Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines

Meeting Report
19-21 February 2001
Chulalongkorn University
Bangkok, Thailand

Note to the reader

The harmonized model of selected indicators included in this document represents an historical snapshot of the network's endeavours to fulfil the mandate of the World Health Assembly in resolution WHA52.19 on the Revised Drug Strategy. It should be noted that these indicators are a work in progress. As such, the network is aware that the template does not yet contain indicators to monitor the impact of expanded intellectual property protections on the development of drugs for neglected diseases. Initial field tests by the Collaborating Centres should help identify any major problems with the indicator template: data that is not accessible, unclear or problematic methodologies for data collection, unclear definitions. After initial field testing, the network's steering committee will review and revise the template as appropriate. After this initial revision, it will be important for the basic indicators to remain constant to ensure data consistency across time; but the steering committee will work to continuously clarify and revise the template based on accumulated experience. In addition, the WHO Collaborating Centre for Health Economics and Drug Policies in London is currently writing a manual for using the template.

This document is not a policy paper but a draft framework to collect data for further analysis. Comments are welcome.

Contents

This report consists of a collection of documents including a brief introduction, opening remarks, WHO perspectives on globalization and access to pharmaceuticals, a template of selected model indicators, and plans of actions from participating WHO Collaborating Centres.

Introduction

The last decade has witnessed a sharp acceleration in the processes of economic globalization, and a major increase in the number, and expansion of the scope, of international trade agreements. As economic globalization and international trade agreements have exerted an ever greater influence over national economies and regulatory policies, concern has grown about their potential impact on public health, especially in the developing world. While many of the trends of economic globalization and new requirements contained in trade agreements are easily identifiable, controversy remains, however, over their impact on public health.

Particularly important are trends and rules relating to intellectual property, which may have a direct impact on the cost and availability of medicines. As increasing numbers of countries, especially developing countries, fall under the disciplines of the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and otherwise expand their intellectual property protections, the debate over the public health impact of these protections has intensified. Views on the subject vary from those who believe increased global trade and enhanced intellectual property protections naturally create public health benefits to those who fear that the failure to prioritize public health concerns in the process of trade liberalization will inevitably lead to public health harms.

The World Health Assembly, the highest governing body of WHO, gave the Organization the mandate to work in this area in its resolution WHA.52.19 on the Revised Drug Strategy.

Box 1. Resolution WHA.52.19 on the Revised Drug Strategy

This resolution requests the Director-General, *inter alia,*

to cooperate with Member States, at their request, and with international organizations in **monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements,** so that Member States can effectively assess and subsequently **develop pharmaceutical and health policies** and regulatory measures that address their concerns and priorities, and are able to **maximize the positive** and **mitigate the negative impact of those agreements.** (Emphasis added)

At a meeting held in Bangkok, Thailand in February 2001, WHO initiated a process to monitor and analyse the impact of trade agreements on access to drugs in partnership with four WHO collaborating centres in Brazil, Spain, Thailand and the United Kingdom.

The meeting began with a series of opening statements, including one from

Dr Supachai Panitchpakdi, who will assume the position of Director-General of the WTO in 2002. Excerpts of his remarks are included on page 9 of this report.

Following opening comments, the meeting undertook an intensive review of the WHO's draft paper on "Globalization, TRIPS and Access to Pharmaceuticals." The paper was significantly strengthened by incorporating revisions proposed by meeting participants. The final version of the paper is included on page 13 of this report.

The main emphasis of the meeting was to develop a framework of operations for a nascent Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines. The meeting resulted in the establishment of a steering committee to oversee the operations of the network, which will be made up of the four WHO Collaborating Centres. The members of the steering committee, as well as experts who participated in the Bangkok meeting as advisors in their personal capacity, are listed at the end of this introduction.

The meeting established that the network, through the individual and collective work of the Collaborating Centres, would undertake research that shed light on four questions:

* How is patenting affecting drug pricing?

* How are patents and enhanced intellectual property protections affecting the rate of introduction of generic drugs?

* Are TRIPS and expanded intellectual property protections spurring development of drugs for neglected diseases?

* Are TRIPS and expanded intellectual property protections contributing to an increase or decrease in transfer of technology and direct foreign investment in developing countries?

The meeting participants developed a harmonized model of selected indicators to be adapted according to the characteristics of different regions. These indicators are intended to offer important information though of course not definitive answers regarding the four questions, though they relate more to some of the questions than others. The template is included on pages 25-35 of this report.

- Each of the four Collaborating Centres will conduct research in their region or in the region in which they maintain expertise and contacts, using a version of the model of selected indicators adapted to their circumstances. The Collaborating Centres together will adapt, use and refine the model of selected indicators; publish and analyse the collected data; and conduct additional research and analysis on important trends in the interaction between globalization and access to drugs. The final section of the meeting report includes short summaries of the missions of each Collaborating Centre.

Steering Committee

Dr Jorge Bermudez, WHO Collaborating Centre for Drug Policies, Rio de Janeiro

Dr Joan-Ramon Laporte, WHO Collaborating Centre for Research and Training in Pharmacoepidemiology, Barcelona

Dr Monique Mrazek, WHO Collaborating Centre for Health Economics and Drug Policies, London

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Acknowledgements

This meeting report has been edited by Mr Robert Weissman. Contributions to the meeting and/or this report were made by Professor Frederick Abbott, Mr Andrew Creese, Ms Daphne Fresle, Dr Hans Hogerzeil, Dr Desmond Johns, Dr Jonathan Quick and Ms Ellen 't Hoen, LL.M.

Highlights of opening address of Dr Supachai Panitchpakdi

Director-General Designate, World Trade Organization

The announcement of a new Thai government on 18 February 2001 signaled the end of the central role that Dr Supachai has played in previous Thai administrations during the last decade. As the person scheduled to replace Mr Mike Moore as the Director-General of the World Trade Organization in June 2002, he would no doubt have the sympathy of many if he chose to shun publicity during this brief intermission in his public career. It is therefore a tribute to the gravity of the topic of globalization and its implications on access to medicines and an expression of the special affinity that he feels for both the topic and his alma mater, Chulalongkorn University, that Dr Supachai agreed to open this meeting on his first day outside government, even though it meant flying in from his home town of Chiang Mai specifically to do so.

It would also appear that much of what he had intended to say had already been covered by the earlier speakers namely, the host, Dr Siripen Supakankunti and Dr Doberstyn, WHO Representative, Thailand. Having concurred with their statements, he set aside his prepared statement and proceeded to speak quite candidly on what he perceived to be the problems of our globalized world and the role that governments and multilateral institutions could play in remedying the situation.

"I am happy to be here" he said, "because I think that the issues that you are dealing with are of paramount importance, particularly if we look at the ongoing process of globalization which has become less and less human. I have attended so many international meetings and conferences around the world in the last few years, where I would see demonstrations and protests by people fearing the unknown factor that was born in the wake of the so called globalization interdependence process around the world, be it Seattle, Washington DC, Prague, Melbourne, even here in Chiang Mai, when we had the ADB meeting last year and in Davos, where I would say that the richest and the most powerful gather once every year."

In the light of this external perception of the WTO, he emphasized his desire to give it a human face adding, "I would like to put a human face on the WTO, which has always been called the rich man's club. I have to change that."

Broadening this point to include an appeal for shared responsibility, he further stated, "These are the facts of life. Globalization must be shown to be a more balanced process and must be managed internationally to provide some kind of benefit for all. Globalization may be part of the capitalist market system but it must be globally managed and I emphasize this now as I have emphasized it everywhere in the world. It cannot just be or be said to be, a process that international organizations like the World Bank, IMF and WTO can take care of.

They can manage their own separate stances. I have not left out WHO, but I am saying that all the major international organizations including the WTO, UNCTAD, UNIDO and UNDP must find a way to work together, otherwise we will not be able to steer globalization in the direction that would provide benefits for mankind.

"There is an opportunity to benefit from market mechanisms" he continued, "I for one being an economist, would not deny that it would be a boost, a boon to the market mechanism, but the spin out effect on the rest of the population, the spin out effect on the poor countries around the world, on the forty eight poor (least developed) countries around the world, is in doubt."

Narrowing down his remarks to address the TRIPS Agreement, Dr Supachai noted that TRIPS had only entered the trade talks during the Uruguay Round and that it was quite possible that at the time, developing countries had not fully appreciated its probable impact.

"Thailand has suffered in this process" he said, "One government came down over the question of IPR (intellectual property rights). It was extensively debated in Thailand and in many developing countries and there are a large number of countries around the world who think that we must review the TRIPS Agreement. At the moment this is partly being done in Geneva. Some countries which cannot meet the commitment of the TRIPS Agreement, are now vying for support to revise TRIPS before the next Round, the 9th Round, which will commence sometime this year. There is already some kind of movement to look into the consequences of TRIPS particularly on developing countries. I am sure that you are also doing this, that you are looking at TRIPS particularly at its impact on the supply of pharmaceutical products. This is one thing that needs to be brought into the bigger picture."

Clearly aware of how his pronouncements were being received in various quarters, he remarked, "People keep reminding me that I should act as the incoming DG, not as a former deputy Prime Minister, because I would have to serve all of these countries, but I will not relent in my criticism of countries which still think in terms of a few decades ago while we are in a new millennium. I will look into the new global equation with much more caution." His subsequent remarks provide some insight as to how and to what extent, such caution may actually be exercised.

"There are many things in the TRIPS requirements that we need to reconsider, so that the requirements would not place an unnecessary burden on the poor countries. It would also enable the poor countries to pursue their developmental goals, for example, educational development and health care development. The protection of the environment and the protection of other rights should be achieved without harming the basic developmental approach of that country. I would like to establish this as an ongoing fact, but this has met with a lot of opposition, particularly from some countries whom I will not name here, because I already faced enough difficulties."

