The Impact of WTO Agreements on Health and Development Policies

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Summary

This policy brief assesses and analyses the role and relevance of the World Trade Organisation (WTO) and the trade agreements it hosts from a health policy point of view paying particular attention to matters of importance for developing countries. It first discusses trade matters in a general framework, then in terms of trade flows and their impacts on health, and finally analyses the implications of three WTO agreements for health and health policies in developing countries.

International Policies, Trade and Development

WTO

The decision to establish the WTO was taken in April 1994 in Marrakech, Morocco, at the completion of the eight-year "Uruguay Round" of renegotiations of the General Agreement on Tariffs and Trade (GATT). The WTO is the successor to GATT, but does far more than simply continue GATT's role. Unlike GATT, the WTO has an institutional foundation and WTO commitments are full and permanent. According to UNCTAD, the persistence of generalised poverty in developing countries is related less to their lower level of integration into the global economy or to insufficient trade liberalisation than it is to the form of trade integration. International trade is of major importance to the economies of the Least Developed Countries (LDCs). During 1997-1998, exports and imports of goods and services constituted on average 43% of their GDP. But while recent World Bank analyses have promoted the benefits of trade liberalisation in poverty reduction, UNCTAD has pointed out that rapid and deep trade liberalisation has been associated, at least in the short term, with a rising incidence of poverty.

The inequality between the developed and developing world has been reflected in the nature of the...
Uruguay Round of negotiations and the resulting WTO agreements. In the Uruguay Round, developing countries were reluctant to approve the TRIPS Agreement governing intellectual property, but it was presented to them as a part of the overall WTO package. Attention also needs to be paid to bilateral agreements that may be used to pressure to countries to liberalise further or to provide protection of intellectual property beyond what has been agreed in the WTO. The WTO has also emerged as a new potential forum for many labour, environment and health related matters. But it is unlikely that the WTO will be the appropriate organization to address these issues. There are several UN bodies with broad representation and normative powers, such as the World Health Organisation (WHO) and the International Labour Organisation (ILO). In health and public health matters, it would make more sense to strengthen the powers of the WHO and ILO vis-à-vis the WTO than to shift more health-related decision-making to the WTO.

Health Policy Advice

1. A rules-based system of global trade, which is what the WTO is, is preferable to a no rules system. In terms of bargaining power, developing countries may have more influence in a multilateral system such as the WTO than in a bilateral arrangement.

2. Mainstream trade policies often assume that welfare will increase as a result of the economic growth that is expected from increased liberalization of trade. This assumption may not be correct. Of importance in this respect is the way in which countries are integrated into the global economy and how any economic growth is distributed.

3. The benefits to developing countries from the WTO’s trade agreements need to be compared with the costs of implementing the agreements and an assessment made of the overall balance of costs and benefits with special reference to the transfer of technology and the implementation of the TRIPS Agreement.

4. In terms of health, substance matters are best dealt with in forums that have a broad representation and sufficient expertise on health. In practice, this would mean the World Health Organisation (WHO), the International Labour Organisation (ILO) and the Food and Agriculture Organisation (FAO).

5. For non-trade issues, UN bodies with broad representation would be preferable than ad hoc bodies or bodies in which representation is associated with funding (for example, the World Bank) or where developing countries do not have direct access (such as the OECD). The role and relevance of other UN agencies and/or agreements can be strengthened and, if necessary, tied with WTO trade policies.

Trade Agreements and Health

Food Security, Nutrition and Consumption of Hazardous Foods

While a better regulatory system in the global trade in agricultural products may well enhance the prospects of the developing world, it is uncertain to what extent more liberalised markets in agriculture would enhance food security within these countries. The core concern from a health perspective is that any problems in food security or the prices of basic commodities may have the strongest impacts not only on the poorest countries, but also on the poorest populations within richer countries, even when they seem to be the ones profiting in general from agricultural exports. The global integration of food and agricultural markets may also lead to a deterioration in diets if local production is replaced by a less nutritious alternative sourced from global markets.

