PROPOSAL TEMPLATE

Proposal Name:

A NEW INCENTIVE SYSTEM FOR TECHNOLOGICAL INNOVATION IN DEVELOPING COUNTRIES

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Please provide a description of the proposal (up to 500 words):

This work has been inspired by the analysis and discussion of Professor Joseph E. Stiglitz's critical elaboration exposed in his book "Making Globalization Work", particularly in Chapter 4, "Patents, benefits and people", which analyses the problems related to trade agreements, the protection of intellectual property rights and their connection with the development of innovations as well as with the access to health, a basic human right.

We have developed some ideas and suggestions on a New Innovation Fund Scheme for developing countries, with more specific characteristics oriented to the generation of financial resources that help researchers, public research centers and institutions, including universities as well as pharmaceutical and pharmochemical companies, develop specific research and development projects.

The proposal of a New Innovation Fund Scheme has a very important characteristic for developing countries. It is an ex-ante financing system of innovation projects, with two alternative modalities for the exploitation of innovations and a collection system for the Fund.

This design seeks to simultaneously benefit local R&D in the pharmaceutical sector and improve market competitiveness.

The inherent characteristics of the New Innovation Fund Scheme for developing countries are as follows:

- It is a public policy aimed at promoting R&D in the pharmaceutical sector.
- It is a model of collection and accrual of resources to finance the Fund.
- It is a transparent and socially efficient fund allocation system for R&D projects.
- It has all the necessary characteristics to attract the assistance of international financial institutions.
- It changes the economic standard for R&D financing projects in developing countries, as it is carried out with the Innovation Fund resources (*ex-ante* concept), as opposed to the prize approach proposed by Professor Stiglitz (*ex post* concept) and the traditional model in which companies fund the R&D projects and recover their investment through the monopoly rent appropriation derived from the exploitation of a patent during its life term.

The scope and application of the Innovation Fund is initially local; therefore, resources will be funded by local bodies. The Innovation Fund may also receive contributions or credits from the regional financial entities. At the beginning, the process must be necessarily national, since the use of this Fund by an innovating company will necessarily imply, as a binding condition, that the latter will waive its monopoly patent, that is, manufacturing licenses will be awarded to other companies of the same

country willing to exploit the innovation, by paying the proper royalties disposed for.

The idea of generating a new national Innovation Fund Scheme is a rational response to the financing deficit for the development of innovations by the local pharmaceutical and pharmochemical industries of developing countries.
It is a new proposal with high possibilities of promoting a legal flexibilization of the models of protection of innovations, that complies with the international agreements in this field, and that may be implemented without need of awaiting their modification.

Describe and justify the potential public health impact[1] of the proposal:

The fact is that the proposal would boost the resources applied to investigations and projects by national companies and public research institutes, with the focus on orphan drugs and regional neglected diseases.

That the scope of the Innovation Fund might be wider should not be ruled out, for instance, at the Latin American level, or it could even be a Fund with participation from developing countries that agree with this proposal.

Its initial application in a country such as, for example, Argentina, might significantly contribute to the further promotion of this innovation incentive policy.

The New Innovation Fund Scheme will make it possible to:

- Incorporate flexibility into the present monopoly patent regime, generating a competitive scenario in the pharmaceutical market for companies that decide to resort to the Innovation Fund.
- Create a new financing system for national innovations.
- Strengthen the technological and scientific systems in developing countries.
- Improve public policies on local industry support.

The initiative generates strategic alliances between the knowledge accumulated by the local human capital and the capital of the national pharmaceutical companies that jointly achieve the development of new local, affordable medicines that address the needs of the regional population. At the same time, it makes it possible to promote and install the idea of the creation of an Innovation Fund in the national and Latin American political and economic agenda.

Clearly, the starting point of this new Innovation Fund proposal consists in achieving the highest level of commitment from all the local pharmaceutical and pharmochemical companies for a fast and effective implementation of the system.

On the other hand, other developing countries would be able to adopt this Innovation Fund proposal, and countries applying similar systems to promote and incentive research and innovation efforts in medicine specialities may sign agreements for the mutual recognition of their respective systems of promotion of innovations.

[1] Principally CEWG criterion 1 but others may be relevant e.g. Equity/distributive effect including on availability and affordability of products and impact on access and delivery.

Describe and justify the technical feasibility[2] of the proposal:

The setting in motion of the Innovation Fund should take place as an essential component of the National Scientific and Technological Policy, so that the scientific and technological system and the Health Ministry may define the composition of the project selection committee, and the scientific, technical and public health criteria to apply in their selection, ensuring the transparency and involvement of all the corporations and institutions of the technological and scientific system and of the universities. Such criteria should privilege projects engaged in jointly by the locally-owned private pharmaceutical companies and the aforementioned institutes.
Any company choosing to develop a specific project in a country such as Argentina and finance it through the Innovation Fund resources must waive the monopoly exploitation of the patent in Argentine territory and allow competitors to exploit the invention in such territory by paying royalties to the Innovation Fund. The innovating company is exempted from paying such royalty, which sets an advantage for them in front of the third party corporations that manufacture and market the invention.
The Innovation Fund resources come from each country's funds, without prejudice of other contributions received from international sources. Moreover it would be supplied by international donations.