Dr Supachai clearly preferred that the review of the TRIPS Agreement commence before the launch of the new Round saying "So we are looking at implementation and I am sure that before the next Round, which I will call the Development

Round, we would have some sort of agreement to look into some of the requirements of TRIPS. I am sure that there will also be some review of the requirements connected to patent rights and the protection of patent rights, that must have some bearing on certain kinds of essential drugs."

Expanding further on this point, he noted "There is a lot of controversy around patent protection for essential drugs. Countries that produce them under patents are saying that only a few essential drugs are under protection and that it was up to each country to enact policies to force the production of cheaper drugs. I have been dealing with the case of our own public health policy to which certain countries may raise some objections, but I have also begun to observe that even these countries who used to have outright objections because of pressure from the pharmaceutical companies, now realize that they may need to change the way that they look at the unchangeable protection of certain rights. I was told that during the G8 Summit in Okinawa and some preceding summits, people were also discussing the TRIPS requirements, the protection of intellectual property rights and the need to make them serve mankind more than they have been doing so in the past."

These remarks were balanced by his recognition of the value of patents saying, "While I am trying to say that we need to change the outlook of the WTO, TRIPS and the protection of intellectual property rights, I am not saying that we have to discard the TRIPS and intellectual property rights protection. I am saying that we still need to encourage more research on drugs, pharmaceutical products and everything. So we will still need to have such protection but there must be some exceptions to the WTO rules as with many other things. We normally grant exemptions when trade negatively affects environmental factors. We also have some leeway in order to exempt some drugs from protection if the problem is of an epidemic scale or if it has serious consequences on a nation."

Dr Supachai then focused on the specific issue of HIV/AIDS and drugs and the role that civil society is playing in this area, remarking that "There are a lot of organizations around the world which are now better organized to fight against the delayed release of expensive drugs and essential drugs that are much needed to counter and fight against disease in poor nations. I think that there are several movements in the right direction. I think that movements like these must be backed up by scientific tests and assessments like what we are doing here, in order to monitor the effects of globalization, TRIPS and the other WTO Agreements with implications for the health sector, trying to look at pricing policy, government policy, compulsory licensing, generics and others. All this will help me and people working in the same direction to address the review of TRIPS".

Clearly someone who is familiar with health issues, Dr Supachai spoke proudly of his participation within the Commission on Macroeconomics and Health. With regards to collaboration with WHO he spoke of his contacts with Dr Brundtland and was unequivocal in saying "During my term, and even before or after, I would like to emphasize the need for the WTO and WHO to work closely together so that the WTO will be able to understand the health issues more than in the past." He further cautioned that "we would need to be patient because the people there are not physicians, they are trade negotiators and diplomats. They need to understand and need to be more receptive to the issues being discussed."

It was evident from his address that he was keen to be informed and in a position to discuss these issues, as these were points which he returned to repeatedly. He said for example that "Rigorous scientific tests that provide the kind of conclusive evidence that would be useful at the negotiating table, will be most appreciated by me and my colleagues." More specifically, he asked that this expert group provide him and the WTO with updates as to the progress of its work.

He combined this with an appeal for the WTO and all of us to be inventive and concluded his address with the following remarks, "We need to be inventive. We need people to go on with their research and they need funds for their research. We need cheaper essential drugs for the poor people. There must be a compromise somewhere between funding arrangements and patent protection, which would compensate them in a way which would move pricing out of the way. I hope that through your deliberations, some proposals will be made available."

[1]Globalization, TRIPS and Access to Pharmaceuticals

A new era in global trade

The World Trade Organization (WTO) is the international organization dealing with rules of trade between nations. Although the WTO became officially operational only in January 1995, it is the successor to the GATT multilateral trading system founded in 1947. In becoming Members of the WTO, countries undertake to abide by its rules. As of 30 November 2000, the WTO counted 140 Members.

The WTO is charged with setting the legal ground rules for international trade. Its objectives are to promote: (1) non-discrimination (2) progressive liberalisation of barriers to trade (3) predictable policies and transparency (4) competition and (5) special provisions for developing countries.

WTO Agreements

In joining the WTO, Members adhere to 18 specific agreements annexed to the Agreement establishing the WTO. They cannot choose to be party to some agreements but not others (with the exception of a few "plurilateral" agreements that are not obligatory). Of greatest relevance to the health sector are: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); the Agreement on Technical Barriers to Trade (TBT); the General Agreement on Tariffs and Trade (GATT); and the General Agreement on Trade in Services (GATS).

Of these agreements, TRIPS is expected to have the greatest impact on the pharmaceutical sector. The TBT Agreement should be of particular concern to producing countries, since its implementation may affect export markets.

Implementation and dispute settlement

The WTO Agreement is a treaty that creates international obligations among its Members. These obligations include refraining from taking actions that are inconsistent with the agreement, and implementing certain provisions via national legislation.

[1] WHO Policy, Perspectives On Medicines, No.3 March 2001, World Health Organization, WHO/EDM/2001.2

The various parts of the WTO Agreement, including the TRIPS Agreement, require that such national legislation embodies certain specific standards. However, in many areas, the WTO Agreement affords considerable discretion in how its obligations are implemented. This discretion, combined with the potential health impact of national legislation, make it imperative that health officials work closely with other parts of government, such as the trade department, and use top-level legal, trade and pharmaceutical expertise when legislation is being drafted. (See Box 1.)

Box 1. Points for policy-makers

- TRIPS establishes intellectual property standards for WTO Members, historically based on the standards of developed countries.·
- TRIPS requires patent protection for all products and processes, with a minimum duration of 20 years from the original date of filing, without any special consideration for pharmaceuticals.
- The TRIPS Agreement permits Members some discretion in enacting and amending their laws and regulations, which can help promote public health goals.
- When establishing standards of patentability for pharmaceuticals countries should consider the implications for health of those standards. Standards which are too broad may lead to inappropriate extension of patent life beyond the period required by TRIPS.
- WTO free trade provisions can stimulate generic competition and reduce the prices for off-patent drugs, but TRIPS may also significantly delay the introduction of new generic drugs, depending on the way national legislation is designed and implemented.
- Developing countries should be cautious about enacting legislation more stringent than the TRIPS requirements ("TRIPS-plus").

Disputes can arise when countries differ in their interpretation of the WTO Agreement. The WTO provides a dispute settlement process that may proceed from a consultation phase to the establishment of, and decision by, a dispute settlement panel, and appeal to the Appellate Body. Trade sanctions may only be imposed if the dispute settlement process has run its course and the losing country has failed to comply with the decision made. For this reason, WTO Members may not unilaterally impose trade sanctions based on alleged failures to comply with TRIPS.

Key requirements of the TRIPS Agreement

The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including those for pharmaceuticals. The Agreement's 73 Articles cover basic principles, standards and use of patents, enforcement, dispute settlement and a range of other subjects. The key requirements for pharmaceuticals are described below and summarized in Box 2.

Patent protection

Members must provide patent protection for a minimum of 20 years from the filing date of a patent application, for any invention, including of a pharmaceutical product or process, that fulfils the criteria of novelty, inventive step and usefulness (subject to certain exceptions - see Box 2).

Rights conferred

TRIPS specifies the rights conferred on a patent owner, but allows for limited exceptions and compulsory licensing, subject to specified conditions. The Agreement also contains provisions on: protection of undisclosed information (including test data); actions to address anti-competitive practices; protection of trademarks (relevant to generic substitution and combating counterfeit drugs); and enforcement.

Transitional arrangements

TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries.

TRIPS specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

Public health and TRIPS

International conventions before TRIPS did not specify minimum standards for patents. Over 40 countries provided no patent protection for pharmaceuticals, many provided only process and not product patents, and the duration of patents was much less than 20 years in many countries.

From the health sector's perspective, intellectual property standards, including those specified in TRIPS, should take protection of public health into account. However, current standards - historically derived from those of developed countries - are not necessarily appropriate for countries struggling to meet health and development needs. Developing countries can therefore use the flexibility of TRIPS provisions and its safeguards to protect public health.

Patentability

What can be patented? TRIPS specifies that patents must be available for all discoveries which "…are new, involve an inventive step and are capable of industrial application" (Article 27).

The difference between the number of new drugs ("new chemical entities") that are developed globally each year, and the number of patents awarded for new

uses of a drug, processes, dosage forms, formulations and different forms of the same molecule, including patents on genes and genomic sequences is enormous. The latter is influenced by national legislation and practices

Yet because "new" and "inventive" are not defined, countries must establish their own criteria for these terms. They should remember that patentability standards which are too broad can contribute to "evergreening". This means that the effective patent life for a new medicine is extended beyond the 20-year TRIPS minimum. Therefore, Ministries of Health must work closely with other ministries to formulate and/or revise national patent legislation to ensure that it takes public health needs into account.

Generic drugs

Promotion of generic drugs requires appropriate legislation and regulations, reliable quality assurance capacity, professional and public acceptance of generic drugs, and economic incentives and information for both prescribers and consumers. The TRIPS Agreement does not prevent Members from requiring generic labelling and allowing generic substitution.

Trade liberalization can increase competition and reduce prices for generic drugs that are already on the market. But if the wording and implementation of TRIPS-compliant national legislation and regulations are inappropriate, the introduction of new generic drugs can be delayed. The economic cost to governments, households and public health can be enormous.

Prompt introduction of generic drugs can be facilitated by: drafting appropriate legislation and regulations on patentability; use of exceptions to exclusive rights which permit early testing and approval of generics ("Bolar" provision) (including allowing access to pre-registration test data); and compulsory licensing.