Global trade also deals with products of questionable or negative value to health. Trade in tobacco, alcohol and soft drinks is just one example of this. In developing countries, the application of the WHO code on the marketing of breast-milk substitutes and infant foods will be of more importance. The tobacco industry has used the WTO to claim that national policies aimed at curbing tobacco consumption, for instance, by insisting on changes in the packaging, contravene WTO trade
agreements. Compared to tobacco, alcohol has gained little attention, even though its abuse is a problem in many developing countries.

**Health Policy Issues**

1. The main policy challenge from a health perspective is to ensure that food security in developing countries and the nutritional value of available food for the whole population is not compromised as liberalisation efforts proceed.

2. The increase in the distances that food products are being transported is problematic, especially of substances that have a high risk of becoming contaminated. Policy-makers should ensure that mechanisms that favour local production are not interpreted automatically as means of protectionism and that a country's scope to ensure food security at the national level is respected during the negotiation process.

3. One challenge for the European Community is to ensure that negotiations do not focus on how Member States' public health regulations restrict agricultural trade as a means of diverting attention from the issue of the EU's export subsidies. In agricultural trade, some products are more health promoting than others are. There is no health reason to support subsidies for the cultivation or export of hazardous products, such as tobacco. Countries should also be able to use price mechanisms to guide consumption of products, such as sugar.

4. The role of agricultural production in people's daily survival is greater in developing countries, which therefore should be allowed to maintain more safeguards and flexibilities in this area.

5. While globalisation and liberalisation may lead to economic growth, the health policy concern is that the consumption that may be good for economics is not necessarily good for health. Globalisation and more liberalised markets in goods also involve substances that are detrimental to health. Policy-makers need to recognise the need for regulatory public health policies on the basis of health concerns. Developing countries should have the opportunity to maintain broad public health policies without being threatened with a trade dispute.

6. The role and prospects of genetically engineered food and products will probably be debated in the context of labelling and trade in agriculture. It is necessary in such debates to ensure that developmental arguments are not misused merely to ensure free markets for GMO products.

**TRIPS Agreement**

**General Issues**

The Agreement on Trade-Related Aspects of Intellectual Property Rights governs many crucial substance areas related to health, such as patents, copyrights, trademarks and government obligations with respect to the licensing of pharmaceuticals.

Many poorest countries do not have to implement the TRIPS Agreement yet, but have complied on the basis of bilateral agreements. It is also likely that such countries will be affected by the TRIPS compliance of other countries that produce key generic pharmaceuticals, such as India. This means that TRIPS matters cannot be set aside simply because the least developed countries do not have to comply yet.

**Patenting and Pricing**

TRIPS grants a monopoly on a patented product to the holder of the intellectual property rights for 20 years as a reward for investment in research and development in that product and as an incentive for further investment. In practice, this leads to monopoly pricing and higher costs of pharmaceuticals. The actual production costs of pharmaceuticals are usually a fraction of the charged price of the patented pharmaceuticals - the higher prices are meant to act as a reward for research and development efforts.

One of the means of dealing with monopoly pricing is compulsory licensing. It is allowed as part of the TRIPS agreement, but the EU and the US have tried to keep the interpretation narrow and have frequently added wordings emphasising a public health crisis or graveness as prerequisites for its...
use. As Ministries of Health would be those using the option of compulsory licensing, it is in their interest to ensure that the compulsory licensing procedure is available and as easy to implement as possible. In any given country, moreover, it is the Ministry of Health that has to deal with the high costs of pharmaceuticals. It is thus in the interests of health policy to support the easier use of compulsory licensing, whereas it is in the interests of the rights holders to support as narrow interpretation as possible.

This conflict of interests has continued even after the public health declaration made at the 2001 WTO Ministerial Conference in Doha, Qatar. Furthermore, it will be difficult, if not impossible, for smaller economies to benefit from compulsory licensing unless they are allowed to import or export patented pharmaceuticals on the basis of compulsory licensing.

During 2002, the TRIPS Council has looked into this issue of compulsory licensing and exports. The European Commission has lobbied it for a narrow measure limited to particular countries and particular diseases. From a health perspective, there is no reason to restrict eligible diseases, a practice that would easily lead to a kind of disease apartheid. There is also little point in allowing certain countries only to use the mechanisms for imports or to act as producers for export, as needs for compulsory licensing may also emerge in developed countries with smaller markets.

