

WORLD TRADE ORGANIZATION (WTO) NEGOTIATIONS: POSSIBLE EFFECTS ON HEALTH AND HEALTH SERVICES IN MALAYSIA

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ABSTRACT

The various World Trade Organization agreements, i.e., the General Agreement on Trade in Services (GATS); the Agreement on Trade-Related Intellectual Property Rights (TRIPS); Agreement on Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) will be implemented in Malaysia since we are a member state of the World Trade Organization. This article discusses the various agreements and presents an analysis of how their implementation may affect health and health services in Malaysia.

Key words: *World Trade Organization (WTO), GATS, TRIPS, SPS, TBT, effects on health and health services in Malaysia*

INTRODUCTION

The World Trade Organization (WTO) came into being in 1995 as the body replacing the General Agreement on Tariffs and Trade (GATT). The main aim of the WTO is to promote international trade through the lowering of trade barriers in its various forms.

According to mainstream economic theory, increased trade on the basis of comparative advantage and specialization will lead to greater output and enhanced overall welfare for all parties concerned. The WTO differs from GATT in that the latter covers trade in goods only while WTO has expanded the scope to cover trade in services and intellectual property as well. Furthermore, WTO has also strengthened the procedure for dealing with disputes arising from international trade (World Trade Organization & World Health Organization 2002). The WTO places great emphasis on two principles dealing with non-discrimination in international trade, i.e., the "Most Favoured Nation (MFN)" principle and the "national treatment" principle. The "Most Favoured Nation" principle means that WTO member states must treat each and every one of its trading partners equally, e.g., if a trade concession is granted to a particular nation, this concession must be extended to all other states which are trading partners. The second principle, "national treatment", means that goods, services and intellectual property of foreign origin should be given the same treatment as those of local origin, i.e., there should not be any

differential and discriminatory treatment of foreign products which are similar to local products (WTO & WHO 2002).

International negotiations conducted under the sponsorship of the WTO have given rise to various "Agreements" which can have an impact on health and health services in Malaysia. These Agreements include the following:

- . General Agreement on Trade in Services (GATS)
- . Agreement on Trade-Related Intellectual Property Rights (TRIPS)
- . Agreement on Sanitary and Phytosanitary Measures (SPS)
- . Agreement on Technical Barriers to Trade (TBT)

THE GENERAL AGREEMENT ON TRADE IN SERVICES (GATS)

The General Agreement on Trade in Services or GATS attempts to promote and regulate international trade in services which are provided through a number of modes. In WTO parlance, these modes include:

- . Cross-border supply
- . Consumption abroad
- . Commercial presence
- . Presence of natural persons

"Cross-border supply" refers to the supply of services in Country B by persons or organizations operating in or from Country A. This mode includes the supply of healthcare-related services using cross-border telecommunications ("telemedicine"), e.g., cross-border consultations, cross-border reading and interpretation of diagnostic test results including medical images such as X-ray charts and CT scans ("teleradiology"), etc. Cross-border supply of health-related services can also include things such as the transmission of medical claims and medical records to service centres in foreign countries (using

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telecommunications technology) where they are processed and subsequently sent back.

"Consumption abroad" refers to the consumption of services by citizens of one country in another (foreign) country. So-called "health tourism" whereby citizens of one country travel to another country to seek routine or advanced medical treatment would fall under this mode.

"Commercial presence" refers to the presence of a firm from Country A in Country B. It can also refer to investment by a firm from Country A in Country B. In terms of the healthcare industry, commercial presence would include firms setting up factories to produce pharmaceuticals, medical supplies and medical equipment overseas. It would also include foreign firms building and operating clinics, diagnostic laboratories, hospitals and other healthcare facilities and foreign firms buying into or buying over existing health facilities owned by locals. Health insurance companies operating in foreign countries would also fall under this mode.

"Presence of natural persons" refers to provision of services by a citizen or citizens of Country A in a foreign Country B. Examples include health professionals such as doctors or nurses working overseas in a foreign country on short-term or long-term contract, and healthcare management consultants providing their expert services for a fee in a foreign country.

Under GATS, WTO member countries make "commitments" to open up a particular service sector (such as health services) to foreign investment, trade and participation. According to a recent joint WTO-WHO publication,

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 can be postponed to a later date specified in the Member's schedule. Such "re-commitments" provide time for the authorities concerned to undertake any domestic regulatory and institutional changes that may be necessary to ensure compliance (WTO & WHO 2002, p. 51)

Adlung and Carzaniga (2001) note that in terms of the health services sector, WTO member states tend to make more commitments in capital-intensive and skill-intensive areas than in labour-intensive areas and believe that this is due to internal political constraints.

