In the EC-Hormones case, the EC did not invoke Article 5.7 of the SPS Agreement. Rather, the EC attempted to justify its hormones ban by arguing that the "precautionary principle" was a general principle under international law. In other words, the EC invoked the "precautionary principle" in general terms as an overriding principle, while never claiming that the ban on imports of hormone-treated meat was in any way "provisional". The Appellate Body noted that the "precautionary principle", other than as reflected in Article 5.7, did not override the obligation to *base SPS measures on a risk assessment.*

117. The only directly relevant jurisprudence on Article 5.7 of the SPS Agreement is from the *Japan-Varietals* case.²¹ In this case, the Panel found that the testing requirement imposed by Japan on certain fruit products could not be considered as a provisional phytosanitary measure in an area where scientific information was insufficient, since Japan had not sought to obtain the information necessary for a more objective assessment of risk and reviewed the measure accordingly within a reasonable period of time. The AB upheld this finding, and commented on the notion of "reasonable period of time":

"In our view, what constitutes a "reasonable period of time" has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure."²²

118. Japan subsequently notified to the WTO that it had completed technical consultations regarding a new methodology on the products at issue in the dispute and currently subject to the import prohibition and expected shortly to notify the WTO of a "mutually satisfactory solution".²³

(vi) Challenges for the future

119. While the SPS Agreement and Codex standards have proven to be helpful in resolving several international controversies over the safety of traded foods, there remain significant challenges. Many developing countries have found that for their exports to meet international food safety and quality standards, they need to invest substantially in both physical and institutional infrastructure. Article 9 of the SPS

- 22. Japan Measures Affecting Agricultural Products, Report of the Appellate Body, WT/ DS76/ AB/ R, dated 22 February 1999, paragraph 93.
- 23. This information is contained in a "Status Report by Japan" notified to the DSB on 8 June 2001 (WT/ DS76/11/ Add.5).

^{21.} Japan - Measures Affecting Agricultural Products, Report of the Panel, WT/DS76/R, 27 October 1998 and Report of the Appellate Body, WT/DS76/AB/R, dated 22 February 1999.



Agreement requires developing countries be provided with technical assistance to do this, but there is still a big gap between what is needed and what is provided. In addition, many of the least-developed countries lack the data as well as the capacity and technical expertise to fully participate in Codex standard-setting processes as well as other fora relevant to food safety and or quality issues (WHO, ISO). The funding for developing countries' participation in Codex work is also a problem. Both the WHO and FAO, among other groups, are providing more technical assistance to alleviate this problem, and more Codex meetings take place in each region to make it easier for develop-



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term health effects of genetically-modified (GM) foods, such as: the potential for gene transfer from GM plants to microbial or mammalian cells; the transfer and expression of a functional antibiotic resistance gene to recipient cells in people or animals; and allergenic effects.

122. Reflecting growing concern about the safety and nutritional aspects of foods derived from biotechnology, the Codex Alimentarius Commission decided in July 1999 to undertake "the consideration of standards, guidelines or other recommendations for foods derived from biotechnology or traits introduced into foods by biotechnology." The same session also established an Intergovernmental Task Force on Foods Derived from Biotechnology, with a three-year mandate, to help formulate a global consensus on the safety and nutritional aspects of foods derived from biotechnology. At its March 2002 meeting, the Task Force reached agreement on a final draft of "Principles for the risk analysis of foods derived from biotechnology," which will provide the necessary framework for evaluating the safety and nutritional aspects of GM foods. The task force also adopted detailed requirements for assessing the safety of GM plants including tests for allergenicity. In April 2001, FAO and WHO published new recommendations to strengthen the process used to protect consumers from the risk that some GMOs could pose for a small percentage of people with food allergies.²⁵ Moreover, the July 2001 meeting of the Codex Alimentarius Commission adopted a draft amendment on the labelling of allergens in food or food ingredients obtained through biotechnology.26

123. Other challenges lie ahead, particularly the need to develop global standards for pre-market approval systems of genetically modified food to ensure that these new products are not only safe, but also beneficial for consumers. On the trade side, arguments are brewing over the feasibility of regulations that would place "traceability" and labelling requirements on bio-engineered foods, and their consistency with WTO trade rules.

^{25.} Evaluation of Allergenicity of Genetically Modified Foods, Report of a Joint FAQ/ WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, 22-25 January 2001.

^{26.} The adopted amendment is contained in Codex document: Alinorm 01/22 (Appendix 3), p 47. The report of the Codex Alimentarius Commission meeting of July 2001 where this adoption will be reflected, had not yet been posted on the Codex web site (http://www.codexalimentarius.net/) at the time of writing.



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D. TOBACCO CONTROL

(i) The threat

124. Since about 1950, more than 70,000 scientific studies have proven that smoking





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(iv) Tobacco dispute: an example of the application of trade rules

130. The health and tobacco trade debate dates back to the late 1980s. At that time, the US government began a series of actions to get Thailand and some other Asian countries to open their markets to US tobacco products. In each case, tobacco manufacture and sales were controlled by state monopolies. The US government succeeded in negotiating bilateral agreements that removed excise taxes and distribution practices that discriminated against US tobacco products - except in Thailand.

131. Thailand argued that its import restrictions were part of a comprehensive policy to control tobacco use. In response, the United States filed a complaint with the General Agreement on Trade and Tariffs (GATT), the predecessor to the WTO, against Thailand (Box 10). In brief, as a result of this case Thailand had to lift its import ban and reduce the excise duty on tobacco because these could not be justified on health grounds so long as the sale of domestic cigarettes was allowed. But Thailand was allowed to continue with its advertising ban since this applied to all products without discrimination. In line with the GATT ruling, the Thai government lifted the import ban in 1990 and legal exports of cigarettes commenced to Thailand in 1991. Thailand was, of course, still free to charge duty on imports. It was also free to set its excise duty at any level so long as it did not discriminate between local and imported products.

132. The opening of the domestic market to foreign producers initially led to an increase in cigarette consumption, but it also served to strengthen national tobacco control efforts. After the GATT ruling, support grew for national tobacco control measures and in 1992 the Thai parliament passed two important tobacco control acts designed to restrict tobacco sales. The measures included increased sales taxes, smoking bans in public buildings, disclosure of ingredients, and requirements for prominent health warnings on cigarette packages. As a result, smoking prevalence declined in the mid and late 1990s.

133. Most countries, however, face strong challenges to implementing effective, comprehensive tobacco control measures. There is often fierce political opposition from domestic producers, who may be fully or partly owned by the government. Meanwhile, foreign producers continue to seek market access. These challenges are further compounded by international tobacco smuggling.



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Box 10 WTO dispute: Thailand-Cigarette Case

Under the 1966 Tobacco Act, Thailand prohibited the importation of cigarettes and other tobacco preparations, but authorized the sale of domestic cigarettes. Cigarettes were also made subject to an excise tax, a business tax and a municipal tax. In 1989, The United States complained that the import restrictions were inconsistent with GATT Article XI (on the "General Elimination of Quantitative Restrictions"), and considered that they could not be justified by either (i) some of the exceptions to the elimination of quantitative restrictions allowed for under that same Article, or (ii) Article XX(b) (on "General Exceptions" pertaining to measures necessary for the protection of human life or health). It also argued that the internal taxes were inconsistent with GATT Article III:2 (on "National Treatment on Internal Taxation and Regulation").

Thailand responded by arguing, inter alia, that the import restrictions were justified under Article XX(b) because the government had adopted measures which could only be effective if cigarette imports were prohibited, and because chemicals and other additives contained in United States cigarettes might make them more harmful to human health than Thai cigarettes.

WHO submissions to the GATT dispute panel confirmed differences between cigarettes manufactured in developing countries like Thailand and those in developed countries, which contained more additives and flavouring to make them easier to smoke, especially by women and adolescents. However, WHO did not find any scientific evidence to show that one type of cigarette was more harmful to health than the other.

The Panel found that the import restrictions were inconsistent with Article XI and not justified under the exceptions which that Article allows for. It further concluded that the import restrictions were not "necessary" within the meaning of Article XX(b) (i.e. not necessary for the protection of human life or health). The internal taxes, on the other hand, were found to be consistent with Article III:2.

Import restrictions were found not to be necessary because other methods could be used to protect public health, including various tobacco-control measures, without favouring domestic production. Two of these were bans on advertising and point-of-sale promotion, which applied to cigarettes of all sources. For this reason, the panel rejected the United States call for the advertising ban to be lifted. Thai health and trade officials welcomed this last decision.



Box 10 WTO Dispute: Thailand-Cigarette Case¹ (cont'd)

Some of these officials said it showed that the GATT dispute settlement process allowed them to defend the advertising ban, whereas countries that had negotiated a settlement bilaterally with the United States outside the GATT had ended up allowing advertising. ("GATT negotiators losing fight against cigarettes" in The Nation, page B4, Bangkok, December 9, 1990).

^{1.} This case was brought under the GATT dispute-settlement system before it was revised with the WTO's creation in 1995. The GATT rules cited were also pre-1995. Dispute symbol: DS10/R - 37S' 200.

(v) Links between WTO Agreements and Tobacco Policies

134. A growing number of countries have comprehensive tobacco control programs. In addition to tax increases and other price measures, these programs include policies to ban or severely restrict tobacco advertising, expand public health information campaigns, restrict sales through vending machines, ban smoking in public places and encourage cessation of tobacco use, and support for tobacco control coalitions (WHO 1999a)³³. Depending on how governments choose to manage trade in tobacco and tobacco products, a number of WTO rules could come into play. The US-Thai tobacco case illustrated the relevance of the General Agreement on Tariffs and Trade (GATT), as it affected taxes, prohibitions, and human-health related exceptions to GATT rules. Other WTO agreements that may be applicable, but which have not yet been involved in tobacco-related controversy among WTO Members, include:

(a) the Technical Barriers to Trade (TBT) Agreement in relation to product requirements such as packaging and labelling;

(b) the Agreement on Agriculture in relation to government support for tobacco production;

(c) the General Agreement on Trade in Services (GATS) in relation to restrictions on cigarette advertising; and



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(d) the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in relation to trademark protection and the disclosure of product information considered by producers to be confidential.

(vi) Framework Convention on Tobacco Control - a new international health treaty

135. The challenges to comprehensive tobacco control policies that lie outside national borders led WHO in 1996 to propose the development of a Framework Convention on Tobacco Control (FCTC). Its purpose is to facilitate multilateral cooperation and action at the global level to address transnational tobacco control strategies, the effectiveness of which in reducing demand for tobacco, is substantiated by overwhelming empirical evidence. These include tobacco taxes and prices, restrictions on advertising and promotion, use of mass media and counter-advertising, design of warning labels and packaging, clean indoor air policies, and treatment of tobacco dependence (Taylor and Bettcher, 2000).

136. The Framework Convention calls for cooperation amongst countries in achieving broadly stated goals, and establishes the general norms and institutions of a multilateral legal structure. An accompanying set of protocols will elaborate additional and more specific commitments and institutional arrangements to achieve the goals. WHO Member States began the FCTC negotiation process in October 2000 at the first session of the Intergovernmental Negotiating Body. A second session was held in early May 2001 and the third in November 2001.

137. At the FCTC negotiating sessions, there has been discussion of certain traderelated provisions in the proposed Chairman's text. These provisions include those designed to combat illegal trade and smuggling, phase out duty-free sales and increase and harmonize taxes internationally; and various packaging and labelling issues, such as bans on the use of labels like "low tar" or "mild," which are criticized for giving smokers a false sense of security. Some countries proposed that tobacco products be exempt from reduced tariffs under regional trade agreements. Advertising limits may also have implications vis-à-vis trade agreements.

138. The draft text proposes as a guiding principle that: "Tobacco-control measures should not constitute a means of arbitrary or unjustifiable discrimination in international trade."³⁴ None of the provisions of the FCTC are inherently WTO-inconsistent; and



many of the restrictions called for by some of its provisions may well be determined to be "necessary" for health protection under WTO rules. However, some governments and NGOs are arguing that health objectives should take precedence over trade agreements. Thus, the relationship between WTO rules and the FCTC will depend on the direction that future negotiations of the FCTC take, and the manner in which its rules are applied by governments.

