

THE FRAMEWORK CONVENTION ON PHARMACEUTICAL INNOVATION AND ITS RELATED PROTOCOLS

Submission to the United Nations High Level Panel on Access to Medicines by the Global Health Law Committee of the International Law Association

Prepared by Xavier Seuba, Senior Lecturer, CEIPI, University of Strasbourg*

Abstract

The Global Health Law Committee of the International Law Association proposes the adoption of a Framework Convention on Pharmaceutical Innovation, followed by four optional protocols touching upon intellectual property management, funding for innovation, administrative and regulatory tools relating to pharmaceutical approval processes, and international cooperation in science and technology. It builds upon previous projects, and identifies a broad material scope and comprehensive institutional setting.

Health innovation is produced by combination of national and international policies and regulations in a wide array of areas, including health, trade, tax, science and industrial development. Trade-related fields include intellectual property, tariffs, technical standards, regulatory systems, investment, services and subsidies. We propose addressing these aspects in the context of a single regime, composed of an umbrella treaty and four protocols. The Framework Convention on Pharmaceutical Innovation would enshrine the principles informing the technical responses adopted in the protocols, and would identify the relevant stakeholders, the coordination mechanism and the areas of further normative action in additional protocols.

The proposed international regime on pharmaceutical innovation would respond to the multifaceted aspects of medicines' innovation and access. It would also enhance policy coherence and spur synergies by treating the 'innovation elements' in light of the same values and legal principles, including a sound human rights basis. The outline and normative technique implemented would facilitate overcoming technical, scientific and legal difficulties and would ease reaching concrete solutions, as demonstrated in international areas of similar complexity, such as environment, human rights and the law of the seas.

The proposal defines pharmaceutical innovation and portrays it as a common interest of mankind. It also identifies the international legal basis for action in the area of pharmaceutical innovation and access, targets key areas of intervention, and identifies and organizes numerous options to address current deficits in the pharmaceutical innovation system.

Introduction

The Global Health Law Committee of the International Law Association is pleased to submit to the United Nations Secretary-General's High-Level Panel on Access to

Medicines a proposal for international normative action to ‘promote research, development, innovation and increase access to medicines, vaccines, diagnostics and related health technologies to improve the health and wellbeing for all’ (UNSG, 2015). It proposes the adoption of a Framework Convention on Pharmaceutical Innovation, followed by optional protocols touching upon intellectual property management, funding for innovation, administrative and regulatory tools relating to pharmaceutical approval processes, and international cooperation in science and technology. It builds, therefore, upon projects put forward by scholars, civil society and states during the last fifteen years (WHO, 2011; WHO, 2012) and proposes a different and broader institutional setting and material scope.

The changing landscape for pharmaceutical innovation

As technological and social changes take place in a rapidly evolving global society, it is necessary to update existing innovation policies, processes and structures. The old linear innovation model has been replaced by a more complex framework, where many actors intervene at several different stages of the innovation chain. Scientific and technological advances, pressing social needs, increased competition and the ever-evolving role of the state, among other factors, have prompted the emergence of innovation models pulling together competences and talents of very diverse stakeholders. More than ever, innovation is highly cumulative and frequently requires collaboration in open, inclusive and enabling environments. As such, innovation reaches unprecedented levels of sophistication. However, contradictory as it may seem, the needs of large segments of the population remain unmet and the overall sustainability of the pharmaceutical innovation system is at stake.

Reflections on the strengths and weaknesses of the pharmaceutical innovation system have been enriched enormously in the last twenty years. The same can be said with respect to the tools that enable innovation. More is known about the complexity of innovation and the need to finely combine many policy, legal and scientific instruments in order to produce innovation. The analysis of these aspects goes beyond this proposal, and the next paragraphs just set the scene of the project proposed to the High Level Panel.