Debates on access to pharmaceuticals have focused on the least developed countries. But these countries tend to be less able to benefit from new more sophisticated treatments that are the ones protected under TRIPS, for instance, treatments for HIV/AIDS. They would often have get better value for their money from prevention, and more specific measures, for instance, to prevent of mother to child transmission of the HIV virus. These countries lack many resources and usually do not have access to most pharmaceuticals, including essential drugs that usually no longer have patent protection. For HIV/AIDS treatments, the major beneficiaries of compulsory licensing would be middle-income countries. While it is clear that some HIV/AIDS medications can be effectively used also in very poor countries, HIV/AIDS cannot be considered as equal to an over-the-counter pharmaceutical. There is also a risk of breeding drug resistant strains of the virus through the widespread use of broad spectrum or highly effective pharmaceuticals without appropriate supervision.

The most sustainable and meaningful way to achieve access to pharmaceuticals in developing countries is through the use and prioritisation of essential drugs following WHO's list of essential drugs; the import or production of generic pharmaceuticals; and when necessary the import or production of generic pharmaceuticals using compulsory licensing. This is to a large extent recognised by most of the UN agencies working with health, as well as by the WHO Commission on Macroeconomics and Health.

Parallel imports, i.e. importing pharmaceuticals from countries where these are legally sold at lower price, are TRIPS compatible when a Member applies international exhaustion of intellectual property rights. A lot of emphasis has been put on the use of tiered pricing, which is based on a company selling the same drug at different prices in different countries, and public-private partnerships. These should not be linked to the developing country choice of the regime for exhaustion of patent rights. While there is nothing amiss with pharmaceutical corporations using tiered pricing, it is necessary to ensure that public funds and resources are not misallocated to purchasing of tiered priced products when the same products could be obtained more cost-efficiently through parallel imports, compulsory licensing or - as is the prevalent practice at the moment - through imports from generic producers.

Research and Development Efforts in Health Technologies

The TRIPS Agreement assumes that patents ensure that innovations eventually become publicly available and that investments are made in important areas. But the current balance of investment in pharmaceutical research and development clearly points out the problems with this approach. The
Commission on Intellectual Property Rights (CIPR) report, commissioned by the United Kingdom, has highlighted that, in the corporate sector, research and development costs are predominantly geared towards larger markets and the diseases of more affluent populations. These account for about 95% of investments while just 5% is allocated to diseases of major importance to developing countries.

Recent emphasis on pharmaceutical research and development as a global public good and the consequent necessity for the developed world to pay higher prices in order to ensure access to pharmaceuticals in the developing world is a problematic approach. Firstly, it gives the incorrect impression that higher pharmaceutical costs in the developed world have to be accepted in order to ensure access to pharmaceuticals in developing countries. Secondly, it provides little incentive to ensure that health-related priorities are realised in the corporate sector’s further R&D efforts. Developed countries will need to pay more to ensure that R&D is carried out into diseases prevalent in the developing world. But the suggested mechanism to address this problem may act more as a smokescreen to obscure the more mundane causes of rising costs of pharmaceuticals in developed countries.

**Pharmaceutical Licensing**

TRIPS Article 39.3 requires governments to provide protection for this marketing approval data. The pharmaceutical industry and some countries have argued for a broad coverage of the Article 39.3 and for a requirement that countries confer exclusive rights on the originators of marketing approval data. In practice, this would benefit mainly the pharmaceutical research-based industry and would hamper the chances of the generic industry to gain faster access to markets and would increase their costs. From a health point of view, openness of the registration process after a decision has been made would clearly benefit the citizens and consumers more than disclosure on a broadly defined basis. This is also important in relation to the openness and accountability of the public administration.

**Trademarks and Health Education**

The TRIPS Agreement also provides protection of trademarks. The tobacco industry has used the protection of trademarks under TRIPS to limit public health regulatory activities. From a health policy perspective, it is important that relatively weaker Southern governments are supported in their efforts to curb smoking and alcohol use or to promote breast-feeding as part of their public health policies. It is thus critical to ensure that TRIPS is not used inappropriately to limit legitimate public health policies.