(vii) The FCTC negotiations are a good example of the need for international cooperation

139. In the past, several of the potential inconsistencies between Multilateral Environmental Agreements (MEAs) and WTO rules may have arisen as a result of the lack of proper coordination between trade and environment officials both at the national and international levels. In this sense, it is noteworthy that the draft FCTC has been modelled on a number of multilateral agreements, several of which are MEAs. As the relationship between WTO rules and those of other international treaties can offer lessons for the FCTC, WHO intends to monitor the deliberations of the WTO Committee on Trade and Environment where such issues are discussed (next sub-section to the report).

140. A conclusion that can be drawn is that proper coordination between trade and health officials at the national and international levels is crucial to negotiating a WTO-consistent FCTC. In this sense the initiative by the WHO to create the Inter-Agency Task-Force on Tobacco Control for greater coordination between all relevant organiza-





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is the case, fewer subsidies could contribute to both reducing excessive pressure on fish stocks as well as promoting less distorted trade.

145. However, there are also risks. The fishery example also points to the importance of management structures and appropriate government regulation being in place. In many developing countries, the pace and scale of liberalization may overwhelm the capacity to develop and enforce environmental and/ or occupational health regulations. In such circumstances, trade may exacerbate the consequences of poor environmental policies.

(ii) "Like products"

146. While WTO rules provide scope for Members to adopt measures aimed at achieving national environmental policies, they impose a key requirement in respect of nondiscrimination. This obligation not to discriminate is closely linked to the concept of "like products" which is at the heart of many environment-related disputes. In essence this means that national environmental policies, in their application, have to treat like products similarly: products that are deemed to be "like", whether they come from different foreign suppliers or from domestic suppliers, should not be treated less favourably.

147. There are a number of specific instances in which governments may be exempted from this fundamental WTO principle. Article XX(b) and (g) are designed to allow WTO Members to adopt WTO-inconsistent policy measures if this is either necessary to protect human, animal or plant life or health, or if the measure relates to the conservation of exhaustible natural resources. The chapeau of Article XX is designed to ensure that such WTO-inconsistent measures do not result in arbitrary or unjustifiable discrimination and do not constitute a disguised restriction on international trade. In the Gasoline case (see below), a WTO dispute panel and Appellate Body ruling disallowed the 'arbitrary and unjustifiable discrimination' against foreign suppliers or producers that was involved in the US application of its environmental measure, and which violated the national treatment principle. This case is described in more detail in Box 11 below.

148. A key issue here is how health is considered when making a determination of "likeness". A recent WTO case concerning asbestos is a good illustration of this complex question.



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Box 11 United States - Standards for Reformulated and Conventional Gasoline (WT/DS2)

Following a 1990 amendment to the Clean Air Act, the Environmental Protection Agency (EPA) promulgated the Gasoline Rule on the composition and emissions effects of gasoline, in order to reduce air pollution in the United States and to ensure that pollution from the combustion of gasoline did not exceed 1990 levels. These rules were established to address the ozone and pollution damage experienced by large US cities, as a result, principally, of car exhaust fumes.

From 1 January 1995, the Gasoline Rule permitted only gasoline of a specified cleanliness ("reformulated gasoline") to be sold to consumers in the most polluted areas of the country. In the rest of the country, only gasoline no dirtier than that sold in the base year of 1990 ("conventional gasoline") could be sold. The Gasoline Rule applied to all US refiners, blenders and importers of gasoline.

The EPA regulation provided two different sets of baseline emissions standards. First, it required any domestic refiner which was in operation for at least six months in 1990 to establish an "individual baseline", which represented the quality of gasoline produced by that refiner in 1990.

Second, EPA established a "statutory baseline", intended to reflect average US 1990 gaso-



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(iii) The Asbestos Case - public health takes precedence over trade

149. This case stemmed from a 1998 challenge by Canada to a complete ban by France on the import and use of chrysotile asbestos. Asbestos is the leading cause of occupational cancer and its health risks have been extensively documented. In France alone, asbestos claims the lives of about 2000 people each year and a ban on chrysotile (white) asbestos is already in place in nine of the fifteen European Union (EU) member states. France produces substitutes for asbestos, for example, polyvinyl alcohol, cellulose and glass fibres (for more detail on the case, see Box 12).

150. The Appellate Body examined whether imported asbestos fibres and domestic alternative fibres were "like products," emphasising that this question must be informed by the obligation of Members to ensure "equality of competitive conditions" between domestic products and like imports. It reiterated the classic 4 general criteria for likeness, namely (i) the physical properties of the products, (ii) their end uses, (iii) consumer tastes and habits and (iv) the tariff classification of products, emphasizing that



Box 12 European Communities - Measures affecting asbestos and asbestos containing products (WT/DS135)

A French Decree prohibiting the manufacture, sale, export, import and use of asbestos fibres and products containing asbestos fibres was challenged by Canada in 1998 on the grounds of less favourable treatment of imported asbestos as compared to domestic substitutes for asbestos, contrary to Article III:4 of GATT 1994. Canada also argued that banning asbestos was an unnecessarily extreme measure because the 'controlled' use of asbestos could reduce the health risks to acceptable levels. The EU argued the case on France's behalf.



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Box 12 European Communities - Measures affecting asbestos and asbestos

containing products (WT/DS135) (cont'd)

For the Appellate Body, the determination of whether a measure which is not "indispensable" may nevertheless be "necessary" involves a process of weighing and balancing a series of factors which include the importance of the common interests or values protected by the measure, the efficacy of such measure in pursuing the policies aimed at, and the accompanying impact of the law or regulation on imports or exports.

One aspect of the "weighing and balancing process ... in the determination of whether a WTO-consistent alternative measure" is reasonably available is the extent to which the alternative measure "contributes to the realization of the end pursued". "The more vital or important [the] common interests or values" pursued, the easier it would be to accept as "necessary" measures designed to achieve those ends. In this case, the objective pursued by the measure is the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks posed by asbestos fibres. The value pursued is both vital and important in the highest degree.

The ban was found to be "necessary" to protect health since the alternative proposed by Canada 'controlled use' of asbestos products - was not demonstrated as practical. Controlled use would pose a significant residual risk to the workers and would not, therefore, achieve the level of health protection desired by France - a halt to asbestosinduced illness and death.

(iv) Domestically prohibited goods

153. The Asbestos case recalls another issue on the WTO agenda of particular relevance to health: trade in domestically prohibited goods (DPGs). As early as 1982, concern was raised by a number of developing countries about goods being exported to them in situations where their domestic sale in the exporting countries had been either prohibited or severely restricted on health and environmental grounds.

154. At the 1982 Ministerial Meeting of GATT, it was agreed to examine the issue. Governments decided to begin notifying any goods produced and exported by them but banned for health reasons by their national authorities for sale in their domestic markets. While the notification system began to function following this Decision, Parties



tended to notify DPGs whose export had also been prohibited rather than the ones which they continued to export. The notification system was not successful, and no notifications have been received after 1990 (despite the fact that the 1982 Decision remains in force). In 1989, a Working Group on the Export of DPGs was established in GATT. The Working Group met 15 times between 1989 and 1991, when its mandate expired, but failed to resolve the issue. In the 1994 Ministerial Decision on Trade and Environment it was agreed to incorporate DPGs into the terms of reference of the Committee on Trade and the Environment (CTE). Numerous other international instruments already address the export of DPGs. This is the case with the Basel Convention on the Transboundary Movement of Hazardous Wastes as well as the PIC and POPs Conventions. These instruments principally address chemicals, pharmaceuticals, and hazardous wastes.

155. The issue of DPGs, as well as the EC-Asbestos and Thailand-Cigarette cases, illustrate some ways in which WTO agreements may influence national environmental and health policies. Other environmental policy issues relevant to trade and health include the conservation of biological diversity, environmental standards relating to the use of process and production methods and, at a more general level, the use of precaution.³⁵

(v) The WTO Committee on Trade and Environment ("the CTE")

156. With the entry into force of the WTO in January 1995, the Committee on Trade and Environment was established. Its work programme builds on the work that had already taken place in GATT since 1991. The CTE has a broad-based mandate covering all areas of the multilateral trading system - goods, services and intellectual property. It has been given both analytical and prescriptive functions: to identify the relationship between trade and environmental measures in order to promote sustainable development, and to make recommendations on whether any modifications to the provisions of the multilateral trading system are required.³⁶ In effect, the CTE has brought environmental and sustainable development issues into the mainstream of WTO work. Perhaps a



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or allow for discrimination between like domestic and imported products (a violation of national treatment principle).

160. In discussing the compatibility between the trade provisions contained in MEAs and GATT/ WTO rules, the CTE observed that of the over 200 MEAs currently in force, just over 20 of them contain trade provisions. Therefore, the dimension of the problem should not be exaggerated. In addition, although there is potential, no disputes have thus far come to the WTO regarding the trade provisions contained in an MEA.





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world, with the exception of only a few countries, such as India and Tunisia, where they are 30 and 20.6 per cent respectively. For active ingredients that go into the manufacture of pharmaceuticals, six developing countries have average tariffs in the range of 20 to 30 per cent (Burkina Faso, Pakistan, Tanzania, India, Kenya and Tunisia).³⁹ Some developing countries allow a limited number of essential drugs to enter duty free.



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(iii) Impact of patent protection and the TRIPS Agreement on the availability of drugs

169. An assessment of the impact of patent protection on access to drugs and vaccines needs to address the balance that is found in the patent regime between:

the effect of patent protection in promoting the invention, development and marketing of new drugs, by providing incentives for research and development;
the effect of patent protection in limiting access to existing drugs and vaccines.

170. An analysis of the extent to which these effects can be attributed to the TRIPS Agreement depends on assumptions about what would have happened in the absence of the Agreement. The TRIPS Agreement resulted from a long and complex negotiation in which countries brought their different interests and perspectives to bear. As is made clear in Section II of this paper, it represents an effort to find a balance between the sometimes conflicting considerations referred to in the previous paragraph. On the one hand, it obliges all WTO Member countries to provide protection for product and process patents, including in the areas of pharmaceuticals and vaccines, for a minimum of 20 years from filing. On the other hand, it enshrines in international public law certain rights that all countries have to implement their patent and other intellectual property regimes in a way which takes into account public health and other public policy objectives. The provisions on compulsory licensing and parallel imports are those most frequently referred to in this connions rque paral rque pad5been the of fAs 2. the absen a5.2(nt trans-

the TRIPS



- the timing of the impact, given the TRIPS transition arrangements;

- the proportion of drugs on the market that will be covered by patent protection, and the importance of these for basic health care; and

- the effect of patent protection on prices, taking into account the safeguards permitted under the TRIPS Agreement.

(iv) Patent protection provides incentives for R&D into new drugs

172. While the importance of patent protection is providing incentives for R&D into pharmaceuticals is widely accepted (see Box 14), there is a debate about the extent to which patent protection for pharmaceuticals in developing countries adds to these incentives. The questions are, first, to what extent does a world-wide requirement to protect pharmaceuticals inventions at the level of TRIPS standards enhance the overall level of incentives for R&D into diseases in general and, secondly, to what extent will such a requirement affect incentives in the case of diseases which predominantly afflict people in developing countries. While there have been some studies of the effect of the introduction of pharmaceutical patent protection on the level of local R&D in the countries that have introduced it,⁴² there does not appear to have been a study which has specifically addressed this overall aspect. However, one expert in this area has observed that extension of product patent protection as a result of TRIPS could result in a rise in demand of as much as 25 per cent of global spending on patented drugs, even without taking into account the case of China (Lanjouw, 1997).43 Nonetheless, widespread concern has also been expressed that, left to itself, the patent system, even after TRIPS implementation, will not lead to sufficient incentives for R&D into the diseases prevalent amongst the poor in developing countries, such as malaria. This has led to widespread consideration of supplementary action at the international level, both in terms of so-called "push" mechanisms, involving financial contributions towards R&D, and so-called "pull" mechanisms, aimed at ensuring the existence of an attractive level of demand in the event that successful drugs or vaccines are generated. Examples of internationally sponsored public/ private partnerships to address these problems are the Medicines for Malaria Venture (MMV) and the International AIDS Vaccine Initiative (IAVI).

^{42.} These studies include: Nogues, 1990 (Argentina); Kawaura and LaCroix, 1995 (Korea); Scherer and Weisburst, 1995 (Italy); LaCroix and Kawaura, 1996 (Japan); Lanjouw, 1997 (India); Maskus, 1997 (Lebanon); Korenko, 1999 (Italy); Lanjouw and Cockburn, 2000 (India). The results vary from study to study and no general picture seems to emerge.