Pharmaceutical innovation refers to the introduction of new products and processes that create value for health. While it is difficult to measure, this definition is a useful starting point. The so-called ‘innovation elements’ encompass varied inputs, processes, legal instruments, finance and economic drivers, policy choices and cultural approaches. Presently, networks of innovators, often of a global nature, have recourse to a wide range of legal and managerial tools of a rapidly evolving innovation toolbox, which must be also observed in the background of specific policy, economic, legal, regulatory and cultural settings. States are sovereign to regulate these elements as they think best. However, there are at least two reasons for international cooperation. First, health is recognized as a legal interest protected by the international community and states benefit from joint action in this respect. Second, innovation is often factually and legally

determined by international elements. In this last respect, numerous international treaties pertaining to very different areas are nowadays distal determinants of innovation.

Numerous tools have been deployed to promote pharmaceutical innovation, mention commonly being made to patents, trade secrets, public funding, pharmaceutical regulatory processes, availability of venture capital, ownership of innovation ‘platforms’ and ‘infrastructure’, science and engineering education, technology transfer, competition, prizes, ‘open’ strategies and liability rules (S. M. BENJAMIN, A. K. RAI, 2008). This enumeration makes it clear that while pharmaceutical innovation relies on patents, it does not necessarily coincide with what is patentable, a quality which has an autonomous meaning and legal consequences. The multifaceted relationship between patents and innovation, as well as the impact of patents on prices and access to health, has spurred debate on the ‘patent-driven model for pharmaceutical innovation’ (E. TORREELE, M. MAZZUCATO, 2015), a model that may result in undersupply or even in inaccessibility of life-saving pharmaceutical products.

The range of actors in the production of innovative goods mirrors that of stakeholders involved in the policy aspects of innovation. International organizations, states, companies and researchers pursue complementary goals, including the provision of public goods, the maximization of social welfare, the enhancement of firms’ competitiveness and the advancement of science. The promotion of policy options that strengthen such interaction and complementarity is crucial both at the national and international levels.

Framework Convention

Health innovation is governed and produced by combination of national and international policies and regulations in a wide array of areas, including health, trade, tax, science, educational and industrial development. The provision of public goods such as health spans across several legal regimes, notably international health law, human rights law and international economic law. Just to give a measure of the complexity, the concerned trade-related fields include intellectual property, tariffs, technical standards, regulatory systems, investment, services and subsidies.

Previous proposals to set up a treaty on pharmaceutical innovation have been of varying scope and have targeted a wide array of topics, including clinical trials, medical ethics, transparency, open innovation, funding for research and international cooperation on science and technology. Global common values and objectives cut across these proposals and could be enshrined in the Framework Convention on Pharmaceutical Innovation. This general umbrella convention would be inspired by core values and fundamental principles, and would identify the problems, relevant stakeholders and areas of further normative action by means of the adoption of additional protocols. The latter could relate to i) intellectual property management; ii) administrative and complementary tools to foster innovation; iii) funding; iv) international cooperation in science and technology.

The model of a framework convention followed by protocols is frequently pursued in contexts of technical complexity and uncertainty, such as international environmental regimes, or with respect to subjects of high sensitivity, such as human rights. Moreover, it has been implemented in other intricate contexts, such as climate change and maritime law.

The development of an international regime to foster pharmaceutical innovation would facilitate reaching an initial consensus on a number of central points, such as the portrayal of pharmaceutical innovation as a common interest of mankind and the identification of the areas of relevance to pharmaceutical innovation. Specific and complex areas would then be approached independently, thus facilitating technical discussion on topics of different nature, complexity and constituencies.

A public health and human rights-based global instrument

The proposed instrument would be based on some fundamental principles. First and foremost, innovation in the area of pharmaceuticals is a common interest of mankind. Compelling humanitarian reasons, international human rights compromises, or just self-interest in view of the global health interdependence support that holding.

A foundation based on human rights is of relevance in this context. Even though some countries have not ratified or accessed to the International Covenant on Economic, Social and Cultural Rights (ICESCR), 164 states are parties to it. It is therefore almost universal in scope, and the work of the Committee on Economic, Social and Cultural Rights, which is in charge of its monitoring, gives it particular global relevance. The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in Article 12 ICESCR provides a useful analytical framework to address practices, regulations and policies with an impact on health. This framework, which has been elaborated further in General Comment 14, builds on two pillars, namely the ‘interrelated and essential elements’ and the legal obligations arising from the right to health. In a nutshell, and in relation to the specific interest of the Framework Convention proposal, states have the obligation to cooperate –including by means of normative action– and to act locally to enhance meaningful and accessible health innovation to prevent, treat and control epidemic and endemic diseases.

