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IFPMA Submission to the Public Hearing on Proposals for R&D Financing

On behalf of the research-based biopharmaceutical industry, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) welcomes opportunities to contribute to the Expert Working Group's (EWG) consideration of proposals related to financing and coordination of research and development (R&D) for diseases that disproportionately affect developing countries. We appreciate the World Health Organization's (WHO) efforts to collect input from public and private stakeholders, including the biopharmaceutical industry, regarding such proposals to ensure overall transparency of WHO processes, and implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The innovative biopharmaceutical industry is committed to working with the EWG in support of its efforts in this area to help achieve the goals of providing additional complementary incentives for R&D into diseases that disproportionately affect developing countries, and the consequent improvement of access to medicines and health in the developing world.

IFPMA had the honor of highlighting our member activities to date and identifying gaps in the area of diseases disproportionately affecting the developing world before the EWG last January 2009. Our Members are active in R&D for these diseases in different ways: while about one third of the projects in this area involve companies on their own, the vast majority includes work in collaboration with partners via product development partnerships (PDPs), through in-kind and financial contributions. Examples of PDPs are AERAS, DNDi, IAVI, IOWH, IVI, MMV, PATH, TB Alliance, and TDR¹. Our members are committed to optimizing their capabilities, and working to avoid duplication with regard to partnerships. To date, members have set up 5 R&D centers which work exclusively on diseases of the developing world – one of which works on new vaccines for these diseases. These industry centers work collaboratively with a whole range of PDPs and academic partners.

It is encouraging that R&D into diseases disproportionately affecting developing countries is increasing in industry, in PDPs and in academia. A recent report noted that biopharmaceutical companies contributed approximately 9.1% of global R&D funding for neglected diseases, more than any country other than the United States.² This does not include investments and contributions companies made to product development partnerships.

Developing a new medicine takes a long time – at least ten years – and is very costly. The average figure amounts to \$1.2 billion, with clinical trials being the largest cost factor. Most of the R&D projects in neglected diseases currently being undertaken by our members, either alone or with PDPs, are in relatively early stages. As these projects progress to clinical trials, the costs will likely increase along with total funding needs. As a direct implication, more strain may be placed on the clinical trials and regulatory infrastructure in developing countries, which is where most trials take place, and approval for products occurs. Moreover, from time to time, what seem to be promising avenues of development turn out to be dead ends. This leads researchers back to the primary stages of research regarding the disease concerned³. The implication is that time horizons and cost estimates for a particular disease in this area may unexpectedly increase drastically.

New funding mechanisms and incentive schemes are being explored. Though most are in their early stages, and the concepts may be refined with experience, their very existence is crucial with respect to the official recognition of the importance of R&D, and the need for increased funding and complementary incentives.

Intellectual Property Systems Remain Critical to the Development of New Medicines and Vaccines

The EWG's mandate is to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate R&D related to diseases that disproportionately affect developing countries. WHO members have recognized that intellectual property

¹ The industry has established or contributed to literally scores of programs, which have transformed the pipeline of R&D products for diseases of the developing world. Other examples are The Global Fund to Fight AIDS, the Accelerating Access Initiative, the Polio Eradication Initiative, Roll Back Malaria, The Global Alliance for Vaccines and Immunization, and the Global Alliance to Eliminate Lymphatic Filariasis.

² Moran, M. et al, Neglected Disease Research and Development: How Much Are We Really Spending?, The George Institute for International Health, (2008).

³ This situation recently happened in the field of dengue.



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provides strong incentives for innovation and the development of new health products.⁴ This concept particularly applies to diseases which disproportionately affect developing countries.

Given that there are currently more than 2,900 medicines in development⁵, including over 170 medicines for diseases disproportionately affecting the developing world⁶, the ability to acquire and implement intellectual property rights, particularly patents, helps justify investing in the inherently risky, costly, complex, and lengthy R&D process that is necessary to successfully bring safe and effective medicines to all patients and countries whatever their socio-economic situation. In 2008, the innovative biopharmaceutical industry invested more than an estimated \$65.2 billion in R&D. If we take into account the significant difference between the levels of complexity and the subsequent associated costs of the R&D process compared with manufacturing operations necessary to produce a particular medicine, we recognize the centrality of the intellectual property scheme. Where countries have strong and effective IP protection regimes in place, there may be a connection between increased incentives for local innovation, foreign direct investment, and the transfer of technologies that foster local innovation and economic growth.⁷

Developing country researchers increasingly rely on intellectual property to nurture and promote their innovations. Intellectual property rights, including patents, underpin economic development and stimulate the creation of new technologies, especially in the biopharmaceutical sector. They are therefore part of the solution for increasing R&D to meet the needs of developing countries, along with other items in the Global Strategy and Plan of Action, such as improving cooperation and coordination in research and development, improving health-systems through improvement of delivery systems and infrastructures, and building capacity in the developing world to more effectively address the critical health needs of developing countries.