**Article 27(b), indigenous knowledge, agriculture and copyrights**

Article 27(b) covers what can and what cannot be patented. The recent analysis from the UK's Intellectual Property Rights Commission has reservations about the possible negative impacts of patents on plants and animals in general. It suggests that, in the absence of any universally-recognised definition of what constitutes a micro-organism, developing countries should remain free to adopt a credible definition that limits the range of material covered by a patent. Matters related to indigenous knowledge and biopiracy deal often with health due to the importance of knowledge in healing properties. Important aspects of IPRs deal also with seeds, farmers rights and food security.

**Implementation**

The implementation of the TRIPS Agreement may have relatively large cost implications for smaller and poorer countries. Implementing the Agreement may not be the most efficient allocation of their public resources, which would be better spent on education and health, for example.

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Policy Advice from a Health Perspective

1. The TRIPS Agreement should be based - as stated in the Agreement itself - on a balance between rights holders and consumers. The achievement of this balance requires a further reassessment of the Agreement's benefits and costs.

2. Concerns in health policies that are common across countries need to be addressed. The interpretation of the TRIPS agreement should not be geared towards further protection of interests of rights holders, but towards ensuring that public health and human rights are protected.

3. Rights to use compulsory licensing should not be narrowed to specific diseases, or the scope of economy or depend on the gravity of public health problems. Imports and exports under compulsory licensing should be ensured in order to take into account differences in capacities between larger and smaller economies.

4. Nothing in the TRIPS agreement prohibits the use of parallel importing if a country applies international exhaustion of rights. The rights to use parallel importing in developing countries cannot be linked to availability of pharmaceuticals on tiered pricing.

5. Research and development efforts on health-related technologies need to be guided by health-related concerns and needs, not market opportunities only.

6. Investing development and health funds in corporate research and development efforts should be done carefully and should ensure that any intellectual property rights remain as public property.

7. On health and health policy grounds, test-data should be disclosed for pharmaceuticals have been registered for sale. The wording "unfair commercial use" should be interpreted in a very narrow sense.

8. Mechanisms to enhance developing country access to current knowledge and information at low costs need to be sought as well as exemptions to intellectual property rights in order to ensure free access to information and knowledge for educational, research and scientific purposes as necessary.

9. Developed countries should ensure that developing countries are not forced to provide excessive protection of intellectual property through bilateral treaties. European Member States should ensure that the European Commission does not require its bilateral trading partners to make commitments beyond TRIPS - so-called TRIPS-Plus agreements.

10. In addition to the TRIPS it may be important to focus as well to the WIPO as well. In this it is necessary to ensure that the WIPO harmonization of the substantive patent law around the world will take into account the interests of developing countries.

Sanitary and Phytosanitary Measures

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) deals with food safety and animal and plant health regulations. In practice, this means that protectionist measures should not be disguised as public health protection measures. The relevance of the SPS Agreement in trade disputes is also related to Article XX of the General Agreement on Tariffs and Trade (GATT) setting general exceptions to GATT. While Article XX gives governments rights to implement sanitary and phytosanitary measures, these have to respect the stipulations set in the SPS Agreement.

In recent years, increasing attention has been paid to the costs of implementing the SPS Agreement in developing countries as well as on impacts of European public health regulations on trade prospects of developing countries. From a development perspective, implementation of SPS clearly imposes additional costs and stricter public health standards can be seen as barriers to trade. But allowing public health regulation to be challenged on the basis of missed trading opportunities will be the start down an unsustainable path to process of deregulation.

The implementation of the SPS agreement could be regarded as a means of improving public health policies in exporting developing countries. But it is far from an ideal solution as SPS covers export products only and is irrelevant to domestic trade and consumption.

Health arguments are going to be misused.
in trade debates. But the solution to this is not to undermine health arguments by considering them first and foremost as protectionist measures, but rather to shift decision-making on substance matters to forums that can authoritatively deal with the matter from a health perspective.