The legal basis for international normative action in the area of pharmaceutical innovation is broader, and includes at least the international fundamental principle of respect and protection of human dignity, which materializes in international compromises to the benefit of public health; Article 55(b) of the Charter of the United Nations and the compromise therein to promote solutions to health-related problems; Articles 25(1), 27(1) and 28 of the Universal Declaration of Human Rights, which recognize the right to health, the right to share in scientific advancement and its benefits, and the right to a global social order where the rights enshrined in the Declaration can be fully realized; Article 15.1(b) of the ICESCR, laying down the right to access to the benefits of science; and Articles 7 and 8 of the Agreement on Trade-Related Aspects of Intellectual Property Rights. Other soft-law

texts, in particular the 2030 Agenda for Sustainable Development and the World Health Organization Pandemic Influenza Preparedness Framework are also of relevance.

Protocol on intellectual property management

Fulfillment of the instrumental purpose of the intellectual property system depends on its actual design. Data shows that intellectual property is a tool to stimulate innovation, and proves as well that social norms, government intervention and competition are also vital to enable that function. Accordingly, development of measures relating to intellectual property management could support such a framework.

Patent statutes have commonly adopted broad language with respect to patentability. The room to maneuver needs to be preserved, since it is ultimately related to innovation output, which is both product and country-contextual. In this regard, even if it is implausible to reach international consensus on precise patentability standards and the regulation of infrastructural innovation, it may be worth merely recognizing the lack of consensus.

Next, a reminder of the flexibility existing with respect to post-grant measures of relevance to innovation would be also meaningful. The measures include, among many others, the research exception, patent opposition procedures and non-voluntary licenses in cases of patent dependency, each of which has national contextual aspects. In the Framework Convention these references may be broad and merely quote the Doha Declaration on the TRIPS Agreement and Public Health, whereas more detail could be provided in the suggested protocol on intellectual property management. In this same context, patent approval processes may also be enriched, for instance by giving special status to patents relating to priority health needs.

Open innovation models, based on cooperation to foster the development of knowledge and economic growth, rely heavily on intellectual property management and balancing of stakeholder incentives. In this sense, new approaches to intellectual property sharing and management, and some arrangements previously considered anticompetitive, such as patent pools, are currently instrumental to promote efficiency and cooperation. Successful international models include the Medicines Patent Pool which could be supplemented by a number of key principles to adjust intellectual property management to contemporary values and needs, in particular transparency with respect to patent status and licensing conditions. Likewise, the impact of other intellectual property categories on innovation, as well as the relationship between intellectual property rights and subsidies, should be addressed in the context of the negotiations.

Protocol on pharmaceutical innovation financing

In 2012, the Consultative Expert Working Group on Research and Development developed detailed ambitious proposals for financing innovation, in particular the identification of a sustainable source of funding. The proposals of the Working Group, and

the discussions that followed, could be the starting point for the ‘financing protocol’ of the Framework Convention on Pharmaceutical Innovation. They included discussion on a ‘governmental agreement to contribute to the global cost of R&D, considering each nation’s level of development, size of economy and capacity to pay’ and delinkage between the costs of innovation and the price of pharmaceuticals, a key concept bridging access and innovation.

Whether the funds collected would be devoted to prizes, grants or directly publicly-funded research should be addressed in the protocol. In that regard, direct subsidization has been identified as the most effective response to inadequate innovation incentives and costly adaptation (K. MASKUS, 2015). In this regard, international norms on subsidies (the WTO Agreement of Subsidies and Countervailing Measures) may be relevant. Likewise, the protocol should set up the requirement that major changes in innovation-related policies are subjected to cost-benefit analyses and the collection of robust data supporting the recommendations. While economic and analytical outputs cannot replace public policy priorities, they are instrumental in identifying and designing the best tools to stimulate innovation.

