Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines

Report of a workshop organized by
the International Health Policy Programme, Ministry of Public Health, Thailand
and the World Health Organization, Regional Office for South-East Asia,
Bangkok, 22-24 November 2006

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1. INTRODUCTION

1.1 Background

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has harmonized standards for intellectual property protection among Member countries of the World Trade Organization (WTO). For most developing countries, these new standards are higher (i.e. offer more protection to the right-owners) than their pre-TRIPS standards. Thus, the implementation of TRIPS has led to concerns, notably with regard to the potential negative implications on prices of, and access to, medicines. While most developing countries have yet to experience the full impact of implementing the TRIPS standards, increasingly, demands are being made to increase the level of intellectual property rights (IPR) protection even further. Such standards are oft referred to as "TRIPS-plus".

The fast changing global environment of IPR regimes and policies may, with varying degrees of uncertainty, affect key elements of pharmaceutical markets, such as competition, prices, expenditures, consumption and access. The balance between imports and domestic pharmaceutical production may also be affected. These uncertainties raise to new policy questions, and currently economic modeling methodologies are being developed to cater to the information-needs of policy makers, notably:

- Decision-makers, such as the negotiators of a trade agreement, must often consider and take quick decisions on proposals related to IPR, which may have a substantial impact on future access to pharmaceuticals and, ultimately, on the health status in their countries;
- Although it is increasingly apparent to most developing countries' negotiators that stronger (TRIPS-plus) IPR protection is likely to have negative net effects on drug accessibility and health status, trade agreements often require trade-offs in a given sector in order to obtain advantages (e.g. tariff reductions to agricultural exports) in other sectors;
- If concessions have to be considered or made in a given sector, it is important to be able to identify and quantify as precisely as possible the future impact, in order to compare it with the expected benefits from other sectors.

1.2 Objective

The objective of the workshop was to build and/or strengthen regional and national capacity to assess the economic impact of TRIPS-plus provisions on the expenses and access to essential new medicines in general, and HIV/AIDS medicines in specific.

1.3 Expected output

Increased knowledge and awareness about TRIPS-plus provisions and how they may affect public health and access to medicines;

Increased awareness about and interest in the use of economic modeling methods as a tool to project the potential implications of TRIPS-plus provision on access to medicines;

Increased national and regional capacity to conduct an economic impact assessment on the implications of TRIPS-plus provisions; and

Increased understanding of the use of economic projections for advocacy purposes.

2. BUSINESS SESSIONS

2.1 TRIPS-plus provisions and their implications on access to medicines (presented by Ms Karin Timmermans)

"TRIPS-plus" is an informal term for protection of intellectual property rights that goes beyond the requirements in the TRIPS Agreement. Some of the important TRIPS-plus provisions are:

- *Data exclusivity* refers to the idea that, for a certain period of time[1], the regulatory authorities are not allowed to rely on the originator's safety and efficacy data for the purpose of registration of generic versions of a drug. By implication, as long as the exclusivity lasts, generic producers would have to submit their own data to enter the market. This would oblige them to repeat the clinical trials, which they may not be able to afford, and which would take time. It would also pose ethical questions, since repeating clinical trials would imply withholding treatment that is already known to be effective from part of the trial participants (the control group). Alternatively, and in practice more likely, generic manufacturers would have to delay the launch of their product until the end of the exclusivity period. Thus, data exclusivity diminishes the likelihood of fast marketing of generics, and delays competition and price reductions. TRIPS, however, mandates data protection[2], but not data exclusivity.
- *Patent term extensions*, i.e. provisions to extend the duration of a patent beyond the 20 years required by TRIPS, in order to compensate for "unreasonable" delays in granting the patent and/or in registering the medicine.
- *Linkage* between patent status and generic registration, meaning that the Regulatory Authority may not register generic versions of a pharmaceutical that is under patent. This would be problematic, since the Regulatory Authority would probably lack the resources and manpower to check the patent status of each product. Moreover, in case there is a patent, regulators may not have the expertise to assess whether the patent is valid and would be

[1] In the United States, data exclusivity lasts five years for new chemical entities and three years for new indications. In the European Union, it is ten years with a possible one year extension in case the drug is registered for a significant new indication.

[2] According to TRIPS, such data should be protected against disclosure, and against unfair (or dishonest) commercial use.

infringed[3]. As a result, it is likely that they will enforce all patents, even invalid ones – and thus create additional and unnecessary hurdles for generic competition[4]. "Linkage" is also problematic in view of the fact that patents are private rights; as such, they should be enforced by the right holders, not by a government body.