**Policy Advice from a Health Perspective**

Health policy arguments with respect to the SPS Agreement and related concerns would highlight the following issues:

1. The importance of public health regulatory measures per se which should not automatically be treated as protectionist measures in trade debates.
2. The problematic basis of arguments advocating the developmental gains of lowering public health regulations.
3. The need to support the developing world in enhancing their regulatory measures and doing so in a broader context than the SPS.
4. The role of the Codex Alimentarius commission and the need to ensure that scientific and public health concerns are made a priority.
5. The need to ensure that regulatory approaches such as the precautionary principle are not regarded merely as protectionist but as a means to address certain public health policy concerns.
6. The need to consider public health regulatory matters as more than product safety and to encompass production processes as well, even though this will be heavily criticised by the developing world.

**General Agreement on Trade in Services (GATS)**

The basic function of the General Agreement on Trade in Services is to liberalize trade in services (WTO 1994c). GATS permits government to implement regulatory measures, but the context in which they can do so and the scope of regulatory measures is of concern. This is for the simple reason that, for trade in services, domestic regulation is considered much more important as a potential trade barrier than for trade in goods. The aim of the agreement is to regulate government action within a framework of progressive liberalization of trade in services. This liberalisation of service provision is portrayed as leading to benefits in broad terms as well as to lower costs.

In the context of the current GATS negotiations, specific concerns relate to 1) safeguarding the role of public services, 2) domestic regulation in relation to regulatory reform, 3) the inclusion of government procurement practices, and 4) cross-subsidization (individuals, populations, areas) and decentralisation capacities to maintain equity.

**Health Policy Issues**

The health policy issues with respect to the GATS Agreement involve both sectoral concerns as well as regulatory measures in other sectors, such as the advertising of tobacco, alcohol and infant foods or matters related to the structure and access of other "services", such as water and sewage.

The benefits of more liberalised trade in health services is based on the assumption that this would improve effectiveness and be beneficial to service provision. However, this is not the case in health systems, where more commercialised systems tend to be more costly and less equitable.

The training, education and work of health personnel cannot be regarded only in the context of a higher GDP, but needs to be considered as part of a national health system. The focus on health care as an industry may easily lure attention away from the fundamental functions of a health system. The primary purpose of health services is to provide quality care for the sick and preventive and promotive services to help people to become and stay healthy. The focus on GDP-generating activities easily leads to a bias in priorities and ineffectiveness in service provision in health systems as a whole.

It is unlikely that health tourism or foreign investments in health would greatly improve
the national health systems in the developing world. While these would provide a ground for private insurance markets, it is likely that expanding markets of private insurance would further increase the tiered nature of services and separate those who can afford to pay from the rest of the population with less chances of cross-subsidisation or risk-pooling between poorer and richer populations.

The education of health professionals is relatively expensive, and in many developing countries there is a great lack of skilled personnel. It is unlikely that the export of an educated health workforce would be a desirable option for developing countries. Given the problem of "brain drain" of skilled workers from many countries, the value of remittances back is minor in comparison with the loss of potential earnings. The brain drain of skilled workers is an issue in the context of the GATS.

As GATS aims at progressive service liberalisation, any future concerns should look at prospects of countries opening and deepening their GATS commitments and thus extending their commitments further in health and social services.

Policy Advice from a Health Perspective

The main policy advice from a health policy perspective is for countries to keep their health and social services out of deeper and broader commitments in GATS. These commitments would probably not provide additional gains and would probably be costly. It would also be difficult for countries to change them in future.

Once countries have made commitments, the focus needs to be on the interpretation of GATS and on ensuring that commitments are interpreted in a narrow rather than broad sense. Developing countries could also try to utilise some exemption mechanisms used by the US and the European Community.

In practice, it is likely that GATS commitments in health will be irrelevant or of minor interest to many of the poorest developing countries. Any foreign investment in health would probably be considered an improvement. It is also likely that GATS commitments would have little to do with any foreign involvement in health, which would be much more dependent on aid and other resource flows.

Countries should not take as granted the GATS exemption of public services to cover all health services. In domestic regulation necessity, proportionality or pro-competitiveness requirements should be avoided as well as any commitments meant to reach beyond a specific sector.

'Brain drain' has been defined as a major risk with respect to trade in health services. There are little grounds to enhance the drain of skilled population from the developing countries and remittances back home rarely cover the lost skills and capacities.

In terms of trade in services and options for developing countries, caution is the operative word. This cautiousness should be extended to services that are important to the determinants of health, such as water and sewage treatment.

Reference