Box 2. Articles of the TRIPS Agreement of greatest relevance to pharmaceuticals

Box 2. Articles of the TRIPS Agreement of greatest relevance to pharmaceuticals

Topic (TRIPS Article)	**Key phrasing from TRIPS agreement** (Note that a number of articles contain further specific conditions, exceptions and exemptions which are spelled out in TRIPS or other referenced agreements.)
Nondiscrimination (Articles 3 and 4)	*"National Treatment...*Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property…" *"Most-Favoured-Nation Treatment…*With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members…"
Parallel importation ("exhaustion of patent rights") (Article 6)	*"Exhaustion…*For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [National Treatment] and 4 [Most-Favoured-Nation Treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."
Objectives of TRIPS (Article 7)	*"Objectives…*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."
Protection of public health (Article 8)	*"Principles…*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."
Process and product patents (Article 27)	*"Patentable Subject Matter...*patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."
Subject matter which may be excluded from patentability (Article 27)	*"Patentable Subject Matter…*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health…" "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."
Exceptions which facilitate prompt marketing of generic drugs ("Bolar" provisions) (Article 30)	*"Exceptions to Rights Conferred...*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."
Compulsory licensing (Article 31)	*"Other Use Without Authorization of the Right Holder...*Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the [twelve] provisions shall be respected."
20-year minimum term of protection (Article 33)	*"Term of Protection…*The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."
Reversal of burden of proof for process patents (Article 34)	*"Process Patents…Burden of Proof...*For the purposes of civil proceedings in respect of the infringement of the rights of the owner…if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process."
Data protection and Exclusivity (Article 39)	*"Protection of undisclosed information...*In the course of ensuring effective protection against unfair competition…Members shall protect undisclosed information…and data submitted to governments or governmental agencies…"
Transitional arrangements for developing country WTO Members (Articles 65 and 66)	Specific transitional arrangements are provided for developing and least-developed countries (see TRIPS text).
Transfer of technology and technical cooperation (Articles 66 and 67)	"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base…[and] shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members."
Mailbox filings (Article 70/8)	"Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall: (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed…"
Review (Article 71/1)	"The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement."

Box 3. Checklist for policy-makers

Government process and resources:

- Identify trade-and-pharmaceuticals focal point within Ministry of Health.
- Establish contacts, perhaps a working group, with trade and other key ministries.
- Obtain reliable specialized legal advice.
- Develop a mechanism to monitor the health impact of new trade agreements.

National patent and related legislation should:

- Promote standards of patentability that take health into account.
- Establish process and product patents for 20 years.
- Incorporate exceptions, trademark provisions, data exclusivity and other measures to support generic competition.
- Permit compulsory licensing, parallel importation and other measures to promote availability and ensure fair competition.
- Permit requests for extension of transitional period for TRIPS implementation, if needed and if eligible.
- Carefully consider national public health interests before instituting TRIPS-plus provisions (see text).

Compulsory licensing

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. The patent-holder, however, retains intellectual property rights and "shall be paid adequate remuneration" according to the circumstances of the case (Article 31). In the pharmaceutical sector compulsory licences have been used to stimulate price-lowering competition and to ensure availability of needed medicines. Most developed countries and many developing countries now provide for compulsory licensing through national legislation.

A comprehensive patent regime should include adequate provision for the granting of compulsory licences. Grounds for compulsory licensing may include public interest, problems linked with national emergencies such as epidemics, public non-commercial use, or anti-competitive practices (Article 31). Whether or not compulsory licences are issued, national legislation which provides for compulsory licensing allows governments to provide the medicine in the case of abuse of rights by the patent-holder, or commercial non-availability. Any such use should be authorized predominantly for the supply of the domestic market of the Member authorizing such use (Article 31f).

Compulsory licences must be granted on a non-exclusive basis. Since the TRIPS Agreement provides for non-discrimination between locally produced and imported products (Article 27/1), a compulsory licence may be granted for importation to satisfy local needs (Article 31).

Parallel imports

Parallel importation is importation, without the consent of the patent-holder, of a patented product marketed in another country either by the patent-holder or with the patent-holder's consent. Parallel importation enables promotion of

competition for the patented product by allowing importation of equivalent patented products marketed at lower prices in other countries. If the importing country's patent regime provides that the patent-holder's right has been "exhausted" (in TRIPS terminology) when the patented product has been placed on the market in another country by or with the consent of the patent-holder, the patent-holder cannot use his/her patent right in the importing country to prevent parallel importation.

Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system, provided that there is no discrimination on the basis of the nationality of the persons involved. It is widely understood to mean that parallel importation is effectively a matter of national discretion.

TRIPS-plus provisions

"TRIPS-plus" is a non-technical term which refers to efforts to: extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics.

Since the public health impact of TRIPS requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements.

Non-WTO Members

As of December 2000, over 50 WHO Member States were either not WTO Members or had observer status only at the WTO. From a public health perspective, countries which are not bound by TRIPS should evaluate TRIPS requirements, and incorporate into national legislation and trade-related practices those elements which clearly benefit national public health interests.

Evaluating impacts of trade agreements

Protection of intellectual property rights aims to promote innovation by providing an incentive to invest in research and development. Yet the TRIPS Agreement, which seeks to fulfil this aim, has proven to be one of the most controversial WTO agreements. At least four questions are commonly raised from a public health perspective (Box 4). In view of the impact that the TRIPS Agreement could have on pharmaceuticals, WHO (in accord with World Health Assembly resolution WHA52.19) is using these four questions to monitor and analyse the effects of globalization and trade agreements on the pharmaceutical sector.

Concurrently, having been awarded observer status on an ad hoc basis by the WTO Council for TRIPS, WHO is able to monitor all relevant issues under discussion at WTO that may have implications for the health sector.

Box 4. Key questions for monitoring the public health impact of TRIPS

1.	Are newer essential drugs more expensive than they would have been if not under patent?
2.	Is the introduction of generic drugs being slowed?
3.	Are more new drugs for neglected diseases being developed?
4.	Are transfer of technology and direct foreign investment in developing countries increasing or decreasing?

WHO Perspectives on Access to Drugs

Access to health is a human right

Access to essential drugs is part of the human right to health. Access to essential drugs depends on: (1) rational selection and use of medicines (2) sustainable adequate financing (3) affordable prices and (4) reliable health and supply systems. Since most poor people in developing countries currently pay for health care, including drugs, out of their own pockets, access to medicines is particularly sensitive to cost. Governments, the UN family, the private sector and civil society each have vital roles and responsibilities in achieving universal access to essential drugs. (See Box 5.)

Patents are an effective stimulator of research and development

Patent protection has been an incentive for research and development for new drugs. But questions remain as to whether the patent system will ensure investment in medicines needed by the poor. Of the 1223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases. The market fails when it comes to ensuring adequate pharmaceutical research and development (R&D) for neglected diseases such as malaria, a range of other tropical diseases and tuberculosis. Strong public sector involvement, including through public-private partnerships, is necessary to ensure development of new drugs for developing country priority health problems.

Affordability of essential drugs is a public health priority

Current financial resources are woefully inadequate for meeting the health care and medicine needs of the world's poorest populations. Governments, donor agencies and development banks all have a vital role to play in increasing those resources. But affordable prices are also very important.

Among the four elements needed to ensure access, the affordability of essential drugs - specifically those still on patent - is most likely to be affected by trade agreements. Patent protection awards exclusive rights to an invention and prevents generic competition. But poorer populations in developing countries should not be expected to pay the same price as do the wealthy for newer essential drugs. TRIPS-compliant mechanisms can be used to lower drug prices.
Other options to improve affordability include exchange of price information; price competition and price negotiation within public procurement and

insurance schemes; price controls; reduced duties and taxes; improved distribution efficiency; reduced distribution and dispensing costs and reduced marketing expenses.

Essential drugs are not simply another commodity - TRIPS safeguards are crucial

WHO supports countries in the use of WTO/TRIPS-related safeguards, as appropriate, to enhance affordability and availability of existing medicines, while not discouraging the development of needed new medicines. These safeguards include setting standards for patentability which reflect public health concerns, legislative provision for compulsory licensing, exceptions to exclusive rights and other measures which promote generic competition, and extension of the transitional period. Parallel importation of a patented drug from countries where it is sold more cheaply can also be authorized by governments.

Based on available experience, WHO does not recommend applying TRIPS-plus requirements or extending TRIPS requirements to non-WTO Members before the public health impacts of so doing have been fully assessed.

Box 5. WHO perspectives on access to drugs

1. Access to essential drugs is a human right.
2. Essential drugs are not simply another commodity.
3. Patent protection has been an effective incentive for research and development for new drugs.
4. Patents should be managed in an impartial way, protecting the interests of the patent-holder, as well as safeguarding public health principles.
5. WHO supports measures which improve access to essential drugs, including application of TRIPS safeguards.

Countries must develop informed approaches to health and trade

Countries with the least capacity for interpreting and acting on international trade agreements have most at risk in terms of access to medicines. WHO will continue to provide independent data and technical assistance to countries to help them develop informed approaches to trade and health at national, subregional and regional levels. Countries are advised to carefully monitor the implementation of the TRIPS Agreement in order to formulate comprehensive proposals for the future review of the TRIPS Agreement as provided for in Article 71.1. A network of legal experts who have specialized knowledge and understanding of international trade agreements, pharmaceuticals and public health is also being developed as a resource for developing countries.

Further Reading

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Template of selected model indicators for studying the impact of globalization and TRIPS on access to medicines

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, as defined in the Constitution of the World Health Organization. Progressive realization of that right involves access to health facilities, prevention, care, treatment and support, including access to medicines. Access to essential drugs depends on: (1) rational selection and use of medicines; (2) sustainable adequate financing; (3) affordable prices; and (4) reliable health and supply systems. The World Health Organization has a rich tradition of promoting and monitoring policies designed to secure access to medicines.

The introduction and expansion of intellectual property protections in countries around the world, particularly developing countries with weak traditions of intellectual property protection, is a major new factor potentially impacting on countries' ability to ensure access to drugs. Basic economic theory and the underlying logic of intellectual property suggests that the adoption of new intellectual property rules will exert influence on drug pricing and availability, research and development systems, foreign direct and domestic investment patterns (The World Bank, *Global Economic Prospects*, 2002).