Specific Proposals to Stimulate R&D

We would like to comment on several proposals that have been put forward as potential mechanisms for stimulating R&D. These include: product development partnerships,⁸ “orphan drug” legislation, advance market commitments, patent pools, and prizes. None of these mechanisms is a stand alone solution. They should be viewed as complementary mechanisms to existing IP systems for stimulating further R&D. While this list is not exhaustive, and there are other mechanisms such as tax incentives or priority review vouchers, that may also be considered, product development partnerships, “orphan drug” legislation, patent pools, prizes, and advance market commitments were mentioned most frequently during the negotiations that led to the Global Strategy and Plan of Action.

1. Product Development Partnerships

A recent approach used to encourage R&D for neglected diseases is the public-private partnership (PDP) model, in which the private and the public sector work together. Companies provide the R&D, technology, manufacturing and distribution expertise with funding and logistical contributions from public sector partners, such as governments, or philanthropic organizations like the Bill & Melinda Gates Foundation. Academic institutions are also involved in providing research capabilities and disease area knowledge.

This is a viable model, which leverages the respective strengths of each partner, enabling both industry and government to do what they could not do alone. Success here requires flexibility, transparency and trust. This cooperative tool is a crucial link in the process of bringing new discoveries to patients, particularly for those few diseases that affect neglected populations, where there are fewer private dollars to spur medicine development.

Most importantly, it is a model that is working. A number of these PDPs have been established and have transformed the pipeline of R&D projects for diseases of the developing world. We believe that further encouragement of the PDP approach, in a systematic, long-term framework guaranteed by donor and government protocols, is essential to ensure its sustainability. We urge the Expert Working Group to build off the success of these efforts in developing the long-term financing framework that can ensure the sustainability of this model.

⁴ Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property Rights, paragraph 25.

⁵ Adis R&D Insight Database, Wolters Kluwer Health, accessed 13 February 2009.

⁶ This data includes the ten TDR diseases as well as HIV/AIDS.

⁷ Park, W. and D.C. Lippoldt, “Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries,” OECD Trade Policy Working Papers, No. 62, OECD Publishing, 2008.

⁸ See www.globalhealthprogress.org for more information.



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2. “Orphan Drug” – type Mechanisms

In the U.S., the EU and several other countries, “Orphan Drug Acts” have produced impressive results in terms of new drugs made available in disease areas where the market mechanisms were insufficient to achieve these results alone. Legislation or other mechanisms similar in spirit to these “Orphan Drug Acts”, (e.g., a “Tropical Diseases Drug Act” or something similar) could provide a favorable framework of financing incentives to increase R&D for drugs targeting diseases of the developing world. Such a package could include both research incentives (R&D tax credits, research grants, lower regulatory fees, fast-track approval) and market incentives (e.g., advanced purchasing commitments).

By providing a series of “push/pull” mechanisms, this model represents a comprehensive and potentially stand-alone approach. This can increase the possibility of success for small companies thus enhancing the competition and the concurrence. Subsequently, both lowering prices and stimulating R&D would be possible. The Expert Working Group could help to develop a model incorporating these mechanisms for use at the global level.

3. Advance Market Commitments

Several WHO member states have been engaged in efforts to fund an advance market commitment (AMC) pilot to stimulate the development of products to address diseases that disproportionately affect the developing world.⁹ This commitment by governments to help fund the massive effort needed to achieve the health-related Millennium Development Goals is a very positive development. The AMC approach may help to replicate market forces, in that it makes money available only if companies succeed in producing the desired product. Our research-based biopharmaceutical companies around the world have the necessary know-how, and the AMC’s innovative financial incentive can encourage them to take on the risk associated with bringing new medicines and treatments from the laboratory to the poorest countries that need them. Given that the AMC approach is still rather new, however, additional time may be needed to identify the best models within this approach.

4. Patent Pools

Patent pools generally are created when “a group of patent holders each decides to license their respective patents to each other and to third parties collectively.”¹⁰ They may not accurately be called financing mechanisms, but can be mechanisms which facilitate transactions.

To promote transparency and certainty, there are several general principles a “patent pool” should embody. These include: that patent pools be voluntary associations of entities formed without coercion; that objectives of any patent pool are clearly defined; that patent pools complement rather than replace elements of existing intellectual property regimes; that the rights and obligations of contributors and licensees of contributed rights are clear; and that patent pools reduce transaction costs, and not increase administrative costs, relative to other options such as direct licensing.

We are aware of several different proposals that are being termed “patent pools.” One proposal by GlaxoSmithKline calls for voluntarily contributing patents for nascent technologies to develop new treatments for neglected tropical diseases.¹¹ In exchange for licensing its own essential patents for practicing the technology to other members of the patent pool, a contributor gains a license to the essential patents of others that it does not own. Although biopharmaceutical products have not typically been the focus of patent pools, this *quid pro quo* is a motivation for a patent owner to voluntarily join a patent pool.