43. Lanjouw, J.O. The Introduction of Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?, Growth Center Discussion Paper, Yale University, and NBER Working Paper no. 6366, 1997.



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Box 14 Effect of the patent system in promoting the invention, development and marketing of new drugs

A key function of the patent system is to provide incentives for research and development into new inventions, by giving inventors exclusive rights over their inventions for a limited period of time. Several studies try to answer the questions of whether, in general, strong intellectual property protection stimulates investment in R&D and, in particular, pharmaceutical patent protection encourages the development of new drugs.

This is important because it is possible that innovation and technological development in the private sector may possibly be spurred by factors other than patents, such as commercial rivalry, market conditions and technical barriers to imitation. Indeed, studies based on firm-level surveys (Mansfield, 1986; Levin et al, 1987) showed that in most industries these other factors are the most important instruments in capturing the returns from R&D investments. However, these studies found that, in the pharmaceuticals and chemicals sectors, patents were seen as the most important factor for R&D decisions and the development of new products. In a recent and more extensive study (Cohen et al, 2000), these findings were broadly reaffirmed. Overall, for all US industry groups studied, lead time, trade secrets and complementary manufacturing, sales and service efforts were seen as more important than patents in appropriating the fruits of innovation. But again, this study confirmed that it was the pharmaceutical sector, with the medical equipment sector, that gave the highest score to patent protection. This study suggests that secrecy, lead time and complementary manufacturing capability are also of high importance in the pharmaceutical industry.

Scherer (2000) suggests that there could be three probable reasons for the special importance of patents to pharmaceutical innovation. First, patents for new pharmaceuticals, unlike for new products in many other areas of industry, give effective protection since patent claims can be defined more precisely for chemical molecules, thus making it relatively easier to prove infringement. Second, pharmaceutical R&D costs are particularly high and so the legal protection offered by patents is especially important to secure the commercial benefits.⁴⁴

Third, in the absence of protection, imitation costs would be low given that knowledge created by originator firms in the therapeutic value and safety and efficacy of the molecule can be used by others with very low costs.

^{44.} For instance, studies have shown that the US pharmaceutical industry devoted the largest fraction of its revenue to R&D from among 230 industries: this proportion has been increasing over time to reach a current level of around 20 percent (Scherer, 2000, 1302).



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Box 14 Effect of the patent system in promoting the invention, development and marketing of new drugs (cont'd)

A further factor which appears to differentiate the pharmaceutical industry from many other industries is the relatively long life-span of pharmaceutical inventions and the corresponding lower significance of lead time as a factor for appropriating benefits.⁴⁵

With regard to the average cost of producing a new, innovative drug, industry circles place the figure at around US\$ 500 million (IFPMA, 1998, 9). A recent study published by an NGO (Public Citizen, 2001) claims that it could be closer to US\$ 100 million or less, even taking account of industry data. Both claims base their estimates on data provided in an earlier study (DiMasi et al, 1991), the author of which placed the average cost of developing a new drug at US\$ 231 million in 1987. This study has been updated by the same author and the cost (in 2000) is placed at c.\$800 million per new drug. The increase has been attributed to increased costs of drug development, particularly in the clinical testing period.⁴⁶ A further aspect of the innovative pharmaceutical industry that is often discussed in relation to the degree of incentive required for R&D is the element of risk. Industry generally claims that the industry is particularly risky, relying on a relatively small number of so-called "blockbuster products" for the bulk of profits and with a very large number of drugs that fail to break even. There are studies which support this view (Scherer, 2000; Grabowski and Vernon, 1990, 1994). On the other hand, the Public Citizen tttrld be whibcorre-





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178. While some new drugs may be more expensive in some countries as a result of more widespread patent protection, it is important to keep the extent of the problem in perspective. The vast majority of the 300 or so drugs on WHO's Model List of Essential Drugs are not under patent protection in any country. The need to implement patent protection according to TRIPS standards will not, in general, affect the price of drugs now on the WHO model list. The cost and affordability of drugs have been amoung the criteria for inclusion in the WHO model list, so the limited number of patented drugs on the model list does not necessarily reflect the actual need for key patent-protected life-saving drugs by people in developing countries. But the fact that billions of people lack access to essential drugs, most of which are not protected by patents, underscores the other problems contributing to inadequate access - poorly developed supply and distribution systems, lack of financing, lack of generic drug production or import capacity, and affordability of even generic drugs for people in poorer countries.

179. In addition, most developing countries already provided product patent protection for pharmaceuticals prior to the entry into force of the TRIPS Agreement and, of those that did not, some have introduced it prior to the end of the transition period to which they are entitled under the TRIPS Agreement (2005 for developing countries and 2016 for least-developed countries ⁵⁴). Furthermore, developing countries not already providing patent protection to pharmaceutical products are only required to implement such protection for drugs or vaccines that were new for patentability purposes after the end of 1994. TRIPS rules are therefore, "less of an issue for the vast share of existing [off-patent] drugs than it is for new and future essential drugs patented after 1995." (Loewenson, 2000).⁵⁵ The impact of the TRIPS rules in these countries has not been or will not be immediate, as the new products covered by the patents take time to be developed and obtain marketing approval. As a result, the impact of these TRIPS rules in those developing countries began gradually after 2000, with full impact only by 2015. Nor are patent protection requirements a significant deterrent to the utilization of most vaccines currently on the market in developing countries, although it should be noted that the structure of the vaccine market differs considerably from that of the pharmaceutical market in the context of the TRIPS Agreement (see Box 15). Yet, some of the most effective new drugs to combat HIV/ AIDS, malaria and tuberculosis - diseases that inflict enormous human and economic loss - were invented after 199556 and as such will be entitled to patent protection in more developing countries.

^{54.} See Articles 65.2, 65.4 and 66.1, and the Doha Declaration on the TRIPS Agreement and public health.

^{55.} Loewenson, R. Essential Drugs in Southern Africa Need Protection from Public Health Safeguards under TRIPS, BRIDGES 4:7 September 2000: 18-23

^{56.} The effective period of patent protection for pharmaceuticals that use new chemical entities is very much shorter than the nominal 20year period, especially in developing countries, because of the time taken to obtain marketing approval from the public health authorities.



Box 15 What is the difference between vaccines and other pharmaceuticals in the context of TRIPS?

Vaccines have the following special characteristics:

1. There are relatively few vaccine manufacturers. These manufacturers work closely with the public sector to ensure a reliable supply of essential vaccines, and to facilitate technology transfer through partnerships and joint ventures.

2. Vaccines are a heat-sensitive biological product. Since they are administered to healthy children, often by injection, the safety and quality requirements for vaccines are

(vi) However, the TRIPS Agreement contains public health safeguards

180. The TRIPS Agreement affords discretion to WTO Members in how its obligations are implemented, as long as national laws conform to the minimum standards under the Agreement. In discussions leading up to the TRIPS Agreement, it was argued that unqualified IPR rights are not necessarily appropriate for countries struggling to meet health and development needs. Developing and other countries can therefore use the flexibility of TRIPS provisions and its safeguards to protect public health. These are dis-



cussed in more detail in section II above of this paper, but three of the most important are compulsory licensing, parallel imports and measures to enable the early introduction of generics. There are also important measures that can be taken outside the field of intellectual property.

Making generic drugs available upon patent expiration

181. To keep drug prices affordable, many countries promote the production or impor-



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Box 16

WTO Dispute: Canada - Patent protection of pharmaceutical products, complaint by the European Communities (WT/DS114/1) (cont'd)

Canada countered that its laws were valid exceptions under Article 30, which allows "limited exceptions to the exclusive rights conferred by a patent."

In March 2000, the dispute panel validated the Canadian law allowing generic drug makers to test patented drugs or undertake other actions necessary for the purposes of seeking marketing approval for their generic versions or file for licences prior to the patent's expiration. But it found that stockpiling of generic products was not permitted under TRIPS Article 28. According to the Panel ruling, the key issue was whether stockpiling with no restrictions on amount could constitute a "limited" exception to patent owner's rights. "With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect." (WT/ DS114/ R, para. 7.33). Thus, manufacturers must wait until patent expiry before starting commercial production. According to an article at the time, "Generic drug manufactures note that the ruling would result in only modest production delays for generic drugs, but goes a long way to protect consumer interests by cutting time-to-market for generic drugs by as much as two to three years" ("DSB Rules On Generic Drugs", Bridges, 8 February 2000, International Centre for Trade and Sustainable Development, Geneva).

Compulsory licensing (and government use)

182. Compulsory licensing enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder. National laws in most developed and developing countries provide for the granting of compulsory licenses, which is an important component of any comprehensive national patent regime. In some countries, compulsory licenses have been used more particularly in the pharmaceutical sector to stimulate price-lowering competition and to ensure, *inter alia*, availability of needed medicines.

183. Compulsory licensing is one way in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. It is explicitly allowed by the TRIPS Agreement subject to certain con-



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ditions set out in Article 31 (see Section 2). The Doha Declaration on the TRIPS Agreement and Public Health clarifies some of these provisions, while maintaining Members' commitments in the TRIPS Agreement. It makes it clear that each Member is free to determine the grounds upon which compulsory licences may be granted. This, for example, is a useful corrective to the views often expressed in some quarters implying that some form of emergency is a pre-condition for compulsory licensing. The TRIPS Agreement does refer to national emergencies or other circumstances of extreme urgency in connection with compulsory licensing, but only to indicate that in these circumstances the usual condition that an effort must first be made to seek a voluntary



Doha Declaration on the TRIPS Agreement and Public Health makes it clear that the effect of the provisions in the TRIPS Agreement on exhaustion is to leave each Member free to establish its own regime without challenge - subject to the general TRIPS provisions prohibiting discrimination on the basis of the nationality of persons.

Measures outside the field of intellectual property

186. The scope afforded in the TRIPS Agreement for domestic regulation and a government's health policy in general is an important part of the "balance" in the Agreement. Governments have available a range of public policy measures outside the field of intellectual property to address issues of access to and prices of drugs. For example, many countries use price or reimbursement controls. Article 8 of the TRIPS Agreement makes it clear that WTO Members may, in formulating or amending their rules and regulations, adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the Agreement.

187. Where patent protection confers pricing power for drugs of vital public health or life-saving importance, differential pricing is one way of ensuring that prices in poor developing countries are as low as possible while higher prices in rich countries continue to provide incentives for R&D. Also called "tiered" or "equity" pricing, differential pricing involves charging lower prices in poorer countries and thus spreading the burden of providing incentives for research and development more equitably. The TRIPS Agreement does not stand in the way of such arrangements.

188. The WHO and WTO Secretariats jointly organized a workshop for interested parties in April 2001 in Høsbjør, Norway to examine the legal, institutional and political environment that would favour widespread use of differential pricing and how the practice could be used and promoted to improve poor countries' access to essential drugs.⁵⁷ The meeting reviewed several options for implementing differential pricing, including: bilateral negotiation of price discounts between companies and governments; use of bulk purchasing power; and voluntary or compulsory licensing arrangements. Participants emphasized that global mechanisms or international cooperation would be needed to support some of these options. It was also pointed out that the TRIPS Agreement does not affect decisions to set different prices for drugs, nor would differ-



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(vii) The right to use compulsory licensing under the TRIPS Agreement, and the issue of parallel imports: experiences of some countries

192. A good deal of concern has recently been expressed about whether the right of countries to use the public health safeguards provided for in the TRIPS Agreement is sufficiently recognized and accepted. Given that developing countries have only recently come under an obligation to comply with TRIPS norms, the evidence on difficulties in using TRIPS safeguards is limited. However, the concern has been sufficiently wide-spread for the WTO Council for TRIPS to initiate a work programme aimed at clarifying the flexibility available in the TRIPS Agreement, so as to give greater legal certainty and security in its use.

193. Part of this concern has resulted from the fact that, at the end of the Uruguay Round, at least one WTO Member, the United States, did not accept that the standards of protection of intellectual property provided for in the TRIPS Agreement were necessarily adequate and decided that it would continue to seek higher standards of protection through other means, including its procedures under the Special Section 301 of its



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Box 17

US White House Executive Order 13155, May 20, 2000 - Access To HIV/AIDS pharmaceuticals and medical technologies

"In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/ AIDS pharmaceuticals or medical technologies if the law or policy of the country: (1) promotes access to HIV/ AIDS pharmaceuticals or medical technologies for affected populations in that country; and (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15))."