The proposed alternative may be implemented without modifying the TRIPs Agreement now in force or the local patent laws. Such modification would imply complex international negotiations; it has been observed that the policies of some developed countries have consisted, so far, in including TRIPs-plus standards in several free trade agreements signed between a developed country, e.g. USA, and Latin American developing countries..

Describe and justify the financial feasibility[3] of the proposal:

The financial feasibility supports on the financing sources for the New Innovation Fund Scheme:

- Specific item of the Health Ministry budget.
- Bank debit and credit taxes contributed by pharmaceutical companies.
- Contributions from pharmaceutical and pharmochemical companies on their payrolls
- Share of the collection of taxes on tobacco products, firearms, alcoholic beverages and games of chance
- Royalties paid by laboratories willing to produce the innovative medicines obtained by other laboratories, resorting to the innovation fund.

The existence of such New Fund Scheme will enable the promotion of projects based on scientific innovation, which contents must be related to a combination of factors, such as:

- Addressing developing countries diseases.
- Strengthening ongoing research projects or lines of scientific work that demand higher resources.

[2] Principally CEWG criterion 4 but others may be relevant e.g. Rational and equitable use of resources/efficiency considerations.
[3] Principally CEWG criterion 5 but others may be relevant e.g. Cost-effectiveness.

- Identifying scientific knowledge accrued by the local human capital, this may be potentially developed to obtain new national products.

Two alternative plans for the exploitation and protection of innovations are put forward, both associated with different financing percentages for the projects, funded through the Innovation Fund resources:

A. Composite System of Monopoly/Competitive exploitation

- Financing supplied by the Innovation Fund, which consists of non-refundable contributions equal to 40% of the total project amount. This percentage increases to 50% if the company signs a research and development agreement with institutes belonging to the scientific and technological system or with public national universities.
- During the first 2 years, the innovative laboratory holds a monopoly position.
- From the third year, competition is open to third companies, and payments are made to the Innovation Fund. The innovating company is exempted from paying such royalty.

B. Competitive exploitation system

- Financing supplied by the Innovation Fund, which consists of non-refundable contributions equal to the 60% of the total amount of the project. This percentage will be increased to 70% if the company signs a research and development agreement with institutes belonging to the scientific and technological system or with public national universities.
- Freedom to manufacture and market innovations, complying with the requirement of royalty payment to the Innovation Fund. The innovative company is exempted from paying the royalty.

Describe in what way the proposal addresses cross-cutting issues[4]:

Both systems for the exploitation of a certain invention have the following advantages:

- They finance important R&D projects for the Health System, through non-refundable contributions.
- The best research projects are selected based on an assessment carried out by an Ad Hoc Scientific Committee. The Ministry of Sciences, Technology and Innovation and the Ministry of Health will define the composition of that Committee and the scientific, technical, public health and economic criteria to be applied to such selection and to the assignment of resources.
- The Innovation Fund is assigned by stages.
- Each project is audited by an Ad Hoc Committee composed by professionals and scientists from the Ministry of Science, Technology and Innovation and the Ministry of Health, which verifies that the stages are being complied with within the pre-agreed terms, before carrying out a new fund assignment.
- Once an innovative product is selected, it receives a patent (which includes a compulsory license for which royalties are paid to the Innovation Fund), which commercial exploitation will be performed in a competition frame within the national territory. The innovative company may enforce its rights in third developed countries and sign license agreements with corporations belonging to developing countries with which an agreement was signed to acknowledge the respective systems of incentive and promotion of innovations.

[4] "Cross-cutting Issues" refers principally to CEWG criteria 7-12, if not addressed elsewhere in the submission e.g. Potential for delinking R&D costs and price of products.

- The medicine may be freely manufactured and marketed, complying with the required manufacturing standards and payment of royalties to the Innovation Fund.

Identify key steps necessary to begin implementation and key issues to be resolved for implementation to begin:

The implementation of our proposal depends on National Policy decisions about the core matter of it. The national researcher companies have to resign the patent right at national level, in order to receive financing supplied by the Innovation Fund, which consists of non-refundable contributions equal to the 60% of the total amount of the project. This percentage will be increased to 70% if the company signs a research and development agreement with institutes belonging to the scientific and technological system or with public national universities (competitive exploitation system).

This system is an alternative to Stiglitz' proposal of having different patent protection systems, depending on whether developed or developing countries are involved. It also represents an alternative to the current system derived from the TRIPS Agreement, as it offers public resources such as non-refundable contributions in favor of companies with approved projects, which sign an agreement with the INPI to waive their rights to enforce their patent rights and be bound to issue licenses as requested, with the corresponding payment of royalties to the Innovation Fund.

A regime of competitive exploitation is therefore created, from a financing fund for innovations, with a socially-efficient allocation of resources. Freedom to manufacture and market innovations, complying with the requirement of royalty payment to the Innovation Fund, except the innovative company who is exempted from paying the royalty.

Provide the evidence base for the proposal including literature references and other relevant information:

We annex the complete article with our proposal. The reference literature is the following:

- Joseph Stiglitz, Making Globalization Work, Chapter 4, 2006
- Frederick Abbott & Graham Dukes, Global Pharmaceutical Policy, Chapter 2, 2010

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