Thus it is vital to draw on WHO's extensive experience in drug policy and price monitoring and elaborate on it in order to assess the effect of globalization and TRIPS on access to drugs.

The following template is intended primarily to monitor the pharmaceutical implications of globalization and the implementation of the TRIPS Agreement in countries. It was designed by a steering committee consisting of the secretariat, representatives of WHO Collaborating Centres and independent experts. It will be field tested and refined; and is subject to ongoing revision and updating based on experience. The template endeavors to shed light on four questions:

* How is patenting affecting drug pricing?

* How are patents and enhanced intellectual property protections affecting the rate of introduction of generic drugs?

* Are TRIPS and expanded intellectual property protections spurring development of drugs for neglected diseases?

* Are TRIPS and expanded intellectual property protections contributing to an increase or decrease in transfer of technology and direct foreign investment in developing countries?

It is designed with the understanding that neither globalization nor the TRIPS Agreement are monolithic. The process of economic globalization contains many contradictory trends and impulses. The TRIPS Agreement, while establishing a universal minimum set of obligations for all Members, also contains exceptions, built-in flexibilities and ambiguities that mean implementation will inevitably take different forms in different countries; and attributions of particular national policy revisions to the requirements of TRIPS must recognize the range of choices available to national decision makers on how to implement the TRIPS accord. Moreover, the TRIPS Agreement itself is embedded in the broader process of globalization, and exists amidst other trade and other international agreements that impose particular and related requirements on countries. Thus, caution must be exercised in seeking to establish evidence-based conclusions about the overall effect of TRIPS on access to drugs.

The template is also designed with the understanding that, whatever the impact of globalization and the TRIPS Agreement on access to drugs, they are not the sole nor necessarily primary determinant. Traditional factors -- including countries' wealth, public and private spending on health, commitment to essential drugs policy, procurement system, national insurance mechanisms, price controls, distribution systems, and consumer awareness -- continue to vitally influence access to drugs.

At the same time, the changes in national policy effected by globalization and TRIPS are real and discrete. TRIPS, for example, requires many countries that previously did not grant patents on pharmaceuticals, or did so only in limited circumstances, to grant both process and product patents for a minimum term of 20 years. While the TRIPS requirement for protection of undisclosed data (registration or marketing approval data) is ambiguous, many countries are beginning to grant set periods of exclusive protection for undisclosed data, and some trade agreements include such requirements. It is important to gather information on how these and other specific policy mandates are being implemented in countries, and, to the extent possible, gather data that will offer insights into how these national policy changes are affecting overall access to drugs.

In pursuit of this goal, the template circumscribes the information it is seeking. As WHO has said in offering indicators for monitoring national drug policies, "Although a national drug policy is ultimately intended to improve the overall health of a population, health impact indicators are not included in this manual for three main reasons: the multifactorial nature of health status, the consequent complex issues of causality associated with drug policy and health status, and the unresolved methodological difficulties of selecting reliable health indicators directly related to the use of drugs" ("Indicators for Monitoring National Drug Policies," WHO/EDM/PAR/99.3). For these reasons, this template does not include health impact indicators. For reasons of focus and with an eye toward resource limitations, the template does not include a full range of indicators for monitoring national drug policies.

What the template does include are indicators for assessing relevant aspects of pharmaceutical financing, pricing, investment, registration, prescription regulation, intellectual property protections and consumption.

Some of the indicators relate to broad national policies and practices. Others correspond to the market or regulatory situation for a particular drug.

As described in the elaboration below of the categories of indicators, analysis of the indicators should reveal correlations among trends in the different indicators, for example, between intellectual property protections and levels of foreign direct investment. These correlations can be tracked within countries, between countries, and over time. There will be some opportunity for testing against partial "control" categories, including between WTO Members and non-members; but there is no perfect control, because no Member stands outside the processes of economic globalization.

Revision of the template and assessment of the data

A fundamental element of the methodological approach of the Network will be to continuously revise the survey instrument based on results from the field. Initial field tests by the Collaborating Centres should help identify any major problems with the indicator template: data that is not accessible, unclear or problematic methodologies for data collection, unclear definitions. After initial field testing, the Network's steering committee will review and revise the template as appropriate. After this initial revision, it will be important for the basic indicators to remain constant to ensure data consistency across time; but the steering committee will work to continuously clarify and revise at the margins the template based on accumulated experience.

The indicators in the template are wide reaching, covering a broad array of policies and detailed information for numerous drugs. The experience obtained in the course of the data collection will indicate which data are more and which less robust. Bad data may well be worse than none, or useless; but imperfect data, so long as its limitations are acknowledged, is far preferable to none, offering important signals about national situations. While there will be significant limitations in the analytic conclusions that can be drawn from the data, the Network is optimistic that the data will enable a much more evidence-based discussion of the potential impact of globalization and TRIPS on access to pharmaceuticals.

Selection of drugs for monitoring

The Bangkok meeting participants agreed on an initial list of drugs to be monitored. These drugs fall into three categories: (1) non-patented pharmaceuticals included in the WHO Model List of Essential Drugs; (2) non-essential drugs under patent protection to serve as the “control” group, and
(3) patented pharmaceuticals which are important drugs for treatment of HIV/AIDS and AIDS-related opportunistic infections.

Selected drugs included on the WHO Model List of Essential Drugs (EDL), 11th edition, 1999

Essential Drugs / No patent protection.
Criteria: different therapeutic groups, different indications [chronic and acute diseases, severe and mild diseases], different populations [aged, infants], different status [OTC, prescription], and old and new drugs.

One or more criteria have been used to select the proposed drugs: erythromycin (antibiotic; prescription; old drug; heavy use; cheap); ciprofloxacin (antibiotic; prescription; new drug; expensive; all ages except infants); rifampicin (antibiotic, specific disease; cheap; all ages; prescription); doxycycline (antibiotic, cheap-expensive, prescription; except infants); cyclophosphamide (antineoplastic; low use; prescription; specific population; severe disease; expensive; highly specialized use); hydrochlorothiazide (cardiovascular-diuretic; chronic disease; old drug; aged population; cheap); atenolol (cardiovascular drug; new drug; aged population; chronic disease), and salubutamol (respiratory tract drug; inhalation route; specific disease; all ages; prescription).

Selected drugs not included on the WHO Model List of Essential Drugs (EDL), 11th edition, 1999

A list of non-EDs under patent protection is suggested to serve as the control group. These drugs had been selected for different reasons, high usage, potential health impact, new drugs of therapeutic groups already included in the first category of drugs to be monitored, non-therapeutic drugs, new drugs with useful, well-known and safe alternatives.

The suggested list includes: candesartan and atorvastatin, (cardiovascular drugs); celecoxib (antiinflammatory drug); olanzapine (central nervous acting drug), levofloxacin (antibiotic drug; same therapeutic group as ciprofloxacin and ofloxacin); montelukast (respiratory tract drug; same group as salbutamol); esomeprazol (digestive tract drug); orlistat and sildenafil ("non-therpeutic" drugs).

Selected drugs indicated for the treatment of HIV/AIDS and other severe and life threatening infections

Important drugs indicated for the treatment of HIV/AIDS and opportunistic infections under patent protection (Includes **some** drugs on the WHO Model List of Essential Drugs) .

Probably the most important price and access evolution in the following few years will involve access to drugs for treating HIV/AIDS and related opportunistic infections. The WHO Model List of Essential Drugs (EDL) includes fluconazole (opportunistic infections, antifungal), zidovudine and nevirapine (antiretrovirals; specific indication; prevention of MTC transmission). EDL includes ciprofloxacin as a model of quinolone antibiotic (it has been included in the first group of drugs); ofloxacin, a new quinolone, could serve as an example of drug under patent protection to compare with ciprofloxacin. The same applies for azithromycin, a new macrolide antibiotic similar to erythromycin from the first list. The remaining suggested drugs are antiretrovirals recommended by the WHO guidelines and other international organizations involved in HIV/AIDS treatment but are not included in the latest available EDL (1999). The fixed-dose combinations (lamivudine + zidovudine) and (zidovudine + lamivudine +abacavir) have been included although they are not marketed in all countries because their use is likely to increase during the following years.

Following is an initial list of drugs chosen to be monitored:

Selected drugs included on the WHO Model List of Essential Drugs (EDL), 11th edition, 1999

Drug	Dosage*	
Erythromycin	250 mg	stearate/ethylsuccinate
Ciprofloxacin	250 mg	HCl
Rifampicin	150 – 300 mg	
Doxycycline	100 mg	HCl
Cyclophosphamide	25 mg	
Hydrochlorothiazide	25 mg	50 mg (if 25 mg not available)
Atenolol	50 – 100 mg	
Salbutamol	Inh. 100µg	As sulphate

* If not indicated, pharmaceutical dosage forms are **tablets**.

Selected drugs not included on the WHO Model List of Essential Drugs (EDL), 11th edition, 1999

Drug	Dosage*
Candesartan	4 mg
Celecoxib	200 mg
Orlistat	120 mg
Sildenafil	50 mg
Olanzapine	10 mg
Levofloxacin	500 mg
Atorvastatin	10 mg
Montelukast	10 mg
Esomeprazol	20 mg

* If not indicated, pharmaceutical dosage forms are **tablets**.