- *Limitations of the grounds for compulsory licenses*, which may preclude issuing a compulsory license for reasons of public health. Requirements to limit the grounds (or reasons) for issuing a compulsory license are "TRIPS-plus" since the TRIPS Agreement leaves countries free to determine the grounds for issuing a compulsory license.

Other TRIPS-plus requirements deal with the administrative procedures related to patent applications and/or the granting and revocation of patents. The effect of all TRIPS-plus provisions is that they complicate or delay the marketing of generics.

TRIPS-plus provisions can be encountered in different bilateral or regional agreements, including bilateral trade agreements. Thus, the health sector should be alert and warn negotiators about the potential negative implications of such provisions with regard to public health and access to medicines.

2.1 Rationale for economic modeling

(Presented by Dr Suwit Wibulpolprasert)

IPR provide incentives for innovation, research and development of medicines. However, there are significant differences in the pace and level of development between countries. Notably, many developing countries are faced with a 'double' burden of both communicable and noncommunicable diseases, while their purchasing capacity is relatively low. The same policies may therefore have very different consequences, due to differences in context.

Economic modeling can generate evidence on the potential economic impact of policy measures or changes in policies, and can be expanded to estimate health impact. Quantitative estimates on economic and health implications may help to:

- calculate the additional budget necessary to purchase the same quantity of medicines;
- estimate the number of patients that will not have access to medicines and/or the number of lives lost in case the budget is fixed;
- determine whether or not certain trade-offs between health and other sectors benefit the country;

[3] For these reasons, Regulatory Agencies in the EU have so far refused to implement such "linkage" between patent status and registration of medicines.

[4] In 2002, the US Federal Trade Commission found that when generic companies initiate patent litigation, they prevail in a significant number of cases.

- establish whether the government would need to subsidize and compensate the health sector to compensate for the negative effects of trade-offs with other sectors.

Impact assessments can help policy makers and stakeholders understand the implications of complex legal provisions, and can facilitate informed decision making.

2.2 Concept of economic modeling

(Presented by Dr Joan Rovira)

Generally speaking, a model is a simplified representation of reality, created with a practical purpose in mind. Models are meant to facilitate the conceptualization and understanding of real phenomena by selecting and isolating the key elements and the relationships between those elements. Models can be physical (e.g. a map, a small prototype of an aircraft, a clinical trial) or abstract; abstract models can be conceptual (e.g. a diagram) or quantitative (i.e. based on economic, statistical or other equations).

Models can be used to project the evolution of a system, for instance when it is not feasible to perform a (controlled) experiment. Models can also be used to forecast the impact of an intervention in a system, or to extrapolate the results of an intervention to a different time and setting.

Advantages of the use of models include the fact that the investment required to assess the effects of an intervention is relatively limited, and that they can facilitate and improve a decision making process. Modeling furthermore can facilitate substituting implicit reasoning by explicit, transparent assumptions. Moreover, using a model may be the only way to prospectively assess the evolution of a system or of an intervention. The main disadvantage relates to the fact that a model may be difficult to validate, which can reduce its credibility. This is because the projections of the model can be verified only after policy changes have taken effect, which may take several years.

Models, however, are analytical tools; thus, they can complement but not substitute empirical analysis. Importantly, a model is only as good as the theory, assumptions and data on which it is based.

2.3 The Thai model to assess the impact of TRIPS-plus provisions

(Presented by Ms Chutima Akaleephan)

In 2004-2005, the International Health Policy Program (IHPP), Ministry of Public Health, Thailand, with financial support from the Fiscal Policy Research Institute Foundation, Ministry of Finance, had carried out a research on the implications of Thai-US free trade agreement (FTA) on drug expenditures and on access to essential medicines, in order to assess the potential impact of the ongoing FTA negotiations. The study aimed to project the possible increase in drug expenditures

and the reduction in access to essential medicines due to the additional market exclusivity caused by provisions in the FTA. The magnitude of the additional expenditures was estimated//obtained//assessed by calculating the average price differential between innovative drugs and their generics in a competitive market. This differential -as well as the average consumption pattern of medicines facing competition- was then used to estimate the potential cost savings due to introduction of generic competition; the 'foregone' savings due to prolonged market exclusivity caused by TRIPS-plus provisions represent the cost imposed by a TRIPS-plus situation. Both drug expenditures and accessibility were measured in terms of Defined Daily Dose (DDD).