194. Two cases relevant to the use of the flexibility in the TRIPS Agreement that have arisen in the WTO are often referred to. One is the dispute between Canada and the European Communities in which the WTO panel endorsed the compatibility of the "regulatory" or so-called "Bolar" exception with the TRIPS Agreement, but found against the stock-piling provision in the Canadian law (see para. 59 above for further details).

195. The other was a complaint brought under the WTO dispute settlement system in May 2000 by the United States against a provision of the Brazilian industrial property law of 1996. The provision in question had not been used and therefore the dispute was about the consistency of the Brazilian legal framework for the grant of compulsory licences with the provisions of the TRIPS Agreement. In its request for establishment of a panel, the United States alleged that Article 68 of Brazil's 1996 industrial property law, imposes a "local working" requirement which stipulates that a patent shall be subject to compulsory licensing if the subject matter of the patent is not "worked" in the territory of Brazil. Specifically, the United States challenged the provision whereby it claimed that a compulsory license shall be granted on a patent if the patented product is not manufactured in Brazil or if the patent owner chooses to exploit the patent through importation rather than "local working," then Article 68 would allow others to import either the patented product or the product obtained from the patented process. The United States argued that Article 68 of Brazil's 1996 industrial property law discrimi-



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nates against US owners of Brazilian patents whose products are imported into, but not locally produced in, Brazil. Article 68 was also said to curtail the exclusive rights conferred on these owners by their patents. For the United States such legislation was part of an industrial policy.

196. Brazil contested the industrial policy nature of its challenged provision. It argued on the contrary that its legislation was compatible with TRIPS and referred to the US requirements as being contrary to and above the TRIPS standards. For Brazil, its legislation was not discriminatory and in fact it contained provisions parallel to those of Sections 204 and 209 of the US Patent Code, in particular with regard to the local working requirements. According to Brazil, under Section 204 "Preference for the United States Industry", the US Patent Code required that small business firms and universities that receive federal funding "manufacture substantially" their inventions in the United States. For Brazil, Section 209 of the same Code also established a local workselsnUnite

59. See document WT/ DS 224/ 1.

^{61.} On 5 July 2001, the parties to the dispute notified to the DSB a mutually satisfactory solution on the matter (WT/DS199/4).

^{60.} The United States requested the establishment of a Panel (Brazil - Measures Affecting Patent Protection, complaint by the United States (WT/DS199/3)) in January 2001. A panel was established in February 2001 and Cuba, the Dominican Republic, Honduras, India and Japan reserved their third party rights.



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Constitution. The background of this domestic dispute is the following. In 1997 the Parliament of South Africa adopted the Medicines and Related Substances Control Amendment Act (the "Medicines Amendment Act") to assist in implementation of its 1996 National Drug Policy. That Policy was designed "to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and rational use of drugs by prescribers, dispensers and consumers" (National Drug Policy for South Africa, Department of Health, January 1996). The Medicines Amendment Act included several key components, among them provisions on generic substitution of prescription drugs, rationalization of pricing and reform of the Medicines Control Council. The Medicines Amendment Act empowered the Minister of Health to authorize and prescribe conditions for the parallel importation of drugs under patent in South Africa.

199. Prior to the provisions of the Medicines Amendment Act taking effect, 39 pharmaceutical companies sued the South African Government in order to block its implementation. The companies alleged that the Act was inconsistent with the newly adopted Constitution of South Africa in that it authorized the Minister to abrogate the rights of patent holders and violated the terms of the TRIPS Agreement. The Government argued that its legislation was entirely consistent with the TRIPS Agreement that allows WTO Members to authorize parallel importation, that the legislation did not address compulsory licensing, that the Minister was not granted broad powers to abrogate patent holder interests, and that, therefore, the legislation was entirely consistent with the South African Constitution. No case was brought to the WTO claiming that South Africa had breached the TRIPS Agreement.

200. In April 2001, the pharmaceutical companies in the High Court of Pretoria withdrew their suit against the government, and agreed to pay the government's legal costs in defending this case. The government reiterated its commitment to honour its obligations under the TRIPS Agreement and the companies recognized the right of South African to enact national laws or regulations, including regulations implementing the Medicines and Related Substances Control Amendment Act, in accordance with the South African Constitution and the TRIPS Agreement. The South African Government has since published for comment its proposed implementing regulations, including some that would authorize parallel importation of patented medicines.

201. Various other instances have been referred to where countries have considered that they have been under pressure from industry and/ or foreign governments not to



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avail themselves fully of the flexibility provided in the TRIPS Agreement. These matters have not been brought to the WTO. However, it should be noted in this connection that Article 1.1 of the TRIPS Agreement explicitly states that Members may "but shall not be obliged to" implement in their law more extensive protection than is required by the Agreement. One of the preambular provisions of the TRIPS Agreement emphasizes "the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures". Moreover, Article 23 of the WTO Dispute Settlement Understanding commits Members who believe that other Members are not living up to their TRIPS (and other WTO) obligations to seek recourse in accordance with the Dispute Settlement Understanding and not to make determinations or take action except in accordance with it.

(viii) TRIPS and access to medicines - positions taken in some other international fora

202. At its April 2001 session, the UN Commission on Human Rights adopted a resolution (2001/33) calling upon States to refrain from taking measures which would deny or limit equal access to pharmaceuticals used to treat pandemics such as HIV/ AIDS. In addition, the Commission called upon States to ensure that, as members of international organizations, they apply international agreements in support of public health policies that promote access to affordable pharmaceuticals and medical technologies.

203. The World Health Assembly's annual meeting in May 2001 devoted substantial attention to lack of access to essential drugs, which has become acute in light of the devastating human and economic impact of HIV/ AIDS in many countries. WHA, as WHO's governing body, adopted a resolution (WHO Medicines Strategy, 54.11) which noted that "the impact of international trade agreements on access to, or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated." It also requested the Director General of WHO to "enhance efforts to study and report on existing and future health implications of international trade agreements in close cooperation with relevant intergovernmental organizations." In cooperation with other intergovernmental organizations, WHO will continue to provide its Member States with information about options within TRIPS for protecting public health, pursuant to previous resolutions adopted by WHO's governing body (World Health Assembly Resolutions 52.19 and 53.14).

204. In June 2001, a special session of the UN General Assembly on HIV/ AIDS also addressed the role of global trade policy in affecting the availability of low-cost generic



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drugs and national manufacturing capacities. The special session's final declaration noted "that the impact of international trade agreements on access to or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated."

(ix) WTO Discussions on TRIPS and access to drugs

205. At the request of the African Members of the WTO (the African Group), the TRIPS Council held a special discussion on intellectual property and access to medicines as part of its week-long regular meeting in June 2001. This was the first time that this matter had been put on the agenda of on WTO body. The work that subsequently took place in the Council for TRIPS fed into the preparatory work for the WTO Ministerial Conference held in Doha, Qatar in November 2001 and into the Declaration on the TRIPS Agreement and Public Health that was adopted by consensus by the WTO Ministers at that Conference.

206. The text of this Declaration can be found in Box 18. Its aim is to respond to the concerns expressed about the possible implications of the TRIPS Agreement for access to drugs. It does so in a number of ways. First, it emphasizes that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health and reaffirms the right of Members to use, to the full, the provisions of the TRIPS Agreement declarations signal an acceptance by all WTO Members that they will not seek to prevent other Members from using these provisions.

207. Second, the Declaration makes it clear that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. Further, it highlights the importance of the objectives and principles of the TRIPS Agreement for the interpretation of its provisions. Although the Declaration does not refer specifically to Articles 7 and 8 of the TRIPS Agreement, entitled, respectively, "Objectives" and "Principles", it should be noted that developing country Members attach particular importance to these provisions. These statements thus provide important guidance to both individual Members and, in the event of disputes, WTO dispute settlement bodies.



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208. Third, the Declaration contains a number of important clarifications of some of the flexibilities contained in the TRIPS Agreement, while maintaining Members' commitments in the TRIPS Agreement. Details have been given in paragraphs 183 to 185 above.

209. With regard to the least-developed country Members of the WTO, the Declaration accords them an extension of their transition period until the beginning of 2016 for the protection and enforcement of patents and rights in undisclosed information with respect to pharmaceutical products. Until then, these countries are exempt from these TRIPS obligations.



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212. This landmark declaration, which affirms that the TRIPS should be interpreted and implemented so as to protect public health and promote access to medicines for all, demonstrates that a rules-based trading system is compatible with public health interests. The careful and systematic attention which WTO Members afforded to finetuning the balance that needs to be found in the intellectual property system is indicative of the prominence accorded to public health on the international trade agenda. The declaration enshrines the principle that WHO has publicly advocated and advanced over the last four years, namely, the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and promote access to medicines.

G. HEALTH SERVICES

(i) The issues

213. The equitable and efficient delivery of quality health services in response to the health needs of a population depends on many factors, including the appropriate combination of resources available on domestic as well as international markets. Ensuring that services meet the needs and expectations of the people depends on national gov-



people in developing countries (UNCTAD and WHO, 1998). For example, a rise in the "brain-drain" of health professionals leaving low-income countries to work in higherincome countries, can increase health personnel shortages in developing countries, leading to problems in access to and quality of health services. It also results in losses to governments with respect to the investment made on training health professionals. The loss on investment from doctors who subsequently emigrated has been estimated at tens of millions of dollars for South Africa alone (Bundred and Levitt, 2000).⁶³ Developing countries that expend resources on the treatment of foreign patients may divert resources that could instead fill domestic supply needs. For-profit private, foreign-invested hospitals tend to target more lucrative markets and disregard the needs of remote regions and disadvantaged groups. In addition, by offering more attractive employment conditions, they exacerbate shortages of skilled staff in public facilities, on which the poor rely.⁶⁴ Regulatory strategies could be used to reduce such risks, but, as pointed out elsewhere, governments need to be able to enforce an effective regulatory



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(close to 30 cases) or horizontal (less than 10). It is reasonable to assume that these commitments are mostly in line with status quo conditions, rather than liberalizing market access or national treatment. Moreover, it may be worth mentioning that about 80 WTO Members have made market access commitments relating to foreign commercial presence by health insurance companies, through sectoral commitments in financial services covering the relevant subsectors. The vast majority of such commitments are partial commitments, mostly indicating limits on the number of operators or types of legal establishment that are admitted in the market. It does not appear that these commitments represent an explicit effort to encourage investment by foreign health insur-

225. Movement of natural persons (mode 4): Commitments on mode 4 apply to measures governing the supply of services by foreign natural persons within the relevant Members' jurisdiction. An Annex to the GATS clarifies that the Agreement does not apply to measures governments may want to use to restrict access for foreigners that seek employment, citizenship or residence on a permanent basis. If foreign health workers are seen as a desirable way to alleviate health professional shortages and/ or attract new expertise and skills, countries might undertake GATS commitments under this mode.

226. To date, most GATS mode 4 commitments have remained very limited in breadth and depth. There is evidence in may cases that actual policies provide better access conditions for foreign health professionals than those bound under the GATS. So far, close to 50 Members have made partial commitments for medical and dental services and less than 30 for midwife services under mode 4. As noted before, a partial commitment means that the country concerned has reserved the right to place specified limitations on those who seek access. In turn, this increases the predictability of restrictions the country may elect to operate. In current schedules, no WTO Member has made a full commitment on health services in mode 4, probably because countries want to maintain the flexibility to decide, depending on the limitations made, on the number, type, and professional specialization of foreign personnel allowed to work in the country.

227. Overall, it appears that the commitments undertaken for hospital services carry less stringent limitations, and are thus "more liberal", than those made for the other



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health services. This can be observed for developing as well as developed economies. For example, the following Members have undertaken full commitments on market access for mode 3 in this sector: Burundi, Ecuador, Kyrgyz Republic, Malawi, Swaziland, Denmark, Germany, Greece, Ireland and the United Kingdom. The commitments for the latter five countries, covered by the Schedule for the European Communities, are, however, subject to a cross-sectoral limitation indicating the non-coverage of services considered as public utilities; these may be subject to public monopolies or to exclusive rights. Other large economies with commitments in this sector include the United States and Japan. With the exception of two subsequent accessions (Ecuador and Kyrgyz Republic), the commitments have been applied since the entry into force of the GATS, i.e. January 1995 or, depending on domestic ratification procedures, some months later.

