ICTSD Programme on IPRs and Sustainable Development

Policy Coherence and Access to Medicines

A Methodology for Country Case Studies

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1. INTRODUCTION

Trade policy coherence entails the systemic promotion of policy actions across government agencies in a manner that is mutually beneficial. Policy coherence in the field of trade and health remains a fundamental challenge at both the international and national level. The need to address this discrepancy has also been emphasized in resolutions that were put forward at the World Health Assembly of 2006.

To help facilitate the creation of an enabling framework for sustainable access to essential medicines in developing countries, ICTSD is currently engaged in a project aimed at enhancing trade-related policy coherence. In this pursuit, it seeks to engage in applied policy, legal and economic research and informal multi-stakeholder dialogues at the national level.

More specifically the project will:

- Provide a better understanding of the interface between different trade-related policies impacting access to essential medicines in selected developing countries;
- Identify mechanisms and policy options for improving trade-related policy coherence in promoting access to medicines in selected developing countries;
- Put forward a set of policy options to the relevant policy-makers that could enhance policy consistency for ensuring sustainable access to essential medicines.

These objectives will be achieved through applied policy, legal and economic research and informal multi-stakeholder dialogue at the national level. The final outputs of the project, particularly the methodology, case studies and national dialogues (see outputs below), are not intended to be academic exercises but rather practical tools for promoting coherent domestic policy reform and adjustment.

More information and details about the project can be found on the website of the ICTSD consultation on "Developing a Methodology to Facilitate Trade-Related Policy Coherence for Sustainable Access to Essential Medicines", held on 7th November 2006, at www.iprsonline.org.[2]

2. CONTENT OF THE POLICY COHERENCE STUDIES

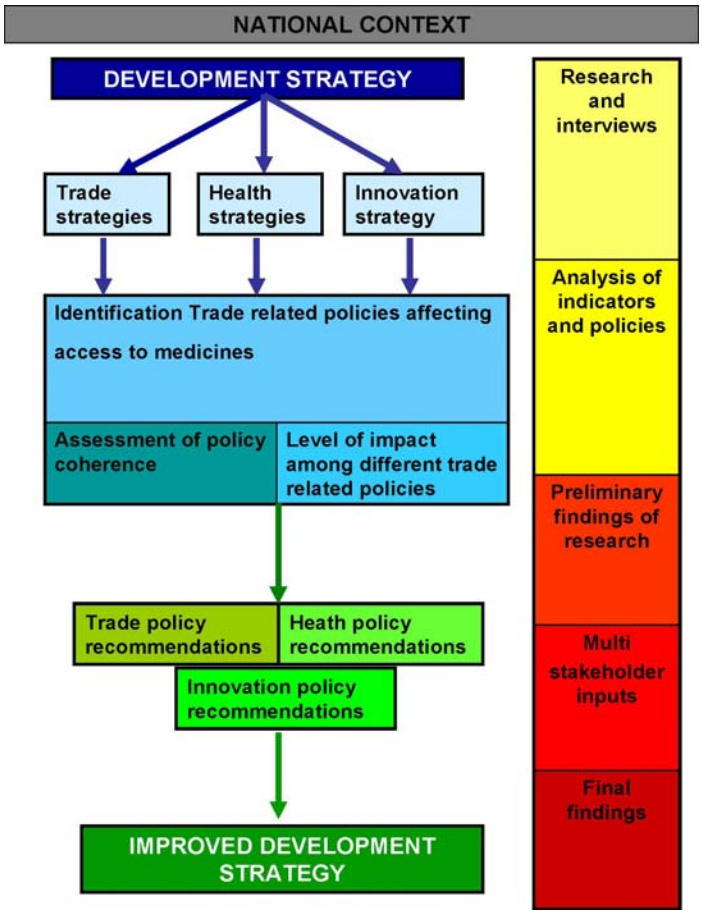
The consultants/research institutions will prepare a national case study on policy coherence and access to medicines (about 50-70 pages). The consultants/research institutions will address the following questions:

- What are the main trade policies that affect access to medicines in the national context?[3]
- Which trade-related policies and regulations have the highest impact on access to medicines in the national context?
- Are there groups of diseases and sectors of the population where trade policies have a particularly large impact in terms of access to medicines?
- To what extent are trade-related policies mutually supportive in the national context?
- To what extent does coherence among those policies impact (positively or negatively) access to medicines?
- Does dialogue exist between trade and health authorities on policies making and negotiations at domestic, regional and multilateral levels?
- Is there an institutional mechanism devoted to trade and health-related issues?
- What should be taken into consideration to improve policy coherence at the national level?
- What recommendations should be put forward to improve trade-related policy coherence?

3. PROJECT FLOW CHART

In carrying out the research for this project, the consultants/research institutions will use as a guide the following flow chart. It will aid in understanding the policy and research process. See figure 1 below:

Figure 1



The flow chart identifies five stages in the process of addressing the questions identified in sections 1 and 2. These stages are as follows:

1) **The research and interview phase**: In this phase, the consultants/research institutions will examine the broad national context. They will also undertake national consultations and interviews with relevant stakeholders. To this end, they will consult several indicators, such as national development plans, macro-economic data and information on public health, which are further explained in section 4.

2) **The analysis of indicators and policies**: In this phase, the consultants/ research institutions will identify relevant trade-related and health policies. They will also assess which policies have stronger, weaker or no impact on access to medicines and how policies relate to each other in a coherent or incoherent manner. A set of policies have been identified in section 5 to facilitate the work of the consultants/research institutions.

3) **The generation of preliminary findings**: Once the first two steps are completed, the consultants/research institutions will present their preliminary finding and respond to the main questions above. The research will take the form of a draft national study on trade-related policy coherence and access to medicines

4) **The multi-stakeholder dialogue and a road map for implementation**: The consultants/research institutions will present the preliminary findings to relevant stakeholders in order to solicit input and improve the accuracy of the case studies and preliminary findings. During the dialogue a road map for implementation will be prepared under the guidance of the organisers. The road map for implementation is a simple tool that usually takes the form of a table in which the participants indicate the main problems and concerns, options for improving the current situation, potential actions and resources needed, as well as governmental organisations, institutions, or other parties responsible for carrying out the actions identified.

5) **Generation of final findings**: Based on inputs and comments provided in the multi- stakeholder consultation, the consultants/research institutions will revise the national studies and preliminary findings. The findings will be addressed mainly to governmental authorities, but also to other stakeholders, depending upon their areas of competence. The final output will take the form of a national study on trade-related policy coherence and access to medicines. These studies could provide the basis for national policy discussions and national development strategy reform.

4. MAP OF RELEVANT STAKEHOLDERS

In advancing the project, the consultants/research institutions will use a multi-stakeholder approach in the implementation of the project. This approach implies the involvement of a number of actors in different phases of the project to ensure a balanced and legitimate outcome. The following table provides guidance on the type of actors that should be involved in the process:

STAKEHOLDER GROUPS	***RELEVANT INSTITUTIONS***
1. *The Executive Branch of the Government*	Ministries of Trade/Commerce/Industry, Health, Intellectual Property/Patents Office, Tax and Customs authorities, Science and Technology, Foreign Affairs
2. *The Legislature*	National parliaments and parliamentarian commissions
3. *Academic/Research Organisations*	Universities, think tanks, and national research centres
4. *Civil Society Organisations (CSOs)*	Northern and Southern umbrella groups, consumer organizations, development CSOs, health CSOs, community-based organizations, other local CSOs
5. *Industry and Industry Associations*	All relevant industry, including pharmaceutical (research based and generics), medical devise companies, biotechnology, associations of pharmacists, chambers of commerce, small and medium sized enterprises
6. *International intergovernmental organizations*	WHO, UNCTAD, WTO, WIPO and the Global Fund

5. INDICATORS, DATA AND ANALYSIS

The national case studies should be divides into three sections (described in greater detail below). Each section should focus on a particular aspect of the problem and should draw on national data to whatever extent it is available.