The study found that for 42 top selling medicines in 2003, the introduction of competition would have saved approximately 260 million US dollars. Thus, TRIPS-plus provisions could, by postponing the introduction of competition, result in significant additional expenses. Alternatively, the consumption would be about 35% lower. The study furthermore proposed and recommended policies and alternatives for the negotiations. In addition, it also looked into possible measures to alleviate the negative implications, should TRIPS-plus measures be introduced.

Overview of methodology:

(1) Classify drugs in 2003 into 3 groups: a) drugs that are not patented and for which generic versions exist, b) drugs that are not patented but without competition in the market, and c) patented drugs.

(2) Assess total national volume and value of consumption in DDD.

(3) From the drugs for which generic versions exist (group a) four parameters were estimated from two existing national databases: a) percentage market share of generics, b) average growth in total consumption, c) price ratio of generic to innovative drugs, d) annual price increase of innovative drugs.

(4) From the two other groups (group b and c) two parameters were estimated: a) average growth in total consumption, b) annual price increase of innovative drugs.

(5) It was assumed that drugs without competition, whether patented or not, have the same monopoly behaviour; hence they were combined into a single group.

(6) Based on the afore mentioned parameters, the future consumption, price and value of drugs without competition (groups b and c) were simulated under a TRIPS-plus scenario.

(7) The patent expiry of drugs in this group and the subsequent occurrence of generic competition was estimated for the current situation (i.e. a TRIPS-compliant law, without TRIPS-plus provisions), and based on the profile and pattern of consumption, the potential cost savings, as well as changes in consumption, were estimated.

2.4 Assessing the impact of TRIPS-plus on access to ARVs in Thailand (Presented by Dr Jongkol Lertiendumrong)

Since human immunodeficiency virus (HIV) infection is an important health problem in Thailand, which contributed significantly to the DALYs lost in 1999 and 2004 respectively, the Thai government has launched an antiretroviral therapy (ART) programme, with limited coverage, since 1992. Due to the unaffordable drug prices, however, it was not until October 2003 that this public-subsidized programme was extended nationwide. One of the crucial factors that made treatment scale-up possible was the production of generic antiretrovirals (ARVs) by the Government Pharmaceutical Organization, which made them affordable for the public sector.

This study aims to examine the impact of TRIPS-plus measures with regard to the additional expenditure for the ARV treatment programme, accessibility to the drugs and its consequences on HIV morbidity and mortality. In addition, the effects are compared among TRIPS and TRIPS-plus scenarios, and the morbidity and mortality are presented as life years saved/lost in case budget constraints make it impossible to fully cover the costs.

Preliminary findings indicate that total expenditure on ARVs under a TRIPS-plus scenario may be 3 to 7 times higher than in the current (TRIPS-compliant but not TRIPS-plus) situation.

Overview of methodology:

(1) Assess drug price from actual price difference between innovative and generic drug according to national treatment regimens. There are four regimens for first line drugs (one basic and three alternatives regimens) and eight regimens for second line.

(2) Apply Markov model to estimate the number of patients in a specific clinical stage, using 2007-2020 cohorts of AIDS cases (Asian Epidemiologic model or AEM) as the basis. The projection is made for 20 years and three sets of parameters, namely, rate of follow-up, rates of drug tolerability, and treatment failure. These parameters were fixed for the 20-year projection. From this, the total number of patients on each of the 12 different treatment regimens for the period 2007 to 2039 is estimated.

(3) Using 2006 prices as the baseline, the price differential between generic and innovative drugs (see 1) was applied in the modeling to estimate future costs.

(4) Total budget implications are estimated by comparing the current situation of TRIPS with future TRIPS-plus. The economic impact is calculated as a percentage of the total budget of the Universal Coverage Scheme.

(5) Assuming that there is no additional budget to absorb the cost caused by TRIPS-plus measures, the total number of life years lost due to inaccessibility to ARV is estimated.

2.5 The IPR impact model

(Presented by Dr Joan Rovira)

This model was originally developed and applied in the WHO/PAHO Region. The model simulates the impact of the changes in the intellectual property regime on cost, consumption, national production and prices of medicines. The model captures the impact of a change in intellectual property rights and policies by comparing a baseline scenario with an alternative scenario. The baseline scenario reflects the market conditions prevalent during the specified baseline year. An alternative scenario provides a glimpse of the market conditions that will prevail once the specified changes in the intellectual property rights regime are introduced.