POSSIBLE IMPACT OF GATS ON HEALTH SERVICES IN MALAYSIA

According to the WTO agreements, health services which are provided by the Government are excluded from coverage under GATS (meaning that conditions such as having to provide "market access" and ensuring "national treatment" to services supplied by foreigners do not apply). However, this is true only if the services are supplied on a non-commercial basis and there are no competing service suppliers. These conditions mean that the Government has to be the sole provider of such health services within its national boundaries (i.e. no private sector organisations – commercial as well as charity-oriented Non-Governmental Organisations – are also providing the same services) and such services must be provided on a not-for-profit basis (WTO & WHO 2002).

The Malaysian Government has made some GATS "commitments" in the case of health services. These are posted on the official WTO website and they include (WTO 2003):

1. Medical specialty services such as forensic medicine, nuclear medicine, geriatrics, microvascular surgery, neurosurgery, cardiothoracic surgery, plastic surgery, clinical immunology and oncology, traumatology, anaesthesiology, intensive care, child psychiatry and physical medicine. Limitations on the supply of these medical specialty services include the following: the services can only be supplied by a "natural person" in a private hospital of at least 100 beds in specified locations. The establishment of individual or group practices is not permitted and the qualifying examinations used to determine competency are to be conducted in the English language.
2. Management consulting services in pharmacy including consultancy pertaining to the manufacture of drugs in raw form, new drug delivery systems, biotechnology, and new methods of drug and vaccine production. Limitations include the following: the services must be supplied through a joint-venture corporation established in partnership with Malaysian individuals or Malaysian-controlled corporations. Bumiputera shareholding in the joint venture must be at least 30 percent.
3. Private hospital services supplied by a foreign corporation. Limitations include the following: the services must be supplied through a joint-venture corporation established in partnership with Malaysian individuals or Malaysian-controlled corporations. Foreign shareholding in the joint-venture must not

exceed 30 percent. The hospital must have at least 100 beds and the establishment of feeder outpatient clinics is not permitted.

Thus, in the light of the "commitments" made by the Malaysian Government as described above, in terms of health services, foreigners will be permitted to provide specialist medical services, private hospital services and management consulting services in pharmacy (subject to certain limitations) in the Malaysian market. In the case of specialist medical services, the individual foreigners will need to pass a competency test (with English as the medium of communication) and can only practice within a private hospital of at least 100 beds. These foreign specialists will not be allowed to open their own clinics outside the private hospital to which they are attached. Cross-border supply of specialist medical services, e.g., cross-border supply of child psychiatry consultations is not permitted. Some issues which arise include: what about recognition of foreign medical degrees? Will all foreign specialists in the areas named be allowed to take the corresponding Malaysian competency test no matter which medical schools they graduated from? Will these foreign specialists also be permitted to work later on in Government hospitals since the Malaysian Government is already employing foreign specialists because of a shortage of specialist doctors in the public sector as more and more Malaysian specialists leave the public sector for the private sector?

To sum up, in terms of "natural persons", the Government is not permitting foreign GPs to practice in Malaysia. Foreign specialists who have passed competency tests in specified areas can only work in private hospitals with at least 100 beds or in public hospitals under Government contract. There is no mention of other health personnel such as nurses, pharmacists, physiotherapists and so on. Presumably, "market access" and "national treatment" have not been granted to foreign nationals who can supply these services. In terms of "commercial presence", foreign healthcare corporations are not permitted to set up chains of GP clinics, specialist clinics, nursing homes etc. but private hospitals (100 beds and above) with up to 30% foreign ownership are allowed. Foreign management consulting firms dealing with pharmaceuticals can supply their services but only through commercial presence in the shape of a locally-incorporated joint venture corporation with at least 30% Bumiputera participation. The Malaysian market remains closed to the "cross-border supply" of health services by foreigners at the present moment. However, there is no restriction on "consumption abroad" of health services by Malaysian citizens, i.e., Malaysians are free to seek healthcare in Singapore, Australia, the United

Kingdom, the USA and other countries if they wish to do so.