Table 1

WTO Members' commitments on medical, hospital and other health services, and on health insurance (number of Members), 3rd Quarter 2000

	Medical and	Midwife and	Hospital	Other	Health	
	Dental	Nursing	services	Human	Insurance	
	Services	Services		Health	(in Financial	
				Service	Services)*	
TOTAL	52	28	42	15	78	
-	-	-		-	-	
MARKET ACCES	S					
Mode 1	Full	16 (-2)	7 (-1)	13	7	10
	Partial	10	4	0	1	59
	Unbound	26	17	29	7	31

Mode 2

Full

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Table 1

WTO Members' commitments on medical, hospital and other health srvices, and on health insurance (number of Members), 3rd Quarter 2000 (cont'd)

	Medical and	Midwife and	Hospital	Other	Health	
	Dental	Nursing	services	Human	Insurance	
	Services	Services		Health	(in Financia	al
				Service	Services)*	
	TREATMENT					
Mode 1	Full	19	7	16	8	29
	Partial	8	4	0	1	32
	Unbound	25	17	26	6	39
Mode 2	Full	27 (-1)	9	36 (-1)	9 (-1)	42
	Partial	21	19	4	5	26
	Unbound	4	0	2	1	32
Mode 3	Full	17	8	29 (-23)	7 (-4)	29
	Partial	30	19	10	7	62
	Unbound	5	1	3	1	9
Mode 4	Full	1	0	2 (-1)	0	6
	Partial	47	27	37	15	82
	Unbound	4	1	3	0	12

* In a few cases, Members may have specifically excluded health insurance from coverage under their insurance-related commitments, but this has not yet been tabulated.

<u>Source</u>: WTO, 2000.

Note: EC Member States are counted individually.

() Reduced number of full commitments if horizontal limitations are taken into account.

(v) Effects of country GATS Commitments on health services

228. What have been the effects of GATS commitments in the health service or insurance sectors? Nearly all information to date suggests that current patterns and levels of health services trade are occurring irrespective of GATS. Nor is it evident that foreign investment by health insurance companies has been influenced by GATS commitments in





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to patients. Does this make the provision of the services "commercial"? Because none of these issues has yet resulted in a dispute between WTO Members, there is no definitive interpretation and, as noted above, while WTO Member governments could seek clarification within the current GATS negotiations, they have not yet expressed the need to do so. This may have something to do with the fact that, for a country that has not committed on health services, the application, or not, of the governmental services carve-out would not have market access or national treatment implications, but merely determine the applicability of the MFN principle and some procedural obligations (related to transparency for example). Non-application of the carve-out would imply that the MFN requirement comes into play, meaning that all existing and any new trade restrictions would have to be applied vis-à-vis all WTO Members.

(vii) Trade liberalization as a risk to quality, equity and other public policy objectives?

232. There is a concern that opening health markets to foreign competition poses risks to equity, access and quality of services available to the poor. Some evidence indicates that benefits of opening markets are concentrated among the wealthy. For example, a multinational investment fund that has invested in several Latin American managed care companies and acquired public hospital management contracts, has sought to reduce the proportion of uninsured patients in its hospitals (Stocker, et.al, 1999)⁶⁸. A potential benefit of foreign direct investment is that it may provide high-quality services that are not currently available domestically. In the absence of government regulation, these services are, however, likely to be only available to those who can afford it.

233. Governments which make commitments to allow foreign suppliers to provide health services can enforce the same standards for the protection of the public on foreign suppliers as on nationals, and can, indeed, impose additional requirements on foreigners if they so choose. In the latter case, a national treatment limitation would need to be scheduled. To increase potential benefits of foreign direct investments for the population at large, governments can, for instance, with regard to private health insurance, require all private insurance plans - foreign and domestically-owned - to offer a basic package of benefits, prohibit "dumping" of high-cost patients onto the public system, and prohibit the exclusion of people with pre-existing conditions and diseases. In addition, governments can require private health providers to provide a certain amount of free care to the poor, or tax the facilities and dedicate the revenue to support public health services. To limit any reduction in health service capacity for dis-



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advantaged groups, a government may require private hospitals, for example, to: (a) reserve a minimum percentage of beds for free treatment to the needy; (b) offer some basic medical services in remote rural areas; or (c) train a higher number of staff than required for their own purposes.

234. Turning to exports of health services (those provided to foreigners), the GATS does not impose constraints on the terms and conditions on which a host country treats foreigners consuming services within its territory: any restrictions on the services provided to tourists or foreign patients are beyond the Agreement's scope. WTO Members thus remain free to subject such services to quotas, taxes or charges, and to use any proceeds to enhance the quantity and/ or quality of basic health services.

235. While liberalization (at home or abroad) might increase the outflow of qualified staff from the public sector to the private sector (at home or abroad), there are no legal impediments in the GATS on governments' rights to discourage such movements of personnel. To lessen the costs of the brain drain, countries might consider a variety of measures that would help to compensate for the loss of trained health professionals. Countries could levy taxes on those who leave the country, or require deposits or financial guarantees, with the costs borne by the countries or private organizations that do the recruiting. In addition, there are "positive" measures that might limit the risk of a "brain drain", for example enhanced career development opportunities and conditions of employment; foreign investment in a country's hospital sector, possibly combined with inflows of foreign patients, might also enhance domestic employment opportunities and, in turn, dissuade staff from leaving.

(viii) GATS recognizes the right to regulate

236. The preamble of the GATS Agreement expressly "recognizes the rights of Members to regulate, and to introduce new regulations, on the supply of services within their territories in order to meet national policy objectives ...". Countries without commitments in the health sector or the health insurance sub-sectors are free to adopt any policies, regardless of their effects on trade, with the main binding constraint being the MFN principle. It requires that regulations must not discriminate between like foreign services or service suppliers of different origin or nationality. In sectors where Members have scheduled full commitments on national treatment, they are obliged not to discriminate against foreign services or service suppliers in their regulations, but are, of



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course, still free to regulate the sector to meet public policy objectives. If a country wishes to reserve the right to apply more stringent rules to foreign services or suppliers than to national ones, these rules would need to be covered by limitations on national treatment in its schedule.

 (ix) . . . but regulatory capacity may be weak or non-existent in some developing countries

237. While GATS gives governments a wide scope to regulate private health providers and insurers to protect equity, such regulations may be weak or non-existent in a number of developing countries. According to the WHO, as of the mid-1990s, "with a few notable exceptions (Hungary, Colombia), there are, for instance, virtually no comprehensive regulations for health insurance. Moreover, where there are regulations on the books, enforcement is often limited or ineffective "(Chollet and Lewis, 1997).⁶⁹ This may equally be true in certain cases of the regulation of health facilities, professionals and services. Until regulatory systems are in place and the capacity to implement them is strengthened, there is a risk that suppliers will compromise efforts to achieve equity in access or financing, or engage in consumer fraud, although publicly owned and operated facilities are not immune from regulatory failure or negligence either. Strengthened regulation may be a precondition in a number of countries for liberalization to be consistent with health sector objectives. This is a challenging task, especially for those developing countries whose regulatory systems have limited human and financial resources. The possibility of undertaking pre-commitments, i.e. commitments that apply only years after the conclusion of the new round (see paragraph 81 above), may help to provide the time needed for careful regulatory reform. The countries concerned may also benefit from joining forces, seeking synergies or working with relevant international organisations to strengthen capacity in this area.

(x) Liberalization calls for greater regulation

238. The need to regulate the private sector typically increases as competing suppliers enter the market. Governments need to act to prevent any adverse effects and channel any gains to benefit health. Greater, not less, regulation has accompanied more open markets in financial services and telecommunications, and this will be essential for



(xi) The on-going GATS negotiations provide an opportunity for input





H. FOOD SECURITY AND NUTRITION

(i) Nutrition and health

245. Malnutrition or under-nutrition (inadequate calorie intake relative to needs) is responsible for an estimated 16 per cent of the global burden of disease, and about a third of the burden of disease in Sub-Saharan Africa (Murray and Lopez, 1996)⁷⁰. It increases the risk of communicable and non-communicable diseases, and worsens the prognosis when such diseases are contracted. In pregnant women, it increases the risk



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into agricultural production as well as food. If trade barriers are lowered more for processed than for unprocessed products, this might also encourage the development of processing industries and increase the value-added of exports. Likewise, lower trade barriers for labour-intensive manufactures could generate new export opportunities, e.g. for textiles, leather goods and wood products. It is therefore no surprise that developing countries have been very active, for instance, in the on-going WTO negotiations on agriculture.

252. By reducing export subsidies as well as subsidies linked to production and by lowering trade barriers, trade liberalization may, at least in the short term, reduce supply and increase demand, thus raising world food prices, particularly for cereals and temperate crops. Least-developed and net food-importing developing countries have therefore been concerned about the impact on their food import bills. On average, food imports represent about 16 per cent of total imports of least-developed countries, and 11 per cent for net food-importing developing countries, although this varies enormously from one country to another, with figures up to 30-40 per cent in some of the latter group (FAO, Agricultural Trade Database). Cereals account for some 40 per cent of food imports in these countries as a whole, and oils and fats for a further 20 per cent.

253. In principle, the benefits of trade liberalization in terms of improved market access have the potential to offset the costs of higher world food prices. Moreover, to the extent that the price distortions on the world market are eliminated, this would ut the ir arage stim ce Leal productiont of



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flexibilities to address their food security concerns, including flexibility to support their own production of essential food crops and for such assistance to be exempt from any reduction commitment as part of a proposed Development/Food Security Box. There have also been calls for the strengthening of the current disciplines on export restrictions to increase the reliability of global food supply, for example by preventing developed countries from taxing their food exports and thereby reducing supply on the world market when prices are high. Furthermore, proposals have been made for developed countries to make more specific commitments in respect of food aid, and a number of other concrete proposals are on the table designed to address the concerns of net foodimporting developing countries.

EMERGING ISSUES

I. EMERGING ISSUES

260. Advances in technology constitute one of the major driving forces behind globalization and international trade, as well as health improvements. But technological advances sometimes occur faster than the pace at which societies can understand or respond to their implications for public policy. Within the health arena, there are two important technological advances that have the potential to revolutionize health care biotechnology and information technology. A third emerging health issue is related, paradoxically, to the centuries-old use of herbal medicines and traditional knowledge for treating illnesses. All three issues represent the next wave of policy issues involving health and trade.

1. Biotechnology

261. Though the range of activities that come under the term are diverse, biotechnology can be generally defined as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services" (OECD, 1982).⁷⁶ Biotechnology has already made enormous contributions to biomedical research and is beginning to translate into real-world applications in disease prevention and treatment. But as the scope of its application grows wider, from humans and animals to genes and viruses to plants and trees, its impact on society and on economies is also widening.



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262. The fruits of biotechnological discoveries of the last 20 or so years have already led to new diagnostic tests, pharmaceuticals, and medical treatments for a long list of diseases, from diabetes (production of human insulin proteins) to molecular-based detection of tuberculosis. The recent decoding of the human genome represented the culmination of years of scientific inquiry and ushers in a new age of potential medical advances. Data on human chromosomes are already being used to investigate the genetic underpinnings of health and disease.

(i) Concern about patents

263. Like the controversy over patents on drugs or vaccines of vital public health importance, the patenting of biotechnology products raises several concerns. One set of concerns relates to the patentability of biotechnological innovations, i.e. whether they meet the basic criteria of novelty, inventiveness and usefulness. There are differences of opinion about whether data on human gene sequences should qualify for patents, even though private companies have already applied for and received patents for them. At issue here is the interpretation of the basic criteria for patentability - novelty, inventive step and industrial applicability - which have for long been found in all patent laws in both developed and developing countries (the WTO TRIPS Agreement refers to these basic criteria without further interpreting them). Some of the data on human gene sequences is already owned by private companies, which are filing patent applications despite arguments about whether the sequences should qualify for patenting. Another concern is that if patents are given to genetically modified proteins or DNA that are key active ingredients in new vaccines, it could lead to significant price increases by limiting competition to a narrow field of vaccine producers, who now usually obtain patents for the production process rather than the chemical products contained in vaccines.

