



*Il Presidente della Commissione Attività Produttive,
Commercio e Turismo della Camera dei Deputati*

Comments on the draft global strategy and plan of action on public health, innovation and intellectual property

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Introduction

The WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property has asked all stakeholders and representatives of civil society for comments on its draft global strategy of July 31. As elected officials and policy experts we are happy to contribute our comments, and we hope to continue a constructive dialogue with the IGWG to identify solutions for public health problems in the developing world.

We believe that the draft global strategy contains a number of inconsistencies, flawed recommendations and inadequate progress indicators. We sincerely hope that the IGWG will take our comments into account and address these significant problems when finalizing the global strategy.

Compulsory licenses

Several sections of the draft strategy call for an expanded use of compulsory licenses, which is inconsistent with the stated goal of advancing pharmaceutical research and development in the developing world.

Section 5.2.b states that Member States should “promote bilateral trade agreements that do not incorporate ‘TRIPS-plus’ protection in ways that might reduce access to medicines in developing

countries.” Likewise, Section 5.2.c. encourages “trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health).” The progress indicators for these goals are simply the number of trade agreements that contain flexibilities and do not contain TRIPS-plus protection by 2015.

Furthermore, Section 6.3.d calls on Member States to “take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health.” The progress indicator is the number of developing countries with manufacturing capacity that have enacted the necessary legislation by 2015.

We are deeply concerned by the strong focus on compulsory licenses in a global strategy that is supposed to advance pharmaceutical research into diseases in the developing world and advance access to life-saving drugs.

The draft strategy rightly notes that “advances in biomedical science have provided opportunities to develop new, affordable health products, and in particular to meet public health needs in developing countries.” These advances did not happen by accident, however. Pharmaceutical research has advanced during the past 50 years due to strong protection of intellectual property rights, which provides an incentive to invest in innovation. 90 percent of all new medicines are developed by the private sector, which has invested enormous amounts of capital on developing a modern, sophisticated research infrastructure.

According to the International Property Rights Index, most developing countries have inadequate protection of intellectual property rights compared to the developed world.¹ If developing countries are to grow their own capacities for research and development, they must improve their systems for protecting property rights.

Compulsory licenses undermine intellectual property rights and should be reserved for emergencies, not as an integrated part of a global strategy for access to medicines. Pharmaceutical companies will be disinclined to research medicines for the developing world if their intellectual property rights are not protected. And investors will lack incentives to pour capital into the R&D capacity of the developing world. Hence, compulsory licensing is inconsistent with the overall goals of the global strategy as well as the sub-goal of promoting R&D in developing countries (Sections 3.1 and 3.2).

Taxes and tariffs

We recommend that more emphasis be put on the need for Member States to eliminate taxes and tariffs on medicines. Taxes and tariffs account for large parts of the end price of drugs in some cases, and Member States can increase access to medicines almost overnight by simply removing these barriers to access.

¹ International Property Rights Index, 2007 Report:
http://internationalpropertyrightsindex.org/UserFiles/File/PRA_Interior_LowRes.pdf

Given the relative ease with which this can be done, the progress indicator for this goal (Section 6.3.c) should be the number of countries removing taxes and tariffs by 2010, not 2015 as stated in the report. Furthermore, any country failing to meet this goal should be classified as non-compliant with the global strategy.

Infrastructure

Section 6.1.a encourages investment in health delivery infrastructure and financing of health products by the Member States. This is a laudable goal, but we believe that the progress indicator should be changed. The current indicator is the number of developing countries “that have increased (as a share of national health budgets) investment in health delivery infrastructure” by 2015. Many countries, however, have inadequate health budgets and rearranging resources within current budgets might cause other public health problems. In many cases, lack of democratic accountability allows governments in developing countries to under-fund their health systems while increasing spending on other priorities such as the military as has been the case in Thailand since the military government took power in 2006.

We therefore believe that a better indicator of progress is the number of developing countries that have increased investment in health delivery infrastructure *as a share of total public budgets* by 2015.

Mandate

In addition to the specific issues covered above, we are concerned that the draft strategy oversteps the WHO mandate. For instance, the recommendation for member states to facilitate an expanded use of compulsory licenses through trade agreements clearly invades the trade portfolio of the WTO and the intellectual property portfolio of WIPO. Yet nowhere does the strategy call for the involvement of these institutions in the process.

The draft global strategy thus ignores comments submitted by Germany on behalf of the European Union that “it is of the utmost importance for the plan of action to stick to the WHO mandate and respect the work carried out in other international organizations, such as WIPO and WTO.”²

² Consultation on “Elements of a global strategy and plan of action”, Comments by the European Union, via Germany in the role of the EU presidency, February 2, 2007.