GATS can be a boon to the Malaysian economy if Malaysian companies can supply cross-border services such as medical claims processing services to health care corporations located in foreign countries via telecommunications. Similarly, Malaysian health care corporations can also can invest in neighbouring Southeast Asian countries as well as further overseas. However negative effects are also possible. If implementation of the GATS agreement induces more highly-skilled Malaysian health personnel to emigrate to work overseas, this would be a negative development (even if they do send back sizable amounts of remittances from overseas).

THE AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS)

"Trade-related intellectual property rights" include things such as trademarks and trade secrets that can be protected by patents. TRIPS will affect pharmaceuticals as well as medical equipment and medical supplies. In the case of pharmaceuticals, patents can be awarded for products as well as for production processes. The World Trade Organization is pushing for patents that provide protection for a period of at least twenty years from the date the application is first filed. Prior to the TRIPS agreement, many countries either did not provide patent protection to pharmaceutical drugs and to the production processes involved in making these drugs or provided patent protection for periods of less than twenty years (Third World Network 2001). In theory, the awarding of patents for pharmaceutical products and production processes is to reward invention and promote technological innovation. Trademark protection supposedly also helps to protect consumers from counterfeit products such as counterfeit drugs which are ineffective or which may even endanger health.

According to the TRIPS agreements, exemptions from patent protection can be made and these include: the "research exception", the Bolar provision (also called the "regulatory exception"), parallel imports and compulsory licensing (WTO & WHO 2002).

The "research exception" permits the scientific study of a patented drug by researchers who are trying to determine the workings of the drug more fully. The "Bolar provision" (or "regulatory exception") refers to TRIPS Article 30 which allows pre-approval testing. Thus this allows

.... 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 (WTO & WHO 2002, p. 44)

"Parallel imports" mean the practice of importing items such as proprietary pharmaceuticals from the cheapest possible overseas source, e.g., if branded drug X produced by multinational drug company Y is sold at a lower price in Country B than in Country A, citizens from Country A can parallel import the drug

from Country B and save money by doing so. It has been documented that the price of branded drugs can vary significantly between different countries although the drugs are produced by the same multinational pharmaceutical company or its affiliates (Rokiah Alavi 2002). In fact, the price of a branded drug can cost more in a developing country than in a developed country! Cecilia Oh from the Third World Network mentions a 1998 study conducted by Health Action International which revealed the following prices for the drug Zantac (100 tablets of 150 mg) manufactured by Glaxo (Third World Network 2001, p. 14):

Table 1: Price of the Drug "Zantac" in Various Countries (100 Tablets of 150 mg)

Name of Country	Price of Zantac (in US\$)
India	\$ 2
Nepal	\$ 3
Bangladesh	\$ 9
Australia	\$23
Vietnam	\$30
Thailand	\$37
Indonesia	\$ 41
Malaysia	\$55
Sri Lanka	\$61
Philippines	\$63
Canada	\$77
Tanzania	\$97
El Salvador	\$132
South Africa	\$150
Mongolia	\$183
Chile	\$196

Source: Third World Network. TRIPS, Drugs and Public Health: Issues and Proposals. Penang, Malaysia: Third World Network, 2001 (pp. 14)

It is interesting to note from the table above that citizens of very low income developing countries such as Tanzania and El Salvador have to pay for Zantac at prices which are higher than those charged in Malaysia, Australia and Canada.

"Compulsory licensing" refers to the practice whereby the Government of Country A allows a local pharmaceutical company to produce a branded drug X (which is patented and owned by a multinational pharmaceutical company) without the permission of the original patent holder. The TRIPS agreement does not use the term "compulsory licensing" but uses the phrase "other use without authorization of the right holder" instead. Compulsory licensing is permitted by TRIPS during times of "national emergencies", "other circumstances of extreme urgency", "public non-commercial use" and to

combat "anti-competitive practices". The TRIPS agreement states that a drug produced under a compulsory license has to be produced by more than one local pharmaceutical company and mostly for the domestic market. In all cases of compulsory licensing, the original patent holder must still be compensated fairly (WTO & WHO 2002).

Under TRIPS, developing countries are granted "transitional periods" of varying lengths of time before full implementation of the agreement. The so-called "Doha Ministerial Declaration on the TRIPS Agreement and Public Health" made at the WTO negotiations held in Doha (the capital of Qatar) in 2002 allows least-developed countries up until January 1 2016 to fully implement the TRIPS agreement.