Selected drugs indicated for the treatment of HIV/AIDS and other severe and life threatening infections

Drug	Dosage*
Fluconazole **	50 mg
Zidovudine **	300 mg
Nevirapine **	200 mg
Azithromycin	500 mg
Didanosine (ddI)	150 mg
Indinavir	200 mg
Lamivudine	150 mg
Ofloxacin	200 mg
Lamivudine + Zidovudine	150 mg + 300 mg
Zidovudine+Lamivudine+Abacavir #	300 mg + 150 mg + 300mg

* If not indicated, pharmaceutical dosage forms are **tablets**.
** Included on the EDL, 11th edition
# If available as a fixed-dose combination

To monitor change, data should be collected periodically. The agreed initial period for the Network for Monitoring the Impact of Globalization and TRIPS on Access to Pharmaceuticals is six years -- three years prior to the onset of the project and three years forward in time, with data collected annually. Although there may be some difficulties in gathering at least some of the data for the suggested indicators for years past, it is critical that researchers undertake their best effort in this respect; these data will serve as important baseline data, in many cases revealing the state of affairs prior to changes in countries' intellectual property rules spurred by globalization or mandated by TRIPS or other international agreements.

Countries have different health systems; and some questions in the template will inevitably be more relevant than others for each country. An occasional question may be left unanswered if its does not apply to a particular country situation. Collaborating Centre researchers will seek to collect as complete data as possible, however, to facilitate the comparability of country data and solidify the data foundation for subsequent analysis. Data collectors should add explanatory notes on particular aspects of data collection and on any aspect they deem useful for analysing a particular country situation.

As data is collected, the Collaborating Centres will be able to analyse correlations between trends in pricing, investment, intellectual property protections and other indicators, with the ability to do comparisons over time, between countries, and among drugs and categories of drugs. They should be able to begin to identify the impact of new and expanded intellectual property protections on access to drugs.

The specific indicators included in the template fall into six categories: (1) trends in total pharmaceutical consumption; (2) health care coverage; (3) structure of public and private pharmaceutical prices; (4) intellectual property protections; (5) pharmaceutical prices; (6) market share of domestic and foreign firms; and (7) prescription regulation. The content, use, methodology for gathering and limitations of indicators in each of these categories is elaborated below.

Trends in total pharmaceutical consumption

The trends in total pharmaceutical consumption indicators include such data as total national spending on healthcare, total national spending on pharmaceuticals, total public spending on healthcare and pharmaceuticals, expenditures on pharmaceutical imports and on locally produced pharmaceuticals, and consumption of generic medicines as a percentage of overall pharmaceutical consumption.

These are background indicators that, first, provide a context in which to assess changing trends in more particular indicators and, second, may provide important information in aggregate trends in healthcare and pharmaceutical expenditures in the context of TRIPS and globalization. For example, correlations between trends in percentage of pharmaceutical expenditure on imported goods and intellectual property protections, or between sales of generics and intellectual property protections, will offer some insights into how TRIPS and globalization are impacting foreign direct investment and access to generics.

These data are aggregate. The Collaborating Centre researchers will rely primarily on national authorities and international organizations (International Monetary Fund, World Bank, United Nations Development Programme) for the data, also relying on associations of manufacturers or professional associations for certain data. They may make calculations to identify certain data points (for example, public expenditures as a percentage of total expenditures on pharmaceuticals), but they are not expected to do primary data collection.

These data provide a background for analysing, and perhaps some broad indications of, the effects of TRIPS and globalization on access to drugs. But especially because they are aggregate, any conclusions drawn from a country's trends in these data can only be tentative, and must be confirmed through examination of other indicators, use of the data over time and comparison of multiple countries' data.

Health care coverage

The health care coverage data includes percentage of population covered by public and private health care schemes, extent of health care scheme coverage of pharmaceuticals, and reliance on consumer co-payments for pharmaceuticals.

As with the trends in pharmaceutical consumption indicators, these are background indicators that, first, provide a context in which to assess changing trends in more particular indicators and, second, may provide important information in aggregate trends in healthcare and pharmaceutical expenditures in the context of TRIPS and globalization. For example, do co-payment requirements change over time in connection with changes in price and intellectual property rules?

The percentage of population covered by public and private health care schemes are calculated based on aggregate data to be sought from national authorities, international organizations and private health care provider associations and companies. The health care coverage questions on public and private health care schemes' coverage of pharmaceuticals may yield multiple answers, reflecting varying policies among public and private providers, between private providers if there are multiple health care schemes, or between different options offered by one or more private provider. In such instance, the data collectors should gather and report separately information from both the public and private sectors. In the private sector, if there are five or fewer providers, data should be reported for them all. If there are more than five providers, data should be reported for five, including the three largest and a medium and smaller provider.

As with the trends in pharmaceutical consumption indicators, these data provide a background for analysing, and perhaps some broad indications of, the effects of TRIPS and globalization on access to drugs. But especially because they are aggregate, any conclusions drawn from a country's trends in these data can only be tentative, and must be confirmed through examination of other indicators, use of the data over time and comparison of multiple countries' data.

In countries where there are numerous private health care schemes, data collected on pharmaceutical coverage of health schemes will be indicative rather

than comprehensive. Moreover, national government policies to cover pharmaceuticals may not be reflected in on-the-ground reality, particularly in that drugs may not be available to some consumers, despite a government policy to provide them.

Structure of public and private pharmaceutical prices

These data are designed to indicate the relative share of retail price of drugs allocated to manufacturers, wholesalers, dispensers, VAT or sales tax and other taxes. They are to be gathered separately for the public and private sectors.

The data will enable researchers to track over time the changing components of drug prices. This particularized data will help contextualize demonstrated trends in pricing. For example, the data may help explain that across-the-board drug price increases are due to a VAT increase, and not other potential factors. The data will also help illustrate how increased costs in one component interact with others.

The information for these indicators should be obtained from national authorities at the ministry of health, the national drug authority and elsewhere, wholesalers/importers, private insurers, pharmacists through interviews and review of public and private sector documents (such as regulations and price lists).

These are aggregate data, again subject to the important limitations noted above for other aggregate indicators. Moreover, because the data is collected as a percentage of overall price, it may not be possible to use the data to identify increases or decreases in each item (as opposed to the relative expense of each factor). For example, if ex-factory prices fall by 20 percent, but so do other factors, then this data will not reveal the ex-factory price decline.

Additionally, experience will indicate to what extent data collectors are able to assemble precise data on these questions. Given the complexity of the targeted data, it is likely that the data will not be perfect. The data should be robust enough, however, to provide strong evidence of the relative price contribution of the different price factors, especially related to changes over time. Analysts must recognize potential limitations in quality of the data.

Regulations relating to intellectual property rights protection and marketing authorization

These data include indicators regarding whether a country provides patent protection for pharmaceutical products, whether it has modified its national legislation to implement the TRIPS Agreement, whether it permits parallel importation of pharmaceuticals, whether it authorizes compulsory licensing and whether any compulsory licences have been issued for pharmaceuticals, whether generic manufacturers can use patented inventions to obtain marketing approval prior to expiration of the patent (whether a "Bolar" provision is in place), and whether a country provides exclusivity protections for marketing approval test data. Indicators also seek information about marketing approval authorities, linkages between process of marketing approval and issuance of patents, and the length of time for marketing approval of patented and generic pharmaceuticals.

These are basic data to profile a country's intellectual property rights system and system for providing marketing approval for pharmaceuticals.

The data will show whether a country grants patents for pharmaceuticals, whether it avails itself of the flexibilities in the TRIPS Agreement providing for parallel imports, compulsory licensing and Bolar provisions. They also provide important evidence on whether and how pharmaceutical marketing approval is connected to the intellectual property system -- through special protections for marketing approval data that may delay the introduction of generics, or through linkages of marketing approval and patent claims. They provide information as to changes in time for approval of generics which may be associated with changes in certain intellectual property rules. Together, these are the key intellectual property-expanding policies associated with globalization and TRIPS, as well as the most important exceptions and flexibilities. No such basic compilation of national intellectual property rules exists, making the gathering of this information by the Network an especially important task.

Most of this information can be gathered from national authorities, including from the national patent office and/or ministry of commerce or industry and the ministry of health, as well as from review of relevant laws and regulations. Some of the data on marketing approval (specifically questions 4-6 on pre-marketing authorization) will only be available from the national drug or health registration authority. If the national drug authority has not compiled the averages sought in questions four and five, it will be necessary to obtain the raw data from the national drug authority (amount of time for approval of each new and generic pharmaceutical product) and to calculate the desired averages.

These indicators do not by themselves illustrate anything more than the rules of a country's intellectual property system and its system of marketing approval. They may correlate in ways that prove to be of interest with changes in price or investment levels. But double caution must be exercised in drawing related conclusions: first, the correlations must be shown, not assumed. Second, analysts must remain mindful of the distinctions between correlation and causality.

Price of pharmaceutical products

These data include indicators relating to the pricing regulatory system in a country -- that is, whether prices are determined by market forces only, firm price controls, or another system. The bulk of the data in this section includes price indicators for the template's selected drug list, including average public and private prices of each drug, in both branded and generic versions.

Price is obviously a key -- though certainly not decisive -- factor influencing drug availability. The trends in pricing revealed by the data will be important indicators of changes in drug accessibility. Gathering data for both on-patent and off-patent drugs will enable comparisons that will provide some evidence of the effect of intellectual property protections on pricing. Correlations with other collected data, including changes in intellectual property rules and changes in pharmaceutical industry investment patterns will offer evidence for the potential impacts of TRIPS and globalization on drug access.

Information for the pricing regulatory indicators should be obtainable from national authorities, primarily the ministry of health and the national drug authority.

Gathering annual average price data is much more complicated. WHO has initiated a project with several nongovernmental organizations and a private foundation to standardize methods for drug pricing surveys with the aim of increasing the quantity, quality, comparability and transparency of information. Prices for selected essential drugs have been collected for different subsectors of the health system in several countries including Armenia, Brazil, Kenya, South Africa and Sri Lanka. The Network will seek to rely on this methodology to the extent possible: and Network researchers will collaborate with others implementing the WHO pricing project to avoid duplicative work in data gathering.