The model was constructed to compare several different scenarios, in order to assess the effect of different potential changes in IPR. For instance it allows a comparison between the introduction of different TRIPS-plus provisions both separately and in combination. The model can capture the following aspects of stronger intellectual property rights: the introduction of product patents[5], patent term extensions, data exclusivity and linkage. It could be adapted to capture other provisions as long as the effects of these provisions can be quantified either in terms of changes in the market share or extension of the duration of market exclusivity.

For both the baseline and the alternative scenarios the model calculates the percentage of active ingredients (AIs) in the market under exclusivity either due to product patent protection or test data protection. The model can also be applied to calculate the impact of changes in the market shares of branded and unbranded generics.

A key assumption of the model is that strengthening of intellectual property rights will translate into an increase in prices of medicines. This, in turn, can curtail access through increase in pharmaceutical expenditure, reduction in consumption or a combination of the two. The model assumes that the prices of an AI will be higher under exclusivity than under competition, and that prices of branded generics are higher than those of unbranded ones. Moreover, a constant price elasticity demand function is assumed. The market share of the domestic industry is determined by the distribution of the market between AIso under exclusivity and those without protection.

The model assesses the impact of changes in IPR by calculating the differences in market share of the domestic and foreign firms and in the prices between baseline and alternative scenarios. These differences are used to infer the impact on pharmaceutical consumption and expenditure. The impact is calculated as being the difference between the baseline figure and that of an alternative scenario for each given outcome variable. The final impact of changes in intellectual property regime is assessed in terms of:

[5] Currently, the model does not cover process patents, since process patents are not considered to convey absolute exclusive rights

- The change in the total pharmaceutical expenditure or in the value of the pharmaceutical market in nominal terms.
- The change in pharmaceutical consumption (in units).
- The difference in the sales of the domestic industry in nominal terms.

The market can be defined according to the purpose of the analysis. It might refer to the pharmaceutical market as a whole, or a specific therapeutic segment (antiretrovirals, ACE inhibitors, statins, etc) or a specific active ingredient (amoxicilin).

A manual detailing the model and methodology with an accompanying spreadsheet was provided to all participants. Moreover, participants had an opportunity to test them during practical sessions.

2.6 Overview of the different models

(Presented by Dr Viroj Tangcharoensathien)

Dr Tangcharoensathien led a discussion comparing the different models, and presented the findings in a systematic, tabular format.

2.7 Interface research and policy

(Presented by Dr Suwit Wibulpolprasert)

Dr Wibulpolprasert shared the Thai experience on the interface between policy making and research with regard to TRIPS-plus provisions. He stressed the importance of generating knowledge, and of feeding that knowledge into policy decisions as well as social movements.

He explained how, in the context of the Thai-US FTA negotiations, concerns about the implications of possible TRIPS-plus provisions on access to medicines have triggered research in this area. A presentation of the research findings in August 2005 generated considerable interest from civil society and the press. This opened the door to policy makers, and subsequently the research findings were presented to senior officials from the trade and health sectors, and became an input for the negotiators.

2.8 Practical sessions

The workshop included two practical sessions, during which the participants tried to apply the IPR impact model. The participants, working in small groups, were able to practice and understand the model. The main challenge is related to the availability of the required data. However, in some cases, reasonable assumptions can be used instead.

	Thai-general model	Thai-ARV model	IPR impact model
Target drugs	All drugs	Anti-retroviral drugs	All drugs
Nature of approach	Macro level.	Micro level.	Macro level; adaptation for micro level use is under development.
Concept	Assessment of the implications of a stronger intellectual property rights regime on the cost and consumption of medicines	Assessment of budgetary implications of stronger intellectual property rights regime, and of the associated impact on access to ARVs	Assessment of the economic impact of adoption of stronger intellectual property rights regime with application of simulation modeling
Output	Estimates of additional pharmaceutical expenditures	Estimates of additional pharmaceutical expenditures and of lives lost due to inaccessibility to ARVs	Estimates of increases in pharmaceutical expenditures, decreases in consumption and market share of the domestic industry
Data requirements	(1) Patent status of all drugs (2) Time series of volume of consumption of all drugs (3) Actual purchase prices of medicines (4) For competitive drug items: (i) year of entry of generic products, (ii) market share of generic drugs, (iii) ratio of price of generic to innovative, growth of drug consumption, and (iv) price changes of innovative drugs	(1) Epidemiological data of AIDS patients requiring ART (AEM model) (2) Transitional probability of three sets of parameters to estimate total number of AIDS patients on 12 different regimes (3) Actual purchase prices for generic and patented ARVs	Data requirements are more extensive (see Annex 2 for details)
Strengths	Empirical evidence and information fill in the model	Estimates of the number of life years lost due to the fact that ARV medicines are unaffordable can be a powerful tool for advocacy	Allows comparison of a baseline and several alternative scenarios; User friendly; Transparent, since assumptions are clearly stated.
Limitations	Required data may not be available.	Required data may not be available.	Required data may not be available.