Protocol on administrative and technical measures

Medicines’ regulatory agencies and entities responsible for financing drugs play a relevant role in innovation policies. Because of their specificities and the topics of regulation (technical standards, medicines purchasing) they deserve independent attention.

On the one hand, there are policy, governance and normative aspects relating to international quality, safety and efficacy of medicines that need to be addressed. In particular, the inclusiveness and openness of some international standard-setting processes and the way certain standards may impact the development of new drugs must be addressed.

On the other hand, a range of instruments and measures normally implemented at the national level could gain additional recognition in an international treaty. These instruments and measures include procurement agreements, advanced market commitments, conditions of access to government funded research, priority review vouchers, and free access to test data information.

Protocol on science and technology cooperation

International scientific cooperation is key to fulfill the potential of pharmaceutical research. Proposals on the adoption of an international treaty to facilitate and promote the development of science and technology have been on the table for the last two decades (J. H. BARTON, 2002; J. LOVE, T. HUBBARD, 2004). Numerous bilateral agreements and scientific programs like the European Union Horizon 2020 already promote scientific and technological international cooperation, and may be a source of inspiration and funding.

The relevant protocol could address i) rules on research subsidies in areas of public health interest; ii) an agreement to place 'into access pools the patented results of publicly funded research that develops knowledge capable of supporting applied science and R&D, especially in areas of common global concern' (K. MASKUS, K. SAGGI, 2015); iii) measures enabling cooperation between research centers; iii) compromises to facilitate international mobility of scientists, for instance by expanded Mode 4 commitments in the General Agreement on Trade in Services; iv) design of agendas of common interests and priority setting in accordance with public health priorities; v) measures to stimulate technology transfer between developed and developing countries; vi) criteria to support publicly funded research; vii) regulation of conditions for accessing publicly funded research or tax advantages; viii) facilitating access to scientific resources; ix) development of co-funding and joint-funding mechanisms.

Which international structure and adoption process

An instrument of this caliber needs broad international support, including states with research-based economies, emerging economies, as well as countries with pressing health needs. It also requires involvement of numerous international organizations, companies supplying different segments of the pharmaceutical market, scientists, and health organizations.

Prior complex international normative processes were materialized through a range of conferences over a considerable number of years. In the case of pharmaceutical innovation, discussion has advanced since the nineties. On the one hand, discussions relating to the adoption of a treaty have taken place for the last 15 years and have progressed in many respects. The proposal put forward aims at providing the structure and mechanisms, and some update, to proposals previously made. On the other hand, numerous already existing initiatives, developed by multiple stakeholders in international organizations, civil society, the private sector and academia, could fall under the scope of the new regime. The task would be twofold: coordinating and going further when necessary, while constructing broad-ranging stakeholder incentives to participate.

International organizations and organisms that must be involved in this process include the World Health Organization, World Trade Organization, World Intellectual Property Organization, United Nations Industrial Development Organization, United Nations Conference on Trade and Development, United Nations Children's Fund, the Office of the United Nations High Commissioner for Human Rights, and United Nations Development Programme. In addition, perspectives from global health stakeholders including NGOs, private sector researchers, developers, and manufacturers, donors, member countries and medicines procurement agencies will play a critical role to inform these discussions.

The Framework Convention, negotiated in the context of international conferences, could establish a light coordination mechanism or authority in charge of coordinating or monitoring the action of concerned stakeholders. The coordination

mechanism could be based on the recommendations put forward by the Consultative Expert Working Group on Research and Development and stakeholders described herein, and could also benefit from the experience of small and functional international authorities and normative processes, such as the International Seabed Authority or, provided necessary changes are made in order to ensure representativeness, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or similar technical or regulatory groups.

Notes, References and Bibliography

* The perspectives in this submission may not necessarily reflect the totality of views of each member of the GHLC. It is intended to further public dialogue and the development of needed options. Peter Beyer, as current staff at WHO, has recused himself from this submission. Frederick Abbott, co-chair of the GHLC, is a member of the Expert Advisory Group. For the Members of the Committee, see <http://www.ila-hq.org/en/committees/index.cfm/cid/1053/member/1>

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