5.1 National Development Strategies

Examine national development strategies with a particular emphasis on trade-related and public health strategies.

5.2 Relevant Macro-economic Indicators

Analyse the following:

- Overall size of the economy: information on GDP, both in current USD and purchasing power terms. Also, discuss information on per capita income and its distribution; and report the percentage of population that is below the poverty line;
- Size of population and its breakdown between rural versus urban residents;
- Local human capital stock as measured by percentage of population that has completed primary, secondary, and tertiary education. This is important because lack of health-related knowledge is an important barrier to improving healthcare in developing countries;
- Aggregate level and sectoral composition of international trade: this will provide an indication of the areas in which the country has comparative advantage relative to the rest of the world;
- Aggregate level and sectoral composition of foreign direct investment: will tell us if foreign firms can be expected to play a major role in improving access to medicines. It would also be useful to distinguish between FDI in manufacturing versus heath care services, to the extent data considerations permit;
- Overall investment in public health (public and private) and comparison with other sectors (i.e. education, infrastructure, and defense);
- Overall R&D investment: important for measuring the absorptive capacity of the local economy and for being able to innovate on its own for local diseases for which little or no R&D is being done elsewhere;
- Patent applications by locals and foreigners, especially post-TRIPS implementation. Here, it would be useful to know the degree to which such applications come from pharmaceutical companies.

5.3 Healthcare and Access to Medicines Indicators

Analyse the following:

- Overall disease patterns: what are the major health threats and diseases?
- Major therapeutic groups of drugs that are relevant for the diseases that have a higher impact on the population of a particular country;
- Private and public expenditure on healthcare as a percentage of GDP: how does it compare to the average ratio across developing countries?
- Domestic manufacturing capacity for drugs and vaccines.
- Reach of public health services over the countries population and quality of infrastructure with special attention to healthcare services.
- Healthcare workers: how scarce are they? Migration and health care workers? Is brain drain a factor (i.e. nurses)? Is the income generated from remittances relevant in the social context? Which are the effects over the health services supply?
- Availability of health insurance (public private) and percentage of population covered. What is the percentage of drugs paid under insurance vs. out of the pocket purchases?
- If national marketing authorization is required to ensure safety and efficacy of drugs, explain if it is necessary to submit test data or provide evidence of marketing authorization abroad. Is WHO prequalification of the drugs manufacturing practices is required? Is the procedure considered burdensome?
- Calculate a price index for essential medicines: this part of the case-study should draw upon the methodology as well as the international data collected by 30 surveys underlying the study by Gelders et. al. (2006). The survey data they utilize includes the countries for which the case studies are being done (Ghana, Peru, Jordan, and South Africa). Their approach makes it possible to address three crucial issues:
    - Availability of essential medicines: measured by the percentage of health facilities in which the medicine is available at the time of survey;
    - Affordability: measured by the number of days the lowest paid unskilled government worker would have to work to be able to afford the cost of 30 days of treatment for the chronic condition being analysed;
    - Price comparisons: Study variation in prices of medicines within the country as well as in relation to prices in other countries;
- Are there measures taken to fight corruption and unsound purchasing practices in the delivery process of drugs and medical materials? Is counterfeiting of drugs a problem? If this were the case what type of measures have been put in place?

6. THE TRADE-RELATED AND PUBLIC HEALTH POLICY ENVIRONMENT

6.1 General and Institutional Issues

Analyse the following:

- What are the priorities in trade policy?
- What are the priorities in health policy? How are these priorities translated into other areas, such as trade, education or infrastructure?
- To what degree are health concerns taken into account in the design of those priorities?
- Are there coordination mechanisms for the design of trade policy?
- Are other authorities such as the health ministry as well as other relevant stakeholders involved in the negotiations and implementation of bilateral or multilateral trade agreements?