3. CONCLUSION & RECOMMENDATIONS

3.1 Feedback on the relevance and feasibility of economic modeling

Workshop participants summarized key features of the pharmaceutical market in their respective countries, and reviewed the feasibility of making economic projections about the costs of/expenditures on medicines due to changes in IPR policies. The discussions focused on the key policy questions and the availability of the necessary data.

Bangladesh

Bangladesh has a significant generic pharmaceutical industry that produces for the local and export market. Bangladesh is a WTO member, and ss a least-developed country (LDC), has the right to defer the implementation of patents for pharmaceuticals until 2016. However, Bangladesh already has a patent law in place that provides for the granting for patents for pharmaceuticals.

Bangladesh could consider using economic modeling techniques to assess the impact of postponing the introduction of pharmaceutical product patents to 2016 on pharmaceutical expenditures and on the market share of the domestic industry. The country may also wish to assess the implications of TRIPS-plus measures, though their introduction does not appear to be imminent. Participants anticipated that most data required for economic modeling are available or can be obtained.

Bhutan

Bhutan does not have domestic production capacity for allopathic medicines; they are all imported. Moreover, Bhutan has a very small private sector, but the majority of medicines are imported by the public sector. Thus, the Ministry of Health would have most of the data required for economic modeling. Bhutan is currently not a WTO member, but is negotiating WTO accession. A TRIPS-compliant patent law is being drafted as part of the preparations for the accession.

Assessing the impact of the introduction of a TRIPS-compliant patent law on pharmaceutical expenditures would be highly relevant. Bhutan may also wish to assess the impact of TRIPS-plus provisions such as data exclusivity, since countries have, at times, been faced with requests to grant data exclusivity during the WTO accession.

India

India is a WTO member and introduced product patents for pharmaceuticals in 2005. The implications of these patents will become increasingly clear in the years ahead. Moreover, because of its role as a major supplier of generic medicines, developments in India are of importance for the entire Region, and beyond.

In view of an ongoing national debate about the possible introduction of data exclusivity, assessing the implications of data exclusivity on the costs of/ expenditures on medicines would appear to be of interest.

Most of the data required for economic modeling can be obtained, and a pilot project to try out whether the IPR impact model can be applied in a disaggregated manner is envisaged in India. It will be complemented with an aggregated modeling exercise.

Indonesia

Indonesia is a WTO member, has a TRIPS-compliant patent law, and has already been granting patents for a significant number of years. It has a domestic pharmaceutical industry. Data for conducting an economic impact assessment are believed to be available, though they would have to be collected from different departments and agencies. Some data may have to be estimated.

In Indonesia the model could be useful to assess the implications of TRIPS-plus provisions as a preparation for possible future policy debates.

Nepal

Nepal joined the WTO in 2004. As an LDC, Nepal would have the right to defer the implementation of patents for pharmaceuticals until 2016. Nepal has some domestic production capacity for generic medicines, but imports a significant percentage of its medicines, notably from India. Hence, Nepal may be affected by India's policies and laws.

Nepal could consider using economic modeling techniques to compare the implications for pharmaceutical expenditures of introducing pharmaceutical product patents in 2004 versus 2016. Nepal may also wish to assess the implications of TRIPS-plus measures, though their introduction does not appear to be imminent. Meanwhile, the key data required for economic modeling can, most likely, be obtained.

Sri Lanka

Sri Lanka is a WTO member, and has a TRIPS-compliant patent law that provides for patents for pharmaceuticals. Pharmaceuticals are mainly imported. The public sector plays an important role in the supply of medicines, hence it is anticipated that most of the data necessary for economic modeling are available or can be obtained.

