Sustainable access to innovative therapies – OECD Online consultation

Submission of civil society organizations of Colombia

Misión Salud, Fundación Ifarma, Centro de Información de Medicamentos de la Universidad Nacional de Colombia (CIMUN) y Observatorio del Medicamento de la Federación Médica Colombiana (OBSERVAMED)

May 1st 2017

Reflecting on the last 5-10 years, what do you think have been the major changes affecting access to medicines?

Despite immense scientific advances that lead to innovative therapies, States have not been able to guarantee access to medicines for all, either because there do not exist health technologies to cure, treat or diagnose health conditions that affect disproportionately poor people (regardless of the country they live in) or because health technologies do exist but are excessively expensive.

One of the main reasons behind this situation is that the current model to promote research and development (R&D) of health technologies is based on the expectation of pharmaceutical companies of high returns through high-pricing their products. Pricing has been unlike manufacturing costs, resulting in abuses of the monopoly guaranteed by means of intellectual property protection such as patents and test data exclusivity.

This model was established worldwide through the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, and in 2001, the Doha Declaration on the Trips Agreement and Public Health recognized the barriers to access to medicines that result of the TRIPS innovation model, and therefore, it also highlighted the importance of TRIPS-public health safeguards. Indeed, it states, “we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose (promote access to medicines for all)”.

Despite the aforementioned agreements, in the last 10 years the use of those public health safeguards has been limited, because of the multinational pharmaceutical corporations’ and governments’ pressures on WTO members to about compulsory licenses granting. As the United Nations High-Level Panel on Access to Medicines (UNHLP) stresses in its report “the sovereign right to issue compulsory licenses provided for by TRIPS has been stymied by threats of retaliation from governments and corporations against countries who have followed the prescribed process set out in TRIPS”. Such intimidations have undermined the efforts of governments to meet their inalienable duty to protect health, impeded access to innovative medicines by the population that requires

them, constrained public health budgets and limited local manufacturing capacities, among other consequences.

An example of this situation is the Colombian case. Because of the interest of Colombia of issuing a compulsory license for imatinib (marketed as Glivec® or Gleevec® by Novartis) we have recently faced threats like the ones mentioned by the UNHLP. The most recent one can be found in the attached letter (“AFIDRO’s letter to the office of the President of Colombia”).

This letter is the follow up that the group that gathers multinational pharmaceutical companies in Colombia (AFIDRO) makes of a meeting held at the beginning of 2017 at the office of the President of Colombia between them and high-level officials of the government, involving the special representative for the accession of Colombia to the Organization for Economic Co-operation and Development (OECD).

In such letter AFIDRO condemns the efforts of Colombian government to use its right to declare medicines of public interest as a previous step to proceed with compulsory licenses, which is one of the public health safeguards retained by WTO Members to meet their obligations to respect, protect and fulfil the right to health. They argue in the letter that the decisions made by the Ministry of Health in this issue, and in others sensitive to the industry “would do considerable but justified harm to Colombia’s aspirations to get closer to the group of countries committed to the best policies to improve its citizens’ lives” (own translation), which clearly refers to Colombia’s aspirations to become member of the OECD.

As a response to this pressure, and just before the presentation in Paris of the advances of the Colombian government in the process of becoming an OECD Country Member, the Government of Colombia issued a decree that modifies the procedure to declare anything in Colombia of public interest, making it more difficult to issue a compulsory license in the future. Therefore and unfortunately, this decree has been understood as a requisite to be part of the OECD.

What changes would you like to see happen to improve access to innovative therapies?

The current framework of access to medicines vs TRIPS innovation model has leaded human kind to the necessity of identifying solutions for “remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies”. Such task has been assumed by the United Nations Secretary General through the High-Level Panel on Access to Medicines which “views innovation and access to health technologies as a multi-dimensional and global problem that affects all countries”.

In this train of thought the main changes to improve access to medicines that we suggest are:
Firstly, a broad implementation of the recommendations made by the United Nations High Level Panel on Access to Medicines in its report (http://www.unsgaccessmeds.org/final-report/). We encourage OECD countries to commit with their recommendations, as they address the major changes affecting access to medicines nowadays.

Secondly, considering the above-mentioned specific situation facing Colombia, an official recognition of the OECD that using as much as possible TRIPS-public health safeguards, as it is recommended by the Doha Declaration on TRIPS and Public Health, is both a good and required policy to improve people’s welfare. Such pronouncement would bring clarity to the situation in Colombia and, furthermore, will promote the future implementation of TRIPS-public health safeguards included in the TRIPS Agreement so that counties be able of fulfilling their human rights and public health obligations.