The pricing data should be robust, but will nonetheless be subject to numerous limitations both in fullness and quality and in analytic value. On the fullness and quality axis, some of the selected drugs may not be available in some countries, or may be available only in generic or branded versions, or may be available only in the public or private sector. Where categories of products do not exist, data obviously cannot be gathered. Resultant holes in the data collection may somewhat limit subsequent analyses. Furthermore, primarily due to resource limitations, Network researchers may in some cases not be able to obtain the desired number of data points for calculating average prices of certain drugs. In such cases, researchers will have to obtain as much information as possible; and the Collaborating Centres will need to make determinations about whether the data are sufficiently robust to merit inclusion in the finalized monitoring data (with proper notation of data shortfalls). On the analytic axis, it will again be important to recognize the distinction between correlation and causality in drawing analytic conclusions, as well as to recognize the multiple influences on pricing.

Market share

These data include indicators on market share of domestic pharmaceutical companies and presence and type of foreign direct investment in the pharmaceutical sector.

Increasing domestic production and foreign direct investment are important ends unto themselves, for their role in facilitating national economic development and for technology transfer. As articulated in the objectives of the TRIPS Agreement, the "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology." Domestic production and foreign direct investment may also have important implications for pricing and access. The price of domestically produced drugs may be less affected by changes in currency valuation than imported drugs; the use of domestically produced drugs may also save valuable foreign currency. Domestic production capacity may meaningfully assist with the more rapid and widespread availability of more affordable generic drugs; and establishing or expanding domestic production capacity to facilitate bulk production of drugs may maximize economies of scale. There are, as well, likely to be significant linkages between intellectual property

rules and the state of domestic industry and foreign direct investment. For example, enhanced intellectual property rules may correlate with increased levels of foreign direct investment.

These data should be available from national authorities, including the ministry of health and or industry, as well as national trade associations of domestic and international pharmaceutical producers.

The level of foreign direct investment, and especially the strength of the domestic industry, are influenced by numerous factors other than intellectual property rules. Analysts should acknowledge the inherent multifactoral nature of these trends.

Regulation of pharmaceutical consumption -- a stakeholder analysis

These indicators relate to national drug policies on promotion of generics, including use of generic prescribing and generic substitution. These are basic data to profile a country's policies to promote the use of generic drugs.

Indication of policies on generic promotion are an important variable to factor in equations on national consumption of generic and branded drugs. For example, cross-country comparisons of generic reliance, aimed at discovering potential correlations with intellectual property rules, must also account for the presence or absence of specific generics-promoting policies.

These data should be available from the ministry of health or national drug authority.

The existence of broad policies does not guarantee their across-the-board implementation, an important caveat to which analysts must remain alert.

Selected indicators for studying the impact of globalization and TRIPS on access to medicines

Respondent data

Country Represented.....

Participant's Name.....

Institution.....

Contents

I. Definitions used in the template** :

Bolar provision: A "Bolar" provision provides exemptions to exclusive patent rights which permit the testing, using, making (not selling) of patented pharmaceuticals for the purpose of submitting information required for obtaining marketing approval prior to the date of patent expiration. Bolar exemptions facilitate the entry of generic competition because they allow generics manufacturers to submit their products for regulatory approval before the expiry of a patented invention. Without these exceptions, generic manufacturers can only submit their products for regulatory approval after the expiry of the patent term. A recent WTO dispute settlement panel (Canada - Patent Protection for Pharmaceutical Products) upheld the TRIPS consistency of the Bolar exemption provided there was no "stockpiling" of the patented product by the generic manufacturer.

Data exclusivity: Data exclusivity provides a minimum term of protection for undisclosed information (test or other data), such as health registration data, used in the submission for the registration of a pharmaceutical product. Data exclusivity prevents a drug regulatory authority or any other national competent authority from relying on such data to assess further applications relating to the same drug until the expiry of exclusivity.

Domestic Firm: A domestic firm is a firm in which nationals of a given country own no less then a 50% stake of the said firm.

Domestic Industry: The domestic industry is the aggregate of domestic firms in a given country.

Drug Regulatory Authority: A Drug Regulatory Authority is designated by the State to ensure compliance with regulations applicable to drugs: issuing of marketing authorizations, authorizations of dispensaries, etc.

Generic Drug: A pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights. Generic drugs are marketed either under a nonproprietary or approved name rather than a proprietary or brand name. *(Multi-source (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability, Quality Assurance of pharmaceuticals, Vol.1 page 65).*

Generic substitution:	Practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredients. (World Health Organization. Indicators for Monitoring National Drug Policies, WHO/EDM/PAR/99.3).
Health care insurance coverage:	Voluntary and compulsory. Includes all forms of publicly and privately financed prepayment (i.e. tax based, insurance etc.) systems which pool risks among populations.
Market authorization:	An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.
Pharmaceuticals:	Excludes veterinary products, homeopathic products, and herbal products. Includes material for injection, syringes, needles, dermatologicals.
Protection of undisclosed information:	The submission of undisclosed information (test or other data) such as health registration data, is often used as a condition for approving the registration of pharmaceutical products. Article 39.3 of the TRIPS Agreement requires WTO Members to protect such data submitted for the registration of new chemical entities against unfair commercial use provided that their origination involves considerable effort. TRIPS does not require data exclusivity (see definition). It allows a national authority to rely on existing data to approve subsequent marketing applications for a similar product.
Public price:	Price at which drug is sold to the end user in the public health care system.
Private price:	Price at which drug is sold to the end user in the private health care sector. Includes both prescription and non-prescription medicines.
Tax:	e.g. local sales tax, value added tax and excise duties.

** For additional terminological clarification, those employing the template of suggested indicators should consult the glossary in Globalization and Access to Drugs, WHO/DAP/98.9

II. Trends in total pharmaceutical consumption

Table A: Final Consumption in nominal (unadjusted annual) prices, in national currency unit ……..(million, billion, etc.)

Year	Total health expenditure	Total pharma-ceutical expenditure	Total public (government) pharmaceutical expenditure as a per cent of total pharmaceutical expenditure (in terms of sales)	Total private expenditure on pharmaceuticals as a per cent of total pharmaceutical expenditure (in terms of sales)	Percentage of expenditure on imported pharmaceuticals (sales)	Percentage of pharmaceutical expenditure on locally produced goods (sales)	Annual national inflation rate
1998							
1999							
2000							
2001							
2002							
2003							

Table B: Consumption of generic medicines as a percentage of total pharmaceutical consumption

Year	GENERIC MEDICINES AS PERCENTAGE OF PHARMACEUTICAL CONSUMPTION	
	Sales	Volume of Prescriptions (number)
1998		
1999		
2000		
2001		
2002		
2003		

III. Health care coverage

Table C: **Health care coverage**			
Year	Percentage of population covered by public health care system	Percentage of population covered by private health care insurance	Percentage of population not covered by any public or private health care scheme
1998			
1999			
2000			
2001			
2002			
2003			

1. Are pharmaceuticals covered by health insurance or health service schemes?
   Yes/No

   a) Is there any co-payment?

   If yes, how much?

IV. Structure of public and private pharmaceutical prices

Table D: Structure of **public** pharmaceutical price [retail price]			
	1998	2001	2003
Ex-factory Price [percentage of retail price/ current year price as percentage of 1998 price]			
Wholesalers' margin [percentage of retail price/ current year price as percentage of 1998 price]			
Dispensing margin [percentage of retail price/ current year price as percentage of 1998 price]			
VAT or equivalent sales tax [percentage of retail price/ current year price as percentage of 1998 price]			
Other taxes [percentage of retail price/ current year price as percentage of 1998 price]			
Total	100%/100%	100%/	100%/

Table E: Structure of **private** pharmaceutical price[retail price]			
	1998	2001	2003
Ex-factory price [percentage of retail price/ current year price as percentage of 1998 price]			
Wholesalers' margin [percentage of retail price/ current year price as percentage of 1998 price]			
Dispensing margin [percentage of retail price/ current year price as percentage of 1998 price]			
VAT or equivalent sales tax [percentage of retail price/ current year price as percentage of 1998 price]			
Other taxes [percentage of retail price/ current year price as percentage of 1998 price]			
Total	100%/100%	100%/	100%/

V. Regulations relating to intellectual property rights protection and marketing authorization

System of patent protection

1. Is patent protection provided for pharmaceutical products?
Yes / No

a) If yes, how long ago was patent protection introduced?

b) If yes, is this a process or product patent (circle as appropriate)?

Process / Product / Both

c) What is the duration of the patent term?

Please add any comments on the product / process patent issue that may be relevant to your country

_____

_____

2. If the country is a WTO Member, has national legislation been modified to implement the TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights) ? yes / no

a) If yes, when did it take effect?

b) If not, when is this likely to take place?

c) Is the country availing itself of the transition period provided by Article 65 of the TRIPS Agreement?

d) If the country is a least-developing country (LDC), has it availed itself of the transitional period accorded to LDCs in Article 66 of the TRIPS Agreement?

3. Have parallel importing provisions been incorporated into national legislation?

Yes/No/Currently being discussed

a) If yes, have these parallel importing provisions been applied for pharmaceuticals?

Yes/No

b) What regime of exhaustion is incorporated into national legislation?

International/Regional/National

4. Have compulsory licensing provisions been incorporated into national legislation?

Yes/No/Currently being discussed

a) If yes, have these compulsory licensing provisions been applied for pharmaceuticals?

Yes/No

b) If yes, under what conditions?

