ASSESSING THE IMPACT OF NEW IPR PROVISIONS ON PUBLIC HEALTH

Summary of key points raised during the two day ICTSD-WBI-WHO workshop in Geneva, July 31 to August 1, 2006

Note prepared by the organizers

Background and objectives

Since the WTO's TRIPS Agreement came into effect in 1995, developing countries have had to grapple with the implications for their economies and societies of introducing stronger intellectual property rights. The full provisions of the TRIPS Agreement have been phased in under transitional arrangements since 1995, with only least-developed countries still permitted to delay full implementation.

Developing countries have also increasingly entered into bilateral and regional free trade agreements (FTAs) with developed countries, key elements of which include increasing the strength of intellectual property rights beyond those prescribed in TRIPS. A number of these so-called TRIPS-plus obligations may affect the price and supply of pharmaceutical products and therefore their affordability and availability in developing countries.

It is in the interest of developing countries to measure the magnitude of the effect of these new IPR provisions. Since empirical tools for this purpose currently do not exist, there is a need to develop them.

The objective of the joint ICTSD-WBI-WHO impact assessment project is the development of a common methodological framework to improve the capacity in developing countries for evaluating the public health impact of new IPR provisions. This framework is targeted at governments, research institutes, and civil society organizations. The availability of credible empirical evidence can serve a variety of purposes, including: (i) strengthening the overall negotiating capacity of governments; (ii) identifying areas where flexibilities in the negotiations of new IPRs standards may be warranted; and (iii) identifying areas where complementary policies may help alleviate possible adverse public health implications of TRIPS-plus standards.

Main elements of a methodological guide

The envisaged methodological guide will have three components:

1. Identifying the relevant questions to be asked
2. Setting out and implementing the empirical analysis
3. Complementary case studies

Each of these components will be discussed in turn.

Identifying the relevant questions to be asked

As a first step, it is essential to identify the policy and legal changes arising from new IPR provisions such as TRIPS-plus obligations *at the country level* (at a conceptual level, the impact of TRIPS-obligations is thought to be well-understood). What will provisions on patent term extension, data exclusivity and the linkage between patent status and drug approval mean in terms of market exclusivity? In countries that are still implementing their TRIPS obligations, what are the effects of TRIPS versus TRIPS-plus?

The second step is to identify the scope of the impact assessment in terms of the institutional environment for pharmaceuticals, performance outcomes and public health concerns. Relevant considerations include:

- The affordability and availability of drugs, as determined by entry conditions in the pharmaceutical sector and consequent price and availability effects
- The impact on the national health system, the financing of health insurance, and the public provision of pharmaceuticals
- The implications for national public health priorities (e.g., HIV/AIDS programme)
- The consequences for the local pharmaceutical industry

Setting out and implementing the empirical analysis

One area in which empirical modelling is considered feasible and desirable is the analysis of price-effects due to generic competition (or the absence thereof). Partial-equilibrium modelling approaches can either focus on the 'aggregate' pharmaceutical market or on 'disaggregated' therapeutic classes. Aggregate models are easy to implement, require only limited data, and offer big picture estimates, though they have to rely on crude assumptions, limiting their credibility and missing out on important policy questions. Disaggregated models can be more credible, as they can take account of the competitive environment of specific products (e.g. the possibilities for substitution of brand name products by generics) and thus can be more directly linked to the policy changes emanating from new IPR provisions. However, they require more data that is harder to come by and the greater complexity of disaggregated models creates implementation challenges. In the light of the advantages and disadvantages of the two modelling approaches, a combination of both is desirable.

There are a number of modelling choices that need to be made in light of available data and the specific institutional environment of national health systems. These choices include:

- Substitution effects between products with identical or similar therapeutic properties
- Values for demand elasticities: can they be estimated? If not, what are defensible assumptions?
- Pricing to local markets versus international pricing strategies
- Sensitivity analysis
- Modelling of price control regimes
- Other supply side parameters (marginal costs, type of competition between producers, etc.)

The credibility of any empirical analysis relies crucially on the availability and quality of data, and the economic assumptions built into the model. In this regard, it is first important to review existing available evidence that has been assembled with respect to the effects of IPRs policy

changes on pharmaceutical prices. In implementing the partial equilibrium models described above, researchers need to take stock of available data at the national level and identify possible data gaps. Where gaps exist, several follow-up questions arise. Is primary data collection feasible? Is it possible to make use of international databases (e.g., the WHO/HAI project) and use evidence from other countries as benchmarks? What recommendations can be made for official data collection and monitoring at the country level?

Case studies

Case studies can usefully complement an empirical investigation along the lines described above. They serve two primary purposes: (i) to provide evidence to justify key modelling choices and (ii) to offer evidence on the effects of new IPR provisions that cannot be captured by a partial equilibrium model. The case studies would include two levels:

National case studies:

Test data exclusivity and the introduction of new pharmaceutical products. Jordan seems a particular useful case to study, as it has several years of experience with TRIPS-plus standards.

The impact of test data protection on market exclusivity (including the interaction between patent protection and test data protection). Possible country cases: China, Israel.

Ex-post evidence of the price effects of market exclusivity. Possible country cases: Costa Rica, Mexico.

Cross country studies:

- Changing intellectual property regimes and the development of the generic pharmaceutical industry.

  International pricing strategies of pharmaceutical companies, especially with respect to cancer drugs and second-line antiretroviral medicines.

All case studies would serve as public goods, in the sense that the evidence assembled would be of use in all countries currently or prospectively engaged in the negotiation of FTAs.