6.2 Specific Types of Trade-Related Policies and Access to Medicines

Analyse the following:

- Data on tariffs and other trade barriers at a general level: several World Bank databases provide this information;
- Data on tariffs and other trade barriers for the pharmaceutical industry: see the paper by Olcay and Laing (2005);
- Existence of tariffs waivers or exemptions to import of drugs (e.g. tariffs waivers to imports by Ministry of Health);
- Effective rates of protection: such rates of protection are worth calculating if the country imposes tariffs on active ingredients and other intermediates as well as on final goods;
- Potential list of non-trade barriers affecting the import/supply/distribution of drugs across the border or internally (e.g. quotas, excessive regulatory controls, etc);
- Existence of price control schemes, their rational and effects;
- Domestic taxes and any other restrictions on retail and distribution that might prevent local firms and/or multinationals from being to reach consumers (e.g. VAT or interstate taxes);
- Patent status of relevant drugs in comparison to disease burden;
- Parallel trade: a brief discussion of the country's policy on parallel trade. Does it pursue national, international, or regional exhaustion?
- Any cases where the country has used compulsory licensing, including as a negotiating tool? If yes, provide a detailed case study or two;
- The effect of TRIPS: what changes, if any, have occurred in the domestic pharmaceutical market post TRIPS? Has there been any identifiable changes in prices? Or in the range of medicines that are locally available?

- Existence of test data protection and its potential/actual impact over the introduction of generic versions of drugs in the market. If yes provide a detailed case study or two?
- Does the country belong to any bilateral trade agreements that require it go beyond TRIPS in terms of its IPR obligations? If yes explain how such obligations have been implemented in national legislation?
- Openness to FDI in healthcare industry as deduced from a country's existing policies, legislation and regulations;
- Openness under existing legislation and regulations to FDI and entry of foreign providers in other services sectors and activities which impact on healthcare, such as research and development, must also be taken into consideration;
- Openness in other services sectors or activities which may ease the demand for essential medicines given their disease-preventive nature, such as sanitation services, or sewage and refuse disposal, may also be relevant;
- The extent of a country's commitment to existing policies in the above mentioned sectors should be ascertained by examination of its commitments under the GATS and relevant FTAs;
- Main elements of existing commitments in health and health related services, R&D, sanitation, and sewage and refuse disposal under the GATS and relevant FTA of the country under study;
- Percentage of current participation of foreign suppliers in hospital services, medical services, other health-related services, R&D, sanitation, sewage and refuse disposal, health insurance services, medical data transfer, etc.;
- Identify potential commitments that could be deposited in the current GATS negotiations in order improve access to medicines and health care;
- Existing policy and regulations affecting distribution and retail services on pharmaceutical products, including those produced or acquired through compulsory licensing and parallel importation;
- Current regulatory framework on health information to be provided to consumers.

7. MAIN CONCULSIONS AND POLICY RECOMMENDATIONS

In this section, the case study should summarize the main conclusions, respond to basic questions made above and provide policy recommendations that can help improve access to essential medicines. Policy recommendations must be addressed to national authorities but also to other relevant stakeholders in the specific areas of competence. The findings and recommendations should take into account the road map for implementation generated from the national dialogue.

8. DISSEMINATION

We intend to disseminate all the outputs of the project in the national dialogues and in Geneva, possibly at a roundtable around the World Health Assembly or the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. The synthesis report will be printed and distributed among national and Geneva based stakeholders and all the case studies will be made available at iprsonline.org.

ENDNOTES

[1] see http://www.iprsonline.org/unctadictsd/dialogue/2006-11-07/2006-11-07_desc.htm
[2] see http://www.iprsonline.org/unctadictsd/dialogue/2006-11-07/2006-11-07_desc.htm
[3] national context includes the list of policies, data and information mentioned in sections 4 & 5