National emergency/Public non-commercial use/Remedying anti-competitive practices/Other (please specify)/Don't know

5. Are generic pharmaceutical manufacturers allowed to use patented inventions for the purpose of obtaining marketing approval prior to patent expiration; i.e has a Bolar provision been incorporated in national legislation? (see definitions page 38-39)

Yes/ No/Currently being discussed

6. Are there provisions granting a minimum term of data exclusivity for the protection of test data submitted for the marketing approval of a pharmaceutical product? (see definitions page 38-39)

Yes/No/Currently being discussed

Table F: Patent and/or data exclusivity status		
Product	**Dates of patent expiration (if applicable)**	**Date of data exclusivity expiration (if applicable)**
Erythromycin		
Ciprofloxacin		
Rifampicin		
Doxycycline		
Cyclophosphamide		
Hydrochlorothiazide		
Atenolol		
Salbutamol		
Candesartan		
Celecoxib		
Orlistat		
Sildenafil		
Olanzapine		
Levofloxacin		
Atorvastatin		
Montelukast		
Esomeprazol		
Fluconazole		
Zidovudine		
Nevirapine		
Azithromycin		
Didanosine (ddI)		
Indinavir		
Lamivudine		
Ofloxacin		
Lamivudine + Zidovudine		
Zidovudine+Lamivudine +Abacavir		

Pre-marketing authorization

1. Which authority is responsible for granting marketing approval (registration)?

_____
_____

2. What is its affiliation with the Ministry of Health?

_____
_____

3. Is there any linkage between the processes of drug registration (Ministry of Health or Drug Regulatory Authority) and the grant of patent (National Patent Office)?

Yes/No

4. What is the average length of time required for approval of a new pharmaceutical product? (Please indicate with reference to any given year)

Year Length of time (in months)

5. What is the average length of time required for approval of a generic pharmaceutical product upon patent expiration? (Please indicate reference to any given year)

Year Length of time (in months)

6. How many pharmaceutical products are approved by the health registration authority in 2001?

VI. Prices of pharmaceutical products

Production

1. Who sets the prices of patented pharmaceutical products?

a) Market forces Yes / No

b) Regulation Yes / No
c) Other (please specify) Yes / No

2. Who sets the prices of generic pharmaceuticals?

a) Market forces Yes / No
b) Regulation Yes / No
c) Other (please specify) Yes / No

3. Is the process of drug registration linked to the pricing procedure?

Yes /No

4. Are the prices of pharmaceutical products regulated?

Yes /No

If the prices of pharmaceuticals are regulated with what method?

a) International price comparisons
b) Negotiation between manufacturers and national authorities
c) Regulating return on capital
d) Price-volume agreements
e) Price indicated in tender submitted to Ministry of Health
f) Do not know.

5. Is there a clearly defined state controlled mechanism to monitor the implementation of price controls?

Yes/No

a) If Yes, please check all that apply

(i) Duty on imported raw materials _____
(ii) Duty on imported finished products _____
(iii) Maximum wholesale mark up _____
(iv) Maximum retail mark up _____
(v) Maximum retail price _____
(vi) No pricing policy/regulation _____

Price indicators

1. Public and private prices of branded pharmaceuticals

Table G: Average annual public sector prices per standard dose of drugs (original brand)						
Product and dosage*	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**
Erythromycin** (250 mg)						
Ciprofloxacin*** (250 mg)						
Rifampicin (150 – 300 mg)						
Doxycycline*** (100 mg)						
Cyclophosphamide (25 mg)						
Hydrochlorothiazide**** (25 mg)						
Atenolol (50-100 mg)						
Salbutamol***** (Inh. 100 :g)						
Candesartan (4 mg)						
Celecoxib (200 mg)						
Orlistat (120 mg)						
Sildenafil (50 mg)						
Olanzapine (10 mg)						
Levofloxacin (500 mg)						
Atorvastatin (10 mg)						
Montelukast (10 mg)						
Esomeprazol (20 mg)						

continued…

Table G: Average annual public sector prices per standard dose of drugs (original brand) *…continued*						
	1998	**1999**	**2000**	**2001**	**2002**	**2003**
Product and Dosage*						
Fluconazole (50 mg)						
Zidovudine (300 mg)						
Nevirapine (200 mg)						
Azithromycin 500 mg						
Didanosine (ddI) 150 mg						
Indinavir 200 mg						
Lamivudine 150 mg						
Ofloxacin 200 mg						
Lamivudine + Zidovudine 150 mg + 300 mg						
Zidovudine+ Lamivudine+Abacavir 300 mg+150 mg+300mg #						

* If not indicated, pharmaceutical dosage forms are **tablets**. Divide the price of the pack by the number of doses (e.g. tablets) in order to give the price per dose
** stearate/ethylsuccinate
*** HCl
**** 50 mg (if 25 mg not available)
***** As sulphate
# If available as a fixed-dose combination.

Table H: Average annual private sector prices per standard dose (original brand)						
Product and dosage*	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**
Erythromycin** (250 mg)						
Ciprofloxacin*** (250 mg)						
Rifampicin (150-300 mg)						
Doxycycline*** (100 mg)						
Cyclophosphamide (25 mg)						
Hydrochlorothiazide**** (25 mg)						
Atenolol (50-100 mg)						
Salbutamol***** (Inh. 100 :g)						
Candesartan (4 mg)						
Celecoxib (200 mg)						
Orlistat (120 mg)						
Sildenafil (50 mg)						
Olanzapine (10 mg)						
Levofloxacin (500 mg)						
Atorvastatin (10 mg)						
Montelukast (10 mg)						
Esomeprazol (20 mg)						

continued…

Table H: Average annual private sector prices per standard dose (original brand) …*continued*

Product and dosage*	1998	1999	2000	2001	2002	2003
Fluconazole 50 mg						
Zidovudine 300 mg						
Nevirapine 200 mg						
Azithromycin 500 mg						
Didanosine (ddI) 150 mg						
Indinavir 200 mg						
Lamivudine 150 mg						
Ofloxacin 200 mg						
Lamivudine + zidovudine 150 mg + 300 mg						
Zidovudine+ Lamivudine+Abacavir 300 mg+150 mg+300mg #						

* If not indicated, pharmaceutical dosage form are **tablets**.
**stearate/ethylsuccinate
***HCl
****50 mg (if 25 mg not available)
***** As sulphate
# If available as a fixed-dose combination.

Table I: Average annual public sector prices per standard dose (generic equivalents)																			
	Number of generic equivalents on the market	**1998**			**1999**			**2000**			**2001**			**2002**			**2003**		
		Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min
Product and dosage*																			
Erythromycin** (250 mg)																			
Ciprofloxacin*** (250 mg)																			
Rifampicin (150 – 300 mg)																			
Doxycycline*** (100 mg)																			
Cyclophosphamide (25 mg)																			
Hydrochlorothiazide **** (25 mg)																			
Atenolol (50 – 100 mg)																			
Salbutamol***** Inh. 100:g																			

continued…

Table I: Average annual public sector prices per standard dose (generic equivalents)…*continued*																			
	Number of generic equivalents on the market	**1998**			**1999**			**2000**			**2001**			**2002**			**2003**		
		Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min
Product and dosage*																			
Candesartan (4 mg)																			
Celecoxib (200 mg)																			
Orlistat (120 mg)																			
Sildenafil (50 mg)																			
Olanzapine (10 mg)																			
Levofloxacin (500 mg)																			
Atorvastatin (10 mg)																			
Montelukast (10 mg)																			
Esomeprazol (20 mg)																			
Fluconazole (50 mg)																			
Zidovudine (300 mg)																			
Nevirapine (200 mg)																			
Azithromycin (500 mg)																			

continued…

Table I: Average annual public sector prices per standard dose (generic equivalents) …*continued*

	Number of generic equivalents on the market	**1998**			**1999**			**2000**			**2001**			**2002**			**2003**		
		Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min
Product and dosage*																			
Didanosine (ddI) (150 mg)																			
Indinavir (200 mg)																			
Lamivudine (150 mg)																			
Ofloxacin (200 mg)																			
Lamivudine + Zidovudine (150 mg + 300 mg)																			
Zidovudine+ Lamivudine+ Abacavir (300 mg+150 mg +300mg) #																			

* If not indicated, pharmaceutical dosage forms are **tablets**.
** stearate/ethylsuccinate
*** HCl
**** 50 mg (if 25 mg not available)
***** As sulphate
# If available as a fixed-dose combination.

Table J: Average annual private sector prices per standard dose (generic equivalents)																			
	Number of generic equivalents on the market	**1998**			**1999**			**2000**			**2001**			**2002**			**2003**		
		Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min
Product and dosage*																			
Erythromycin** (250 mg)																			
Ciprofloxacin*** (250 mg)																			
Rifampicin (150 – 300 mg)																			
Doxycycline*** (100 mg)																			
Cyclophosphamide (25 mg)																			
Hydrochlorothiazide **** (25 mg)																			
Atenolol (50 – 100 mg)																			
Salbutamol***** Inh. 100:g																			

continued…

Table J: Average annual private sector prices per standard dose (generic equivalent) …*continued*

	Number of generic equivalents on the market	**1998**			**1999**			**2000**			**2001**			**2002**			**2003**		
		Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min
Product and dosage*																			
Candesartan (4 mg)																			
Celecoxib (200 mg)																			
Orlistat (120 mg)																			
Sildenafil (50 mg)																			
Olanzapine (10 mg)																			
Levofloxacin (500 mg)																			
Atorvastatin (10 mg)																			
Montelukast (10 mg)																			
Esomeprazol (20 mg)																			
Fluconazole (50 mg)																			
Zidovudine (300 mg)																			
Nevirapine (200 mg)																			

continued…

Table J: Average annual private sector prices per standard dose (generic equivalent) …*continued*

	Number of generic equivalents on the market	1998			1999			2000			2001			2002			2003		
		Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min	Ave	Max	Min
Product and dosage*																			
Azithromycin (500 mg)																			
Didanosine (ddI) (150 mg)																			
Indinavir (200 mg)																			
Lamivudine (150 mg)																			
Ofloxacin (200 mg)																			
Lamivudine + Zidovudine (150 mg+ 300 mg)																			
Zidovudine+ Lamivudine+ Abacavir (300 mg+150 mg+300mg) #																			

* If not indicated, pharmaceutical dosage forms are **tablets**.
**stearate/ethylsuccinate
*** HCl
**** 50 mg (if 25 mg not available)
***** As sulphate
# If available as a fixed-dose combination.