In Sri Lanka, the model could be useful to assess the implications of TRIPS-plus provisions as a preparation for possible future policy debates.

3.2 Recommendations

The workshop participants recommended that:

(1) Adapting the IPR Impact model for use as a disaggregated model to analyze the impact of TRIPS-plus on specific drug groups, e.g. hypertensive drugs, is useful and should continue.

(2) The manual for the use of the IPR Impact model should be finalized and made available widely.

(3) The International Health Policy Program should document and share the methodological details of the studies conducted in Thailand, and should fine-tune the approaches of the general model and ARV study in Thailand.

(4) Countries may wish to look into the possibility of implementing one of the modeling methods presented in the workshop, in order to gain clearer insights into the possible, practical implications of the introduction of higher standards of intellectual property protection. The key research question(s) can apply to the introduction of TRIPS-standards as well as TRIPS-plus standards, and should be determined on the basis of the actual policy issues and choices facing the country.

(5) There is a clear need for intersectoral collaboration and dialogue in order to assess and address the implications of intellectual property policies and trade agreements on public health and access to medicines. It is important to engage all relevant partners, including civil society.

Annex 1

OPENING ADDRESS BY DR SIRIWAT TIPTARADOL, DIRECTOR, HEALTH SYSTEMS RESEARCH INSTITUTE, BANGKOK

Distinguished Guests, Ladies and Gentlemen,

It is my honour to address the workshop on the assessment of TRIPS-plus implications for health expenditure and access to medicines. On behalf of the Ministry of Public Health, Thailand, we are pleased to co-host, together with WHO/SEARO, this important event, which reflects the attention of WHO and its members to the potential undesirable effects of international trade agreements on the health sector.

It is generally recognized that access to essential medicines is crucial for improving the health of the population. Despite this, however, large numbers of people in low- and middle-income countries are suffering several diseases, for which effective drugs are available in the developed world. Among others, national economic status, funds available, and prices of pharmaceutical products are key determinants of accessibility. In most resource-constrained settings, the 'inability to pay' for medicines has a close link with the lack of capability in many facets including that on trade negotiation. Although the World Trade Organization (WTO) exists as an international body to encourage fair trade through its multilateral regulatory mechanisms including the introduction of the Agreements on Trade-related Intellectual Property Rights (TRIPS), accessibility to essential medicines and therefore, people's wellbeing are intimidated by the effort to extend market exclusivity for innovative drugs beyond those stated in WTO's framework.

It can be anticipated that TRIPS-plus enforcement will delay the availability of generic products in the market. Without generic competition, as we all know, it is likely that original products will be sold at high prices, and thus be unaffordable for the poor. However, there is no empirical evidence indicating the extent to which such trade-related agreements would have implications to the spending on and accessibility to medicines in low- and middle income countries.

The attempt of the International Health Policy Program, Ministry of Public Health of Thailand, and the WHO Regional Office for South-East Asia to organize this workshop would yield invaluable outcomes not only in academic aspects, but also in terms of practical policy development. This is because the insight into the factors and magnitude of TRIPS-plus effects on each country's health sector will help in devising appropriate policy responses. In addition, I fully appreciate that capacity building is one of the prime objectives of this workshop.

In this regard, I wish to thank all resource persons and responsible officials who are providing technical and management support to the workshop.

Distinguished guests, Ladies and Gentlemen,

With these remarks, on behalf of the Ministry of Public Health, Thailand, I wish to extend our warm welcome to all participants and observers to the workshop. I also wish you every success in your deliberations, and look forward to the outcomes of this mission as well as further collaboration among academics and officials from WHO Member countries.

Thank you very much.

Annex 2

DATA REQUIREMENTS FOR IPR IMPACT MODEL

Data required for the application of the IPR Impact Model in a given country:

(1) Initial year of the simulation

(2) Final year of the simulation

(3) **Monetary value of the market (pharmaceutical expenditure)** at consumer prices or at the price paid by the relevant financing institution (e.g. National Health Service, Social Insurance). Ideally the market in the 5 or 10 last years would be required in order to estimate the growth of the market. If there are several independent health systems (e.g. Ministry of Health, Social Insurance, private market) it would be better to make separate estimates for each sector. Values can be provided either in US$ or in local currency

(4) Exchange rate over the period considered in point 3 (in case values are given in local currency)

(5) **Available estimates of the growth rate of the relevant markets**. Indicate if it refers to US$ values, or if it is given in current or constant local prices.