POSSIBLE IMPACT OF TRIPS ON DRUG PRICES AND DRUG AVAILABILITY IN MALAYSIA

The most obvious effect of TRIPS on the developing countries would be a rise in the prices of drugs which were not covered by patent protection previously (i.e. not covered either by a product patent or by a process patent). A process patent is less stringent than a product patent in that the former enables local pharmaceutical companies to produce generic versions of a branded drug through "reverse engineering" and the use of an alternative production process. However, if the branded drug becomes covered by a product patent after the implementation of TRIPS, local pharmaceutical companies would no longer be permitted to produce generic versions of the drug.

In Malaysia, drug patent laws will have to meet TRIPS standards, i.e., patent protection will cover both product as well as process and must be at least twenty years in length. In order to prevent misuse and abuse of such patent laws by multinational drug companies, it will be necessary for the Malaysian government authorities to take action to prevent "evergreening", i.e., the strategy of continuously filing new patents on existing drugs by making minor modifications on them in order to maintain market monopoly (Raghavan 2001).

Parallel imports are permitted under the TRIPS agreement. In theory, Malaysians can "parallel import" a patented drug X from any source located in any foreign country if the patented drug is being sold at a lower price overseas. Again, in theory, this would increase price competition and force the price of patented drug X to be less variable or more equal between Malaysia and other countries. However, in practice, parallel importing is likely to be possible only for Malaysian entities which have the time and sophistication to closely compare prices for a particular branded drug which is being sold in Malaysia and other countries at the same time.

Similarly, in theory, compulsory licensing is permitted under the TRIPS agreement. In theory, any country which is being affected by rising numbers of HIV/AIDS sufferers can declare a "national emergency" and allow local drug companies to produce anti-HIV drugs through compulsory licensing. However, in practice, most developing nations lack the technical expertise necessary to do so. Only the more advanced developing countries are able to produce patented drugs under compulsory licensing. Other developing countries which are being seriously affected by the HIV/AIDS epidemic

can only try to import anti-HIV drugs from more advanced developing countries such as India.

In practice, the multinational pharmaceutical corporations have successfully lobbied their home country governments (such as the government of the United States where many drug companies are based) to exert unilateral pressure on the governments of developing countries to stop allowing their domestic drug companies to produce patented drugs under compulsory licensing (Oxfam 2002). Thailand experienced this pressure from the United States when drugs were produced under compulsory licensing in the former country. Another form of pressure on countries that allow the production of drugs under compulsory licensing within its borders is to attempt to prevent cross-border export of these drugs (Third World Network 2001).

In the case of Malaysia, if local drug companies lack the technical ability to actually produce sophisticated branded drugs under compulsory licensing, this unilateral pressure would make it harder and harder to buy cheaper copied drugs (produced under compulsory licensing) from pharmaceutical companies located in countries such as India. In other words, the seemingly attractive and reasonable "compulsory licensing" provision of the TRIPS agreement would be of little value in practice.

THE AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES (SPS)

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).. (while preventing) ... unnecessary, arbitrary, scientifically unjustifiable, or disguised restriction on international trade (WTO & WHO 2002, p. 35)

In other words, the SPS agreement is designed to prevent disguised protectionism while allowing for the following:

- . preventing the import of contaminated food and beverage
- . ensuring the safety of imported animal feed
- . preventing the import of diseases associated with foreign plants or animals
 - which can affect human beings
- . protecting local plants and animals against imported diseases
- . preventing the invasion of foreign species which can damage the local
 - environment or the local economy

WTO member states are expected to apply international standards such as the "Codex Alimentarius" - established jointly by the FAO (Food

and Agricultural Organization) and the WHO - in order to achieve the above goals, e.g., the Codex Alimentarius can be used to determine the maximum level of pesticide residue permissible in imported food. Thus, the SPS supposedly allows governments to protect the health of local animals, plants and human beings on the basis of objective, scientific information. It also supposedly allows protection against the invasion of foreign "pest" animal and plant species (WTO & WHO 2002).