Table K: Annual quantity sold per standard dose of original brand in public system: Volume of prescriptions

	1998	1999	2000	2001	2002	2003
Product						
Erythromycin						
Ciprofloxacin						
Rifampicin						
Doxycycline						
Cyclophosphamide						
Hydrochlorothiazide						
Atenolol						
Salbutamol						
Candesartan						
Celecoxib						
Orlistat						
Sildenafil						
Olanzapine						
Levofloxacin						
Atorvastatin						
Montelukast						
Esomeprazol						
Fluconazole						
Zidovudine						
Nevirapine						
Azithromycin						
Didanosine (ddI)						
Indinavir						
Lamivudine						
Ofloxacin						
Lamivudine + Zidovudine						
Zidovudine+ Lamivudine+ Abacavir						

Table L: Annual quantity sold per standard dose of original brand in private system : volume of prescriptions

	1998	1999	2000	2001	2002	2003
Product						
Erythromycin						
Ciprofloxacin						
Rifampicin						
Doxycycline						
Cyclophosphamide						
Hydrochlorothiazide						
Atenolol						
Salbutamol						
Candesartan						
Celecoxib						
Orlistat						
Sildenafil						
Olanzapine						
Levofloxacin						
Atorvastatin						
Montelukast						
Esomeprazol						
Fluconazole						
Zidovudine						
Nevirapine						
Azithromycin						
Didanosine (ddI)						
Indinavir						
Lamivudine						
Ofloxacin						
Lamivudine + Zidovudine						
Zidovudine+ Lamivudine+ Abacavir						

Table M: Annual quantity sold per standard dose of generic equivalent in public system: Volume of prescriptions

	1998	1999	2000	2001	2002	2003
Product						
Erythromycin						
Ciprofloxacin						
Rifampicin						
Doxycycline						
Cyclophosphamide						
Hydrochlorothiazide						
Atenolol						
Salbutamol						
Candesartan						
Celecoxib						
Orlistat						
Sildenafil						
Olanzapine						
Levofloxacin						
Atorvastatin						
Montelukast						
Esomeprazol						
Fluconazole						
Zidovudine						
Nevirapine						
Azithromycin						
Didanosine (ddI)						
Indinavir						
Lamivudine						
Ofloxacin						
Lamivudine + Zidovudine						
Zidovudine+ Lamivudine+ Abacavir						

Table N: Annual quantity sold per standard dose of generic equivalent in private system : Volume of prescriptions

	1998	1999	2000	2001	2002	2003
Product						
Erythromycin						
Ciprofloxacin						
Rifampicin						
Doxycycline						
Cyclophosphamide						
Hydrochlorothiazide						
Atenolol						
Salbutamol						
Candesartan						
Celecoxib						
Orlistat						
Sildenafil						
Olanzapine						
Levofloxacin						
Atorvastatin						
Montelukast						
Esomeprazol						
Fluconazole						
Zidovudine						
Nevirapine						
Azithromycin						
Didanosine (ddI)						
Indinavir						
Lamivudine						
Ofloxacin						
Lamivudine + Zidovudine						
Zidovudine+ Lamivudine+ Abacavir						

VII. Market share of domestic and foreign firms

1. Is there a relevant domestic (indigenous) pharmaceutical industry?
yes / no

a)If yes, what is the market share in value of the domestic (indigenous) pharmaceutical industry?

Please check one

(i) <25%
(ii) 26-50%
(iii) 51-75%
(iv) 76-100%

b) what is the annual sales total of the domestic pharmaceutical industry?

2. How many local producers are currently operating?

_____

3. Of the locally operating subsidiaries of multinational corporations, how many have (please tick all that apply):

	1998	2001	2003
a) Research and development facilities only	____	____	____
b) Manufacturing facilities only	____	____	____
c) Research, development and manufacturing facilities	____	____	____
d) Distribution facilities only	____	____	____
e) Manufacturing and distribution facilities only	____	____	____
f) Research, development, manufacturing and distribution facilities	____	____	____

4. How many workers are employed by:

a) the domestic pharmaceutical industry _____
b) subsidiaries of multinational pharmaceutical companies _____

VIII. Regulation of pharmaceutical consumption – a stakeholder analysis

1. Are any of the following mechanisms to regulate pharmaceutical consumption and physician prescribing applied in your country?

a) Cash-limited prescribing budgets
b) Generic name prescribing
c) Formularies
d) Prescribing guidelines
e) Generic substitution

2. Is prescribing by generic name (of the drug) required in the public sector? Yes/No

   a) Is prescribing by generic name (of the drug) required in the private sector? Yes/No

3. Is generic substitution allowed or required at public pharmacies?

   Allowed: Yes/No

   Required: Yes/No

   a) Is generic substitution allowed or required at private pharmacies?

   Allowed: Yes/No

   Required: Yes/No

Thank you very much for your kind collaboration.

The Collaborating Centres

The Collaborating Centres in the WHO Network for Monitoring the Impact of Globalization and TRIPS on Access to Drugs will work individually and collectively to gather and analyse data relevant to assessing how the processes of economic globalization and the TRIPS and other trade and international agreements are related to the challenge of improving access to pharmaceuticals.

The centerpiece of this effort will be to collect and analyse the data included in the template of selected indicators. Each of the Collaborating Centres will collect data on an annual basis for three countries in their region, or in the region of their expertise and on-the-ground contacts. Working as a network, the Collaborating Centres will review their experience in collecting data to make recommendations for clarifications and revisions to the template of selected indicators, as well as sharing learned experience about how to most efficiently and effectively train data collectors and acquire the desired data.

The Collaborating Centres will share their data to develop a substantial pool of data for analysis. They will conduct independent analyses of the data, focusing as appropriate on the data from their own region or on the entire Network data set. While there will inevitably be some overlap in the Collaborating Centres' analytic projects, they will proactively share research plans to avoid unnecessary duplication of effort.

Each of the Collaborating Centres is expected to focus on issues relating to their particular areas of expertise, and on questions of particular importance and urgency for their region or the regions on which they focus. The Centres may also, in conjunction with the data gathering process, collect additional information related to relevant issues of particular concern.

Background information on each of the Collaborating Centres follows:

The Bangkok Collaborating Centre

The Centre for Health Economics is a specialized centre within the Faculty of Economics, Chulalongkorn University. It grew out of the positive development in health economics in the Faculty since 1979. The Centre was formally established in 1990 with initial support from WHO/TDR and the British Council. The Centre is committed to regular teaching of health economics at undergraduate and graduate levels in Thai and to an international graduate MSc course in Health Economics in English. It offers regular international Short Courses in English in specialized areas of Health Economics for graduates and provides other specialized courses in collaboration with Government Ministries and other institutions.

The objectives of the Centre for Health Economics are to: (1) Develop expertise in and commitment to the application of health economics in the formulation of

health care policies, in planning and resource allocation, and in the health care delivery process in the region and Thailand; (2) strengthen health economics research capability in Thailand and South-East Asia, with respect to health policy, health care reform, drug policy and related issues to improve effectiveness, efficiency and equity; (3) encourage research in economic analysis and evaluation of disease control, with special attention to tropical diseases; (4) provide advisory and information services in South-East Asia and other regions on health economics research.

The Barcelona Collaborating Centre

The Foundation *Institut Català de Farmacologia* is a non-profit institution whose Board of Trustees is composed of representatives of local health authorities, the Autonomous University of Barcelona (AUB) and WHO's and other international experts. The FICF is a WHO Collaborating Centre for Research and Training in Pharmacoepidemiology.

Its constituent objective is to promote rational drug prescription and the effective and efficient use of therapeutic resources.

FICF's activity is carried out at the University hospital complex *Vall d'Hebron,* several primary health care centres, and international cooperation in collaboration with Spanish and European regulatory authorities, WHO, scientific societies and other organizations. The main working areas of FICF are (1) support of institutional committees (on drug selection and drug and therapeutics information, ethics committees, and other), advice to health authorities on pharmaceutical policies, national and international regulation and pharmacovigilance; (2) drug information with special focus on telematics; (3) training (pregraduate, postgraduate, specialist training, and continuous education of health professionals), and (4) research.

The London Collaborating Centre

LSE Health and Social Care is a research centre at the London School of Economics and Political Science. The Centre's mission is to produce and disseminate high quality research in health and social care. Major areas of research include: pharmaceutical economics and policy, European and international health policy, healthcare system reform, social and private health insurance, health technology assessment and outcomes, and equity and efficiency of health services.

The Rio de Janeiro Collaborating Centre

The Nucleus for Pharmaceutical Policies of the National School of Public Health comprises a staff of senior researchers with diverse professional experiences, working in an academic environment. Linked to the Ministry of Health, it has been strongly supporting Health Policy formulation, implementation and assessment, dealing with expanding access of populations to Health services and essential medicines. Within this context, the Centre has actively participated in the formulation of the Brazilian National Drug Policy and has leaded the review of the EDL (essential drug list) and National Therapeutic Formulary, also

assessing the implementation of health programmes related with access to medicines.

Additionally, the Centre has organized international seminars for Latin American and Spanish and Portuguese-speaking African countries', addressing the issues of Health Sector Reform and access to essential medicines and has participated in the process of formulating other countries NDP, such as Honduras and Angola. It receives Master Degree and Doctor in Sciences students for studies in Public Health, related to pharmaceutical policies and Health Evaluation studies.

Its recent activities in Brazil include monitoring of the implications of WTO TRIPS Agreement and intellectual property rights regarding access to medicines, availability and affordability of them, as well as the implementation and assessment of the recent Generic Medicines Law. Its members have been participating in several international joint initiatives supported by United Nations Agencies and public interest nongovernmental organizations. Case-country studies in several areas involving access to medicines are being planned.