264. Intellectual property issues in relation to biotechnology have been discussed within the WTO, both in the Committee on Trade and Environment and in the TRIPS Council's review of Article 27.3(b), relating to patentability of biotechnological inventions. In the TRIPS Council, the issues raised include ethical and moral questions relating to the patentability of life-forms; what qualifies as inventive; and how concrete the potential use needs to be - e.g. with respect to DNA and the genome, whether this requires that the gene's function be specified, or a commercial application related to it. In addition, there is debate surrounding the definition of certain terms in the TRIPS Agreement such as "microorganisms"; the meaning of effective sui generis protection of



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new plant varieties, including its relationship to the International Convention for the Protection of New Varieties of Plants (UPOV); the relationship between the TRIPS Agreement and the Convention on Biological Diversity; and the protection of traditional knowledge.

(ii) Food security and safety

265. Biotechnology also holds potential to make food production more efficient, contribute to increased harvests, and improve public health. For example, "Golden Rice", a genetically modified rice that produces beta-carotene which the body converts into vitamin A, may help to alleviate vitamin A deficiency, a major cause of blindness in developing countries of Africa and Asia. But there is not yet complete information on the costs and health effects of this new product compared to alternative methods to reduce blindness. This issue reflects broader safety concerns about genetically-modified foods, such as: the potential for gene transfer from genetically modified plants to microbial or mammalian cells; the transfer and expression of a functional antibiotic resistance gene to recipient cells in people or animals; and, allergenic effects.

266. National and regional regulatory systems exist to examine the safety of genetically modified foods, but there are significant differences in testing methods that produce inconsistent outcomes of safety evaluations. Efforts are under way by WHO and FAO, and the Codex Alimentarius Commission, to determine needed changes in safety assessments of genetically modified foods, and in international rules on the handling of genetically modified foods. An Inter-Agency Network for Safety in Biotechnology (IANB) was formed in 1999, in Paris at the OECD. Its objectives are to share information and to promote co-operation amongst inter-governmental agencies with activities related to safety in biotechnology.⁷⁷

267. Despite the heated public debate in Europe and elsewhere, there has been little formal consideration of the health and safety aspects of biotechnology and GMOs in WTO fora. The most detailed discussions to date have occurred in the TBT Committee, where the GMO labelling requirements of various Members have been under scrutiny. Issues relating to food safety and to the potential spread of genetically modified seeds into the environment may fall under the SPS Agreement. The SPS Committee had discussions with respect to the negotiations of the Biosafety Protocol. The need for transparency and the development of international standards was also discussed in relation to concerns about GMO-related notifications and, in other cases, with regard to the



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absence of notification of measures to the WTO. Also, in the context of the ongoing agriculture negotiations, there has been a proposal to focus disciplines to ensure that processes covering trade in products developed through "new technologies" are transparent, predictable and timely. Nevertheless, there has not yet been substantive discussion of either of these proposals.

(iii) The Cartagena Biosafety Protocol

268. The Cartagena Biosafety Protocol⁷⁸ gives governments the right to prohibit imports of living modified organisms (LMOs) intended for planting or other direct release into the environment for health and environmental reasons. LMOs are basically GMOs such as seeds that have not been processed, and that could live if introduced into the environment.⁷⁹ Prior informed consent must be given before trade can take place, and precautionary prohibitions may be maintained. For products which contain living modified organisms but which are intended for direct consumption or further processing, the requirements are less onerous, but require information on GMO products to be submitted through a clearinghouse mechanism prior to trade, and again precautionary prohibitions are possible. The objective of the Protocol is to ensure an adequate level of protection in the field of safe transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

269. While there is scope for complementarity between the Protocol and WTO agreements, there is also scope for inconsistencies. For example, under the Cartagena Protocol, a country which wants to export LMOs - such as seeds for planting - must seek advance informed agreement from the importing country before the first shipment takes place, and, under certain circumstances, the importer can ask the exporter to carry out the risk assessment. Under the SPS Agreement, it is up to the importer to justify its import measure on the basis of a risk assessment. Here the obligations are different. It is unclear which international agreement would rule in the event of a conflict and to what extent these apparently conflicting obligations would, in practice, be a problem. In any case, if a dispute were brought to the WTO, a panel or the Appellate Body could



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only judge compliance with WTO Agreements. Nevertheless, in doing so the Cartagena Protocol would presumably be taken into account, when the two disputing parties are also signatories of the Protocol.

2. Information technology

270. Informatics and telecommunications are transforming societies and many economies, raising job productivity, creating new jobs, and speeding up communication and information flows. This trend has already stimulated changes in health care delivery, and has the potential to foster greater cross-border supply of health services. Diagnostic and treatment services can currently be supplied across borders using telecommunications technology. For example, a patient may be seen at a video-equipped facility by a medical consultant in another country. Interpretative services, such as those related to pathology specimens and diagnostic imaging are the most immediate growth opportunity given that the transmission of static images requires far less bandwidth than video for diagnosis. In the longer term, information technology allowing real-time three-dimensional control of precision instruments with operator feedback may even support the remote performance of surgical procedures. Its use in cross-border trade to serve the poor, however, could be constrained by high cost and lack of infrastructure and trained personnel.

271. Since 1998, WTO Members have been engaged in a comprehensive work programme aimed at examining trade-related issues relative to electronic commerce. At the time the work programme was initiated, Members undertook to continue the practice of not imposing customs duties on electronic transmissions. In addition, pharmaceuticals ordered electronically, for instance, should be subject to the same border treatment, e.g. tariffs and product verification, as those ordered by regular mail. Except for protection of life or health, pecimens Aeficatiksub 3hsubj2tds 6,g i foy2.1(, for instance, should be srulranssh oppoth, pecime, aorde (Adlund dents, zaniga,jT*(i 20





(c) The relationship between the TRIPS Agreement and the Convention on Biological Diversity in general and the operational implementation of the provisions of prior informed consent and fair and equitable benefit sharing as set out in Article 8(j) of the Convention on Biological Diversity in particular.

(d) The relation of work in the TRIPS Council with intergovernmental discussions on this issue such as in the CBD, WIPO, FAO and UNCTAD.

275. Many of these issues were discussed in a WHO workshop on intellectual property rights in the context of traditional medicine, in December 2000.⁸⁰ Other work in this area is being pursued by WIPO to explore how existing intellectual property rights can be used to provide protection to traditional medicine practitioners. Others stress the difficulties that herbal medicines and traditional medicinal practitioners will face if they rely only on Western models of intellectual property rights protection. Thus, there is a need to develop alternative approaches to promote and protect traditional medicine and assure an equitable sharing of its benefits. In addition, it will be important to promote easy access to traditional medicines for health care needs of developing countries.

276. These three issues - biotechnology, information technology, and protection of indigenous medicines and knowledge - are among several emerging health-and-trade



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maximizing their mutual benefits, is an example of policy coherence. The term refers to efforts to seek synergies between policies in different areas in support of their common goals - in this case, poverty reduction, human development and economic growth. The need for greater policy coherence at the international level has been highlighted at several recent UN conferences, while many national governments are striving to bring foreign trade and development policies into closer alignment.

281. The final section of this report stresses the importance of the goal of coherence between health and trade policies at the national and international level. It describes efforts in two countries - Canada and Thailand - directed towards health-and-trade policy coherence at the national level. Second, it examines efforts to coordinate activities at the international level between WHO and WTO and reviews opportunities to enhance policy coherence. It concludes with suggestions for new avenues through which health, trade and development officials can pursue greater policy coherence and thus make a stronger contribution to the goal of more sustainable human and economic development.

TOWARDS POLICY COHERENCE AT NATIONAL AND INTERNATIONAL LEVELS

B. TOWARDS POLICY COHERENCE AT NATIONAL AND INTERNATIONAL LEVELS

282. Policy coherence is easy to support in principle but hard to achieve in practice. It requires regular dialogue, consultation, and coordinated action between policy-makers and advisors on all sides. Smilar challenges exist, and are being addressed in other policy areas as well (trade and finance, trade and environment, for example). Two divergent perspectives underlie the interface between trade considerations and health interests. From a Trade Ministry perspective, health may be looked at in the context of trade agreements that are essentially about liberalizing trade. By contrast, health professionals may perceive that the need to submit health measures to trade scrutiny will subordinate health to trade interests. These perspectives may cause tension between "trade people" and "health people", and render coherence difficult.

283. Safeguarding health is an objective that nobody would question. In the context of the WTO, government officials involved are likely to examine carefully how health objectives translate into measures with an effect on trade. For example, WTO rules require non-discrimination in the application of trade measures. Discrimination may be particularly difficult to justify on health grounds, as it should not matter where unsafe



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goods or services come from: for instance, meat containing a certain hazardous contaminant should be equally unwelcome irrespective of its origin. The Asbestos case illustrates another example of a health measure with an effect on trade (see section III, Box 10). In this case, there was a need to determine whether the measure was "necessary" to qualify for a general exception under Article XX(b). It was rather easy to determine that asbestos posed a serious health risk, but it was more difficult to decide whether the measures taken did not significantly favour French industry or whether "controlled use" as proposed by Canada might not offer the right level of health chosen by France. Through a process of "weighing and balancing" of different factors involved (such as the importance of the common interests or values protected by the measure or the efficacy of such measure in pursuing the policies aimed at) an import ban was ultimately found necessary to protect health.

284. Emphasizing and clarifying the scope that exists in WTO Agreements for conducting health-sensitive policies, and strengthening the capacity of national health authorities to contribute to policy coordination and to articulate "their" negotiating priorities may contribute to avoiding tensions. In this vein, many countries are increasing collaboration between trade and health to achieve national goals; Thailand and Canada are two such countries.⁸¹ These national examples are followed by a discussion of how WHO and WTO are seeking improved cooperation at the international level.

(i) Thailand

285. The Thai Ministry of Health became aware of the importance of international trade law to health issues in the mid 1980s, when Thailand was placed on the US Section 301 "trade-watch" list, because Thai law did not grant patents for pharmaceutical products. This was also the period when Thailand was engaged in Uruguay Round negotiations, and this led to discussions about the health implications of adding intellectual property rights protection to international trade agreements. Around the same period, trade and health groups in Thailand debated the desirability of opening up the tobacco market to foreign cigarette manufacturers. As a result of the need for a common government policy on these issues, the Health Ministry developed a strong, positive relationship with the Commerce Ministry's Department of Business Economics, which is responsible for all international trade agreements, including those in the WTO.

^{81.} Our thanks go to the Health Ministries of Thailand and Canada who contributed these case studies. It would be instructive to have more information on policy coordination processes between health and trade ministries in other countries that may have chosen different approaches to pursue policy coherence between trade and health.



286. The Thai government's Foreign Trade Policy Committee, chaired by a Deputy Prime Minister, includes the Permanent Secretary for Health. This provides a high-level forum in which health interests can be considered in trade policy discussions. The Committee has several subcommittees addressing trade issues and the Permanent



(ii) Canada

289. Collaboration between the Canadian health and trade ministries began in the early 1990s, prompted by negotiations with the United States and later Mexico on what became the North American Free Trade Agreement (NAFTA). Collaboration continued as Canada negotiated various bilateral trade agreements, the Uruguay Round of the WTO, and the Multilateral Agreement on Investment (where there was no agreement). Discussions included sanitary and phytosanitary measures, technical barriers to trade, intellectual property, investment, services, government procurement, and temporary entry of professionals.

290. Since 1999, the health department - called Health Canada - has taken a more strategic and coordinated approach to the interface with international trade issues to ensure early consideration of health policy concerns in trade discussions. This change was prompted by increasing recognition within the health ministry of the growing impact of international trade on health. This led to closer liaison and dialogue with trade officials and extensive participation by health ministry officials at all levels in the trade ministry's policy committees, working groups, and interdepartmental consultations. Trade officials also sought the participation of other departments to help prepare positions on current trade negotiations.

291. To forge a productive working relationship between the two ministries, Health Canada established a contact/focal point for trade officials to make it easier for trade officials to seek the views of the health ministry. The International Affairs Directorate assumed this role and set up a working group on international trade policy within Health Canada to bring together various health officials involved in health-and-trade issues (e.g., food safety, pharmaceuticals and patent protection, technical barriers, health



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obligations under the WTO. In practice, this means that measures based on international standards, guidelines or recommendations developed by the Codex are presumed to be consistent with the SPS Agreement, and Members who base their measures on them can be confident of their compliance with WTO rules, and confident that consumers are being adequately protected.