Nevertheless, critics have pointed out that the preparation of the Codex Alimentarius has been heavily influenced by private corporations:

Between 1989-91, 96 percent of the non-governmental participants or national delegations represented industry and Nestle sent 38 representatives to Codex committee meetings, which is more than most countries. In the committee on pesticide residue levels, 33 percent of participants came from agro chemical and food corporations. This raises questions concerning the objectivity and impartiality of the Codex in scientific assessment ...Forty two percent of the Codex standards for pesticides are lower than US EPA & FDA standards and fifty times more DDT may be used on or left in residual amounts on peaches, bananas; and thirty three times more DDT may be applied on broccoli.... (Hong 2000, p. 34)

POSSIBLE IMPACT OF SPS ON HEALTH IN MALAYSIA

The main area of concern here would be the adequacy of so-called "international standards" such as the Codex Alimentarius in protecting against the import into Malaysia of food, beverages, animal feed etc. which is contaminated by dangerous chemicals, toxins and disease-causing organisms. If the influence of multinational corporations and their lobbyists on regulatory standards are such that the standards are set at levels which can have a negative impact on human and animal health, developing nations such as Malaysia should not blindly and uncritically adopt these standards in order to comply with the SPS agreement. The government of Malaysia should work hand-in-hand with other concerned governments as well as with technically-sophisticated Non-Governmental Organisations (NGOs) in the developed countries to push for a re-evaluation of lax standards and to limit the negative influence of corporate lobbyists. If these efforts fail, the government of Malaysia should adopt the stricter standards of organizations such as the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) of the United States instead. (However, it is necessary to bear in mind that

corporate lobbyists in the USA can and do attempt to weaken FDA and EPA standards from time to time).

THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE (TBT)

Under the SPS Agreement, measures may be imposed only to the extent necessary to protect life or health, on the basis of scientific information. However, the TBT Agreement permits the introduction of technical regulations to meet a variety of legitimate objectives, including national security, the prevention of deceptive practices, protection of human health or safety or the environment (WTO & WHO 2002, p. 36).

Whenever any WTO member state passes any technical regulation that deals with the above (human health and safety, protection of the environment etc.) and which may negatively affect cross-border trade, the member state is obligated to inform ("notify") the WTO. Thus far, such TBT "notifications" have included regulations pertaining to levels of electromagnetic radiation emitted by radio communications equipment, substances used in cosmetics, and chemicals that may have a negative impact on occupational health (WTO & WHO 2002). According to Hong, the TBT will have an impact on standards pertaining to the production, packaging, labeling and overall quality of foodstuff, pharmaceutical products such as drugs and medical equipment etc. Although both the TBT and the SPS pushes member states to adopt "international standards", the difference is that the former does not specify which standards to adopt (Hong 2000).

POSSIBLE IMPACT OF THE TBT ON MALAYSIA

How may the TBT agreement affect Malaysia? The TBT agreement is most likely to come into play if any trade dispute arises between Malaysia and a foreign country over which technical standard to apply with respect to a product from the foreign country. Trade disputes which arise between two countries and which they are unable to resolve independently are supposed to be referred to the WTO's Dispute Settlement Body (DSB) or the Appellate Body for arbitration. However, there are fears that when two sets of clashing standards exist (such as those of the WHO and those of commercial and industry associations), corporate lobbyists may attempt to push the WTO to decide in favour of the less stringent standards (Hong 2000). Thus, the Malaysian authorities should be proactive and vigilant and constantly monitor the outcome of trade disputes arbitrated by DSB expert panels.

CONCLUSION

In this article, I have discussed the various WTO agreements and analysed how their implementation may affect health and health services in Malaysia. In terms of GATS, it was noted that "consumption abroad" of health services by Malaysians is the least restricted while "cross border supply" of health-related services by foreigners is the most restricted. "Presence of natural persons" and "commercial presence" on the part of foreigners fall in-between.

In terms of TRIPS, full implementation of the agreement will mean product patents, process patents and patents which are at least twenty years in length. Drug prices will be affected and local production of (generic) drugs which become covered under "product patents" will be forced to stop. Certain countries with powerful pharmaceutical lobbies will attempt to make it difficult for countries like Malaysia to carry out parallel imports of drugs and the manufacturing of drugs under compulsory licensing.

As for the SPS and TBT agreements, the Malaysian Government needs to be aware of the danger of so-called "international standards" relating to SPS which are lax as a result of corporate lobbying and the possibility of trade disputes because of competing standards relating to TBT.

WTO negotiations are ongoing and profoundly political. Developing nations such as Malaysia need to work together and be actively involved so that the agreements which emerge from these negotiations (as well as their implementation and legal interpretation) will not work to the disadvantage of Third World nations. The assistance and input of Northern NGOs such as Oxfam, Medecins sans Frontieres/Doctors Without Borders etc. should also be sought in the

battle to modify or prevent the appearance of WTO agreements, rules and regulations that are damaging to the interests of the developing countries.

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