Another proposal labeled a “patent pool” is the mechanism being discussed by UNITAID. This appears to be a “product pool” for medicines, since it aims to license products that are already available for manufacture and sale to companies that have not contributed to the pool. A primary feature of the proposal is establishing an intermediary non-profit entity to control the licensing of all patents that would be relevant to production and distribution of a drug product. It is our understanding that the non-profit entity administering the pool would set criteria for a royalty payment by the “equitable royalty” method based on the therapeutic benefits of

⁹ “Preventing Pneumococcal Diseases: An Advance Market Commitment for New Vaccines,” GAVI Alliance Secretariat at http://www.vaccineamc.org/files/AMC_PneumoFactSheet_2.pdf

¹⁰ U.S. DEP’T OF JUSTICE AND THE FEDERAL TRADE COMM’N. ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION [hereinafter USDOJ] 64 (April 2007). It should be noted that there is no internationally recognized definition of the term “patent pool.”

¹¹ “GlaxoSmithKline CEO Calls for Innovative Measures to Fight Neglected Diseases”, Press Release, Health Affairs, March 19, 2009.



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the medicines and the affordability of royalties in particular countries.¹² This does not follow past or current patent pool structures and, as noted above, primarily appears to be a “product pool”. Voluntary participation of entities contributing to the patent pool should be considered an essential pre-requisite for this or any pooling mechanism.

An additional pool mechanism is one which seeks to facilitate standards compliance. The World Intellectual Property Organization (WIPO) Standing Committee on the Law of Patents recently addressed this issue noting that “a patent pool operates under an agreement enabling the participating patentees to use the pooled patents and providing a standard license for permitting others to use the pooled patents.”¹³ WIPO further stated that for standards-related patent pools, in order to ensure non-discrimination among licensees, a most-favorable royalty is typically included. The license is normally applicable to any patents which may be included in the pool in the future. Additionally, WIPO noted that some patent pools include an obligation on licensees to grant-back any essential patents on a fair, reasonable, and non-discriminatory basis. At the core of such standards-related patent pools is the notion that participation in a patent pool is voluntary at the option of patent holders. As WIPO pointed out, “...some owners of essential patents may opt out from participation in a pool if they do not agree with the licensing terms and conditions of the pool.”¹⁴

In evaluating these proposals and the varying definitions of mechanisms termed “patent pools,” we urge the Expert Working Group to consider the extent to which these proposals embody principles of voluntariness, complement existing intellectual property regimes, and promote transparency and certainty with regard to the objective of stimulating R&D into diseases of the developing world.

5. Prizes

Prize funds have also been put forward as potential mechanisms for stimulating R&D into diseases that disproportionately affect the developing world. Prizes are funds that create rewards for successful development of new products, which would be paid in a lump sum once a product obtains necessary marketing approval. Prizes should be structured to complement and not undermine current IP systems. Prizes could be catalysts for short-term approaches to incentivizing innovation in some circumstances, and as such, probably do not provide a sustainable mechanism for supporting broad R&D into diseases that disproportionately affect the developing world. This view is supported by leading economists Joseph DiMasi and Henry Grabowski who have also noted that there are “numerous and potentially substantial, costs” to prize funds.¹⁵ For example, “the temptation for legislators and administrators to undervalue innovations is especially great for prize awards.”¹⁶ This can lead to weakened incentives for innovation, and leave the innovator with “little choice but to comply with expropriation of much of the value that has been created.”¹⁷

We encourage the Expert Working Group to carefully consider the extent to which prizes function as sustainable mechanisms for meeting the R&D needs of developing countries. As DiMasi and Grabowski point out, other approaches, such as public-private partnerships may be more sustainable policy mechanisms for facilitating “risk and reward-sharing arrangements to advance R&D portfolios dedicated to particular diseases,” such as diseases of the developing world.¹⁸

Conclusion

The research-based biopharmaceutical industry looks forward to supporting the EWG’s efforts to evaluate proposals for new and innovative sources of funding to stimulate R&D. Several existing models hold promise for meeting the goals of providing complementary incentives for R&D into diseases that disproportionately affect developing countries, and the consequent improvement of access to medicines and health in the developing world. These include product-development partnerships and orphan drug-like mechanisms. Other proposals, such as advance market commitments, tax incentives, and priority review

¹² The license terms being proposed would be uniform for all licensees and all patents (e.g., a standard royalty would apply regardless of the relationship of the patent to the product). E. Richard Gold, et al., PRELIMINARY LEGAL REVIEW OF PROPOSED MEDICINES PATENT POOL [Gold et al.] (The Innovation Project) (July 26, 2007) at 43-44.

¹³ World Intellectual Property Organization, Standing Committee on the Law of Patents, Standards and Patents, 13th Session, Geneva, March 23-27, 2009 at 32-38.

¹⁴ World Intellectual Property Organization, Standing Committee on the Law of Patents, Standards and Patents, 13th Session, Geneva, March 23-27, 2009 at 36.

¹⁵ J. DiMasi and H. Grabowski, Should the Patent System for New Medicines be Abolished?, Nature Publishing, Volume 82 Number 5, November 2007 at 489.

¹⁶ Id.

¹⁷ Id.

¹⁸ Id.



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vouchers may also stimulate R&D into diseases that disproportionately affect developing countries, however, additional time may be needed to identify the best models within these approaches. In evaluating these proposals, we urge the EWG to recognize the critical role of intellectual property rights, including patents, as a primary driver of economic development and the creation of new technologies to meet the needs of developing countries. IFPMA is committed to coordinating as an active stakeholder to explore these mechanisms.