297. Moreover, the link between the standard-setting work of the Codex and the scientific input from the WHO is important in that it lends some dynamics to the trade rules. While countries negotiate trade rules in the WTO, the WTO is not a scientific body and it does not develop standards. The WHO's active presence at SPS meetings has allowed WHO staff to provide advice on health matters relevant to trade. Examples are WHO's input on the risks of mad cow disease (BSE) to human health, and on the health effects of genetically-modified organisms in food. WHO representatives have also provided expert testimony to WTO dispute settlement panels, for example in the EC-Hormones case.

298. Aside from formal meetings, staff from the two organizations participate in regional or country-level meetings sponsored by one or both agencies for the purpose of providing technical assistance. For example, the WHO together with FAO provides technical assistance to countries to help them conform to SPS requirements by strengthening National Codex Committees, providing training in risk analysis, surveillance and control of food-borne diseases, and updating food legislation and improvement of food safety control systems. The WTO has frequently organised national or regional workshops on the SPS Agreement in close cooperation with Codex, the OIE and the secretariat of IPPC. In other contexts, the WHO has provided countries with technical advice on how to integrate public health perspectives into national patent legislation, and legally available options under the TRIPS agreement to promote equitable access to essential medicines. In September 2001, the WHO held a week-long training course for health and trade officials on the health implications of multilateral trade agreements, to which the WTO contributed.⁸³

299. In addition to the SPS Committee, the WHO's official relationship with the WTO also includes observer status in the TBT and TRIPS Councils, and at the WTO Ministerial Meetings, though not in the General Council, for instance.⁸⁴ Observer status in relevant bodies increases the WHO's ability to identify mutually-supportive health and trade policies, and to help forestall potential conflicts. The WTO has observer status at the

^{83.} More information on this course can be obtained directly from the WHO.

^{84.} The issue of observer status is decided by WTO Member governments on a consensus basis.





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Box 19 Some trade and health issues in WTO bodies and other international fora (cont'd)	
SPS and TBT	Efficient participation of developing countries in standard-setting processes Biotechnology BSE Antibiotic resistance
FCTC	Negotiations on Framework Convention on Tobacco Control Trade effects of potential provisions concerning international harmonization of taxes, packaging and labelling requirements, exemption of tobacco products from reduced tariffs under regional trade agreements, and advertising restrictions
IHR	Revision of the International Health Regulations. Consistency between WHO recommendations in "health emergencies of international concern" and SPS rules
Codex	Codex food safety standards Effective participation of developing countries in the Codex standard-setting processes (safety, quality and nutritional uses) Safety standards and pre-market approval systems for foods derived from biotechnology (genetically modified foods)

(i) Addressing health issues in WTO rules

302. This document has highlighted ways in which WTO rules affect public health policy across a range of issues (infectious disease control, food safety, tobacco, environment, access to drugs, health services, food security and some emerging issues relevant to health such as biotechnology). All of these issues are addressed at regular meetings of the WTO. They may come up for discussion under a specific agenda item, as did the



(iii) The need for evidence to inform policy

305. To monitor and evaluate the health impacts of existing WTO agreements and assess the potential health effects of proposed WTO rules and disciplines, there is a need for research and analysis. A current obstacle to analysis is the absence of systematic data collection, particularly in the area of trade in health services. Major data



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decide to include health officials on their international negotiating teams. The negotiations provide a crucial opportunity to address perceived imbalances, constraints or clarify provisions that are not sufficiently clear; they also provide an opportunity for amendments to be argued for and made, or even the creation of new agreements or understandings.

307. The importance of addressing concerns in the context of negotiations cannot be overstated. Negotiation in the WTO is a multilateral process, i.e. all Members of the Organization are involved and treated equally. While this makes it difficult and time-consuming to make progress on difficult and/or controversial issues, an eventual agreement can only be reached by consensus of all members. In case of disagreement on the meaning or the implications of a specific provision of a WTO agreement, individual countries can bring the matter to the Dispute Settlement Body. It would then be up to a panel, and possibly, the Appellate Body, to resolve the dispute.

(v) Accession

308. When a country applies for WTO membership, health and other officials have an additional opportunity to learn about the WTO and its agreements. It also provides an important avenue for health professionals in acceding countries to influence health-related trade policy. Accession is a negotiated process. Experience shows that the breadth and depth of the commitments, i.e. the number of sectors included and the levels of access bound, undertaken by acceding countries has increased in recent years.

(vi) Capacity-building

309. Policy coherence requires coordination across the areas of trade and health. This point has been emphasized throughout this whole report. In many developing countries, let alone least-developed countries, such capacity does not exist, or is very weak. Perhaps the greatest challenge in making trade a positive force for development is ensuring that the benefits accelerate development in the poorest countries and for the poorest people. The root of many health problems in developing countries is poverty. The Integrated Framework (IF) for Trade-Related Technical Assistance was set up to help LDCs become more integrated into the global economy.⁸⁶ During the reorganization of the IF in the summer of 2000, the six core agencies (IMF, ITC, UNCTAD, UNDP, World Bank and WTO) stressed that its objective was to ensure that trade policy is "articulated in a broad development context." The group emphasized that its advice and support



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should be closely linked to efforts by LDCs to develop national development strategies, either in the context of preparing Poverty Reduction Strategy Papers (PRSPs) for the World Bank and IMF, or under the UN Development Assistance Framework. WHO might work more closely with the IF to ensure that the trade-related advice offered by the international partners reflects health interests and objectives. In turn, work on these issues at the country level would inform policy-making at the international level in all of these organizations.

(vii) Two critical ingredients to policy coherence

310. Health and trade officials in all countries, along with representatives of civil society and the private sector, may use a wide array of fora and opportunities for achieving more coherence between policies. The resulting synergies would make a valuable contribution to more equitable and efficient human and economic development around the world. As already indicated above, there seem to be two critical ingredients, which significantly contribute to effective health-and-trade policy coordination.

311. The first is leadership. Key people in relevant ministries or international organizations must be knowledgeable about the issues of mutual concern and share information, including on upcoming policy decisions. Senior officials can set an example for collaboration by demonstrating their own commitment - in time, visibility, and resources - to cross-sectoral discussions and debates, including efforts to involve and inform civil society. Leadership is particularly important to avoid potential conflicts between hitherto not closely coordinated policy areas, such as health and trade.

312. Second, cross-sectoral institutions are important. Standing committees, task forces, working groups, or other bodies - whether at the national or international level that allow for regular contacts facilitate collaboration. In addition, government agencies could consult regularly with civil society, the private sector and academic experts to generate knowledge and public awareness of the issues, which in turn feed into the political decision-making process.

313. With these key ingredients, it is more likely that health and trade policies will interact in ways that are mutually supportive within the framework of global rules and institutions. The interface between health and trade becomes more critical in a fast-changing, more interconnected world. With the information and resources available today, policy synergies can be used to advance the common goal of sustainable human development for all peoples.



Inside US Trade *http://www.insidetrade.com*

A weekly newsletter published by Inside Washington Publishers with in-depth coverage of US and international trade policy and WTO-related issues. Available to subscribers in on-line or print version. For subscription details contact iwp@sprintmail.com

World Trade Organization *http://www.wto.org/english/res_e/focus_e/focus_e.htm* The WTO publishes an electronic newsletter, FOCUS, 10 times a year in English, French and Spanish. Articles provide updates on key WTO activities and preview upcoming meetings. You can subscribe from any page on the WTO website by clicking on "Register" and choosing your area of interest.

Trade, Development and Economics Journals

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INTERGOVERNMENTAL TRADE AND DEVELOPMENT ORGANIZATIONS

World Trade Organization *http://www.wto.org* Rue de Lausanne 154 CH-1211 Geneva 21, Switzerland Tel: (41-22) 739 51 11 Fax: (41-22) 731 42 06 email: enquiries@wto.org

The WTO's top level decision-making body is the Ministerial Conference which meets at least once every two years and is attended by Member governments' leading trade officials. WTO decisions are made by the entire membership, nearly always by consensus. WTO agreements must be ratified in all members' parliaments.

The General Council, which is usually attended by ambassadors and heads of delegation in Geneva, or officials sent from Members' capitals, meets several times a year in the Geneva headquarters. The General Council also meets as the Trade Policy Review Body and the Dispute Settlement Body.

At the next level, the Goods Council, Services Council and Intellectual Property (TRIPS) Council report to the General Council. The Goods Council has several committees, among them those on SPS and TBT. (Note: WHO currently has observer status in the TRIPS Council and the SPS and TBT Committees). Numerous specialized committees, working groups and working parties deal with the individual agreements and other areas such as the environment, development, membership applications and regional trade agreements, trade and investment, trade and competition policy, and transparency in government procurement.

The WTO Secretariat, based in Geneva, has around 550 staff and is headed by a Director-General. The Secretariat does not have the decision-making role common to other international agencies. Instead, its role is to provide technical support for the various councils and committees and the ministerial conferences, deliver technical assistance to developing countries, analyse world trade, and provide liaison with the public and media. The Secretariat also provides legal assistance in the dispute settlement process and advises governments wishing to become members of the WTO.



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Technical Assistance and Training for Developing Countries. For an overview of WTO's TA, see: http://www.wto.org/english/thewto_e/teccop_e/teccop_e.htm#guide

The WTO organizes around 100 technical cooperation missions to developing countries annually. It holds on average three trade policy courses each year in Geneva for government officials. Regional seminars are held regularly, with a special emphasis on African countries. Training courses are also organized in Geneva for officials from countries in transition to market economies. The WTO has also set up reference centres in over 100 trade ministries and regional organizations in capitals of least-developed and developing countries, providing computers and Internet access to enable ministry officials to keep abreast of events in the WTO in Geneva through online access to the WTO's immense database of official documents and other material.

For a list of reference centres, see

http://www.wto.org/english/tratop_e/devel_e/listrc_e.doc. LDCs currently are served by the Integrated Framework for Trade-Related Technical Assistance (IF). For further information, go to: *http://www.ldcs.org/*

The Trade Policy Review Mechanism provides a forum in which Member governments may openly discuss and provide an objective analysis of each others' trade policies, separate from the compliance-related and legal work of the WTO. Country Trade Policy reports provide an objective and independent review of the trade policies and practices of individual Members and portray an overall picture of the institutional interaction in trade policy formulation and implementation and the effect of policies on different sectors. In some cases, the reports serve as an input to trade policy formulation and several developing and least developed country Members have found the reviews valuable in identifying areas for potential technical assistance. See:

http://www.wto.org/english/tratop_e/tpr_e/tpr_e.htm



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UN Conference on Trade and Development (UNCTAD) http://www.unctad.org/ Palais des Nations 1211 Geneva, Switzerland Tel: (+41 22) 907 12 34 Fax: (+41 22) 907 00 43 E-mail: ers@unctad.org

UNCTAD is the focal point within the United Nations for development and interrelated issues in the areas of trade, finance, technology, investment and sustainable development. Its main goals are to maximize the trade, investment and development opportunities of developing countries. UNCTAD pursues its goals through research and policy analysis, intergovernmental deliberations, technical cooperation, and interaction with civil society and the business sector. UNCTAD conducts a number of meetings and produces publications to support countries in preparing for a new round of trade negotiations (see "Positive Agenda" site: http://www.unctad.org/en/posagen/index.htm).

UNCTAD has sponsored several expert meetings on health and trade issues, including one with WHO in 1998 on International Trade in Health Services (see UNCTAD/ ITCD/ TSB/ 5 or WHO/ TFHE/ 98.1: International Trade in Health Services: A Development Perspective, available at:

http://www.unctad.org/en/pub/poitcdtsbd5.en.htm. Recently, UNCTAD sponsored a meeting, in conjunction with WIPO and the Convention on Biological Diversity, to examine systems for protecting traditional knowledge, including traditional medicine knowledge and practices (see papers at: http://www.unctad.org/en/special/c1em13do.htm. UNCTAD also prepared a study on International Trade in Genetically Modified Organisms and Multilateral Negotiations: A New Dilemma for Developing Countries in July 2000 (UNCTAD/ DITC/ TNCD/ 1, unedited version).