(6) **Total number of active ingredients (AI) in each market.** Indicate as well, if available, the number of AI that account for 50, 80 and 90 % of the market. Ideally these data should be provided for several years as in point 3.

(7) **Number of AI registered each year in the last 5 – 10 years**. If possible provide estimates of the expected number of AI that will be registered (that will enter the market) in the next 5-10 years.

(8) Number and market share of AI that are less than 5, 5-10 and more than 10 years old. Provide if possible figures for the last 5-10 years.

(9) **Year when product patent protection started or will start.**

(10) **Year when data protection/other forms of market exclusivity started or will start**

(11) **Annual number and market share of AI registered with patent protection** in the last 5-10 years, if applicable.

(12) **Annual number and market share of AI registered with data protection or other forms of exclusivity** in the last 5-10 years, if applicable.

(13) **Nominal patent life**

(14) **Nominal duration of test data protection and other forms of market exclusivity**

(15) Average time between patent filling and registration for products that entered the market in the last 5-10 years

(16) Average time between patent expiration and generic competition (if applicable)

(17) Total population and population covered by the various health insurance schemes (if applicable) and expected trends in coverage.

(18) Short description of the country health system (describe the main traits of the existing insurance schemes: eligibility, financing mechanism, benefit package, co-payments)

(19) **Per capita expenditure in health services and in pharmaceuticals** in each insurance scheme.

(20) Distribution by income levels (e.g in deciles) of the population covered by the insurance schemes as well as of the non-insured.

(21) Describe the co-payment mechanisms/rules for pharmaceuticals in each insurance scheme

(22) Estimates of the price-elasticity of the demand for pharmaceuticals if available.

(23) Value of pharmaceutical production in the country. **Market share of national and foreign manufacturers in each market**. Market share in the submarket under exclusivity conditions.

(24) Local production (including foreign firms with manufacturing plants in the country) going to the national markets.

(25) Export and import of pharmaceuticals (separate finished products and AI)

(26) Cost structure of national and foreign firms. Especially relevant is the share of imported AI and other inputs.

(27) Employment in national and foreign companies.

Annex 3

AGENDA

Wednesday, 22 November 2006

0830-0900	Registration	
0900-0915	Opening session & Welcome ceremony	By Dr Siriwat Tiptaradol Director, Health Systems Research Institute
0915-1000	Introduction TRIPS-plus provisions and their implications on access to medicines	Ms Karin Timmermans
1000-1015	Why economic modeling?	Dr Suwit Wibulpolprasert
1015-1945	The concepts of economic modeling	Dr Joan Rovira
1045-1100	Coffee break	
	Presentation of 4 models	
1100-1230	1. General Model of TRIP-plus impacts: Thailand	Ms Chutima Akaleephan
1230-1330	Lunch	
1330-1500	2. Specific impacts on access to ARV medicines: Thailand	Dr Jongkol Lertiendumrong
1500-1530	Coffee break	
1530-1700	3. PAHO Impact model	Dr Joan Rovira

Thursday, 23 November 2006

0830-1030	Critique and comparison of advantages and possible limitations of the four models, data source requirement	Dr Viroj Tangcharoensathien Facilitator
1030-1045	Coffee	
1045-1200	Discussion and reflections by each country on data availability at country level, compared to data requirement in the models and how to overcome limitations	Dr Viroj Tangcharoensathien Facilitator
1200-1300	Lunch	

1300-1330	Experience sharing and discussion on research and policy interface, the case of TRIPS-plus in Thailand	Dr Suwit Wibulpolprasert
1330-1630	Individual country group work[6]	

Friday 24 November 2006

0830-1030	Practical session 1: PAHO model demonstration	Dr Joan Rovira
1030-1045	Coffee	
1045-1200	Practical session 2: Disaggregated model demonstration	Dr Joan Rovira
1200-1300	Lunch	
1300-1430	Report back of group work, 5 minute per country	Dr Rungpetch Sakulbumrungsil Facilitator
1430-1445	Coffee	
1445-1530	The way forward	Dr Viroj Tangcharoensathien
1530-1600	Closure	Ms Karin Timmermans, and Dr Viroj Tangcharoensathien

[6] Participants were asked to try to compile some data and bring them to the workshop. The objectives of the group work were: i) to discuss how the methodology could be applied in the national context; ii) to review what data is available and where these data can be found; and iii) assuming that participants have sufficient data, to make a first effort to do the calculations.

Annex 4

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