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International Trade Centre (ITC) Palais des Nations 1211 Geneva 10, Switzerland Tel: (+41 22) 730 01 11 Fax: (+41 22) 733 44 39 E-mail: itcreg@intracen.org http://www.intracen.org

The International Trade Centre (ITC) based in Geneva is the focal point in the United Nations system for technical cooperation with developing countries in trade promotion - both export and import operations. ITC is operated jointly with WTO and UNCTAD, and is an executing agency of UNDP-financed projects in developing countries related to trade promotion. ITC conducted a study on the implications of the multilater-al trade agreements for international trade in medical devices (ITC/ 280/ 2D/ 99-III-TO). In conjunction with WHO, ITC's Market News Service issues a monthly report on Pharmaceutical Starting Materials/ Essential Drugs, giving up-to-date indicative prices and relevant commercial data trends on 206 pharmaceutical Starting Materials used in the manufacturing of essential drugs (available on a subscription basis). ITC plans to publish a handbook on tourism and health services.

Regional Trading Organizations

For links to the major regional trading organizations, e.g. NAFTA, Mercosur, ASEAN, European Union, etc., see: *http://www1.worldbank.org/wbiep/trade/TD_REG_ORG.html*.

The European Commission's Trade Directorate has set up several civil society issue groups, one of which is health (*http://europa.eu.int/comm/trade/2000_round/issuegr.htm*). For information on EU trade policy developments, see: *http://europa.eu.int/comm/trade/.*

In addition, some regional inter-governmental organizations provide advice and information on trade-related issues. For example, the Organization of American States (OAS) Trade Unit assists the 34 OAS member countries with matters related to trade and economic integration in the Western Hemisphere and, in particular, with their efforts to establish a Free Trade Area of the Americas. Go to: *http://www.oas.org/* and click on "Trade and Integration" at the top of the website.



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World Bank *http://www.worldbank.org* 1818 H Street, NW Washington, DC 20433, USA Tel: 01-202-477-1234 Fax: 01-202-477-6391

The World Bank operates a comprehensive "International Trade and Development" website: *http://www1.worldbank.org/wbiep/trade/*. It serves "as a research, training and outreach tool for people interested in trade policy and developing countries. Particular emphasis is placed on the new trade agenda associated with the upcoming round of WTO negotiations. In addition to the capacity-building activities of the World Bank Institute and the World Bank's Research Group, it provides information on complementary programs through the Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries (see above under WTO) and the joint World Bank-WTO website (see below).

The site offers distance learning courses and provides an extensive set of information (including data and databases) on various trade topics, including services, intellectual property rights and standards which may be of interest to a health audience. For example, the Standards site, contains many papers and resources providing insight into the effect of environmental, health, and safety requirements on producers of goods, services, and agricultural products. The site also has papers in Spanish, Russian and Chinese.

The Trade and Development Centre (*http://www.itd.org/*). The World Bank's Economic Development Institute runs a joint venture with the World Trade Organization called Information Technologies for Development (ITD). Its website serves "anyone interested in social and economic development and how these are related to trade. It offers information, analysis and comment on these issues and an opportunity to exchange views." Included are interactive guides and training courses on trade policy and interesting case studies from Africa and India on trade-and-health topics; one case describes the failed attempt in the US to patent turmeric for its healing properties.





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Office International des Epizooties (OIE) http://www.oie.int 12, rue de Prony, 75017 Paris, France Tel: 33 - (0)1 44 15 18 88 Fax: 33 - (0)1 42 67 09 87 Website: www.oie.int E-mail: oie@oie.int

Founded in 1924, the OIE is an intergovernmental organization with 158 members. Its main aims are to guarantee the transparency of animal disease status world-wide, collect, analyze and disseminate veterinary scientific information, provide expertise and promote international solidarity for the control of animal diseases; and guarantee the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products. The Office is placed under the authority and control of an International Committee consisting of Delegates designated by the Governments of Member Countries. The day-to-day operation of the OIE is managed by a Central Bureau situated in Paris, placed under the responsibility of a Director General elected by the International Committee. The Central Bureau implements the resolutions passed by the International Committee and developed with the support of elected Commissions.

Organization for Economic Cooperation & Development (OECD) http://www.oecd.org/ 2, rue André Pascal F-75775 Paris Cedex 16, France Tel.: +33-1-45-24-8200

OECD's Trade Committee has not taken up trade-and-health related activities, though there have been some proposals to initiate activity in health-care services (e.g. by EC and some EU Member States). Biotechnology-related work at OECD is undertaken in several different tracks (see *http://www.oecd.org/ehs/icgb/*): e.g. food safety, agriculture, intellectual property rights, and human health. OECD's main focus is on the internation-al harmonization of regulatory oversight in biotechnology and to ensure that environmental health and safety aspects are properly evaluated while avoiding non-tariff trade barriers to biotechnology products. OECD has taken an active role in the food safety and quality debate, in particular the scientific and health aspects of genetically modified (GM) foods. The report on "Food Safety and Quality: Trade Considerations" published in November 1999 examines trade conflicts arising from food safety and quality issues, summarizes the key international agreements, and reviews the potential contributions of economic analysis to conflict resolution.



South Centre *http://www.southcentre.org/* Case Postale 228 1211 Geneva 19, Switzerland



World Intellectual Property Organization (WIPO)http://www.wipo.org/P.O. Box 18



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regional offices around the world. It defends the rights of all consumers, including poor, marginalized and disadvantaged people, by campaigning at the international level for policies which respect consumer concerns. Among its current campaigns are: (1) Trade and Economics, to ensure that international trade agreements benefit consumers by lobbying at the WTO and other global and regional organizations, and researching traderelated issues such as agricultural liberalization, intellectual property rights, competition policy and investment policy; (2) Health, to promote the rational use of essential drugs, universal high quality health care services, and patients' rights, and (3) Food and Sustainable Agriculture, to improve nutrition and food standards by involvement in the Codex Alimentarius Commission and campaigning on GMO and food security issues. A publications catalogue, briefing papers, press releases and updates about campaigns are included on its website.

Consumers International also serves as the Secretariat for the Trans Atlantic Consumer Dialogue (within Cl's Programmes for Developed Economies). The Transatlantic Consumer Dialogue (http://www.tacd.org/) is a forum of US and EU consumer organizations which develops and agrees joint consumer policy recommendations to the US government and European Union to promote consumer interest in EU and US policy making. TACD addresses issues of high priority to consumer organizations such as trade in services, access to medicines, GM foods, private data protection and transparency in government.

Consumer Project on Technology (CPT) http://www.cptech.org P.O. Box 19367 Washington, DC 20036, USA Tel: +1.202.387.8030 Fax: +1.202.234.5176 By email, for intellectual property and health care: James Love : love@cptech.org or Thiru Balasubramaniam : thiru@cptech.org

The Consumer Project on Technology is a non-profit, consumer organization started by Ralph Nader in 1995. Currently CPT is focusing on intellectual property rights and health



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care, electronic commerce (very broadly defined) and competition policy. Its website has a large number of documents, articles, and correspondence among key actors involved in these issues. For example, its web page on health care, regional trade agreements and intellectual property rights, has links to IP activities in FTAA, NAFTA & APEC and other regional trade groups: (*http://www.cptech.org/ip/health/trade/*). The country disputes page has documentation on IP-pharmaceutical issues in 12 countries *http://www.cptech.org/ip/health/country/*.

European Public Health Alliance (EPHA) 33 rue de Pascale 1040 Brussels, Belgium Tel: +32 2 230 30 56 E-mail: epha@epha.org

http://www.epha.org/

EPHA represents over 70 non-governmental and other not-for-profit organizations working in support of health in Europe. EPHA issues a bi-monthly magazine on health policy in the EU and Europe - the European Public Health Update, to which non-members can subscribe, available in English, French and German. EPHA organized a meeting in April 2000 on how WTO agreements and EU policies may affect health policies, both in developing countries and European countries. Some of the papers presented at that meeting are available at: http://www.epha.org/public/campaigns/wto.htm

Health Action International http://www.haiweb.org/ c/o: HAI Europe Jacob van Lennepkade 334-T 1053 NJ Amsterdam, The Netherlands Tel: (+31-20) 683 3684 Fax: (+31-20) 685 5002 E-mail: hai@hai.antenna.nl

HAI is a non-profit, global network of more than 150 health, development, consumer and other public interest groups in more than 70 countries working for a more rational use of medicinal drugs. In addition to the European office, HAI has regional offices for



standards are now being revised - see http://www.iso.ch/9000e/revisionstoc.htm for updates on this revision process. Within the health field, ISO has developed standards for mechanical contraceptives (condoms, IUDs and rubber diaphragms), certain medical devices or surgical instruments, and lab glassware among other things. Recently, ISO developed eco-labelling standards (ISO 14020 and ISO 14024).

MEDACT http://www.medact.org/ 601 Holloway Road London, N194DJ, UK Tel: 020 7272 2020 Fax: 020 7281 5757 E-mail: info@medact.org

Medact is an organization of health professionals challenging social and environmental barriers to health worldwide. It highlights the health impacts of violent conflict, poverty and environmental degradation, and works to eradicate them. Medact has a report on "The World Trade Organization: Implications for Health Policy", available on its website.

Médicins sans Frontières (MSF) http://www.msf.org/ MSF International Office: Rue de la Tourelle, 39\$ Brussels, Belgium, 1040 Tel: +32-2-280-1881 Fax: +32-2-280-0173



agreements (mostly TRIPS). For more information, see: *http://www.accessmed.msf.org/* which has links to numerous documents and articles from around the world.



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Globalisation and Social Policy Programme (GASPP) http://www.stakes.fi/gaspp/ C/ o: STAKES (National Research and Development Centre for Welfare and Health) PO Box 220 FIN-00531, Helsinki, Finland Tel: +358 9 39 671 Fax: +358 761 307

GASPP is a five-year (1997-2002) research, advisory, education and public information programme based jointly at STAKES (National Research and Development Centre for Welfare and Health) based in Helsinki, Finland and the Centre for Research on Globalisation and Social Policy, Department of Sociological Studies, University of Sheffield, England. GASSP conducts research, provides policy advice, organizes conferences and seminars and publishes a number of books and papers (and a journal starting in 2001). GASSP currently has projects on: (1) the implications of the WTO and international trade agreements for health and social policies, and (2) the health implications of other EU policies.

Harvard University, Center for International Development

The Global Trade Negotiations Home Page *http://www.cid.harvard.edu/cidtrade/* is a resource for those interested in analytical information on the multitude of issues, debates, government positions, and organizations that surround international trade policy. It has a large collection of research papers and articles, links to other websites, as well as contact information for additional sources. The site allows you to navigate the Internet to find information on global trade policy and negotiations. Resources and links are organized by: Actors (National Governments, NGOs, International Organizations) and Trade Issue (SPS/TBT, electronic commerce, intellectual property and services, among many others).



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http://nt1.ids.ac.uk/eldis/

Institute of Development Studies (IDS) University of Sussex Brighton, United Kingdom Tel: +44 1273 877330 Fax: +44 1273 621202 E-mail: eldis@ids.ac.uk

IDS operates ELDIS, an Internet-based "Gateway to Information Sources on Development and the Environment". It provides descriptions and links to a wide variety of information sources, including online documents, organization's WWW sites, databases, library catalogues, bibliographies, and e-mail discussion lists, research project information, map and newspaper collections. It also describes available databases, CD-ROMs, etc. ELDIS has a special site devoted to international trade issues, complete with short background papers and links to many other international and research institutions, and statistical sources: http://nt1.ids.ac.uk/eldis/trade/trade.htm. ELDIS maintains a similar site devoted to international health issues, at: http://nt1.ids.ac.uk/eldis/health/health.htm

Links to other trade-related institutes can be found at:

http://www1.worldbank.org/wbiep/trade/TD_INSTITUTIONS.html Links to institutes or organizations that study and research general globalization issues: *http://www.globalpolicy.org/globaliz/websites.htm*

GLOSSARIES OF COMMON HEALTH AND TRADE TERMS

WTO Glossary of Terms: An informal guide to 'WTO speak' http://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/brief22_e.htm

Prepared for the Fourth WTO Ministerial Conference in November 2001. It is an online abridged version of the WTO Trilingual Glossary, "an immense vocabulary of trade"



in English, French and Spanish. Many entries contain a reference to relevant sources and include acronyms, definitions, explanatory notes and other useful information. To order the Trilingual Glossary, order from the WTO on-line bookshop,

e-mail: publications@wto.org or go to: http://www.wto.org/english/res_e/booksp_e/book-



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Glossary of trade terms, expressions and history of the multilateral trading system since 1947. This book is aimed at non-specialists using trade policy terms on a daily basis. The dictionary is available in English and can be ordered at *http://www.adelaide.edu.au/cies/orderform.htm.*