

## Joint IFPMA-PhRMA Submission to the EWG Second 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) and the Pharmaceutical Research and Manufacturers of America (PhRMA), we welcome the opportunity to contribute to the Expert Working Group's (EWG) evaluation of high-level criteria against which R&D financing proposals will be assessed, inventory of proposals for R&D financing, and related framework for fundraising and fund allocation proposals. We continue to support the World Health Organization's (WHO) efforts to collect stakeholder input and ensure transparency as it considers the specific R&D needs of developing countries.

The innovative biopharmaceutical industry is committed to working with the EWG to support its efforts 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. The consultations carried out by the Expert Working Group have produced an extensive list of ideas for further development. Those that are ultimately supported will need to:

- be able to be implemented in the short to medium-term
- be sufficiently credible to engage key funding sources
- be endorsed by key providers of research and development
- be demonstrably non-erosive of existing efforts

As the EWG evaluates various proposals identified for financing and coordinating R&D, and proposals for new and innovative sources of funding to stimulate R&D, we again would like to emphasize the important role of intellectual property (IP) as a strong incentive to ensure innovation and the development of new health products. A proven mechanism over years, IP has provided a critical incentive for the industry to research and develop over 357 new FDA approved innovative medicines from 1998 to 2008, which have led to great advances in health around the world.<sup>1</sup> IP rights, including patents and data exclusivity, underpin economic development and stimulate the creation of new technologies, especially in the biopharmaceutical sector. They should therefore be recognized as an important 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.<sup>2</sup>

### **Criteria for Proposals**

First, we would like to comment on the high-level criteria that the EWG identified, against which each R&D financing proposal will be measured by the EWG. At the outset, we would like to emphasize that it is important to evaluate each proposal against a range of criteria and also understand that the importance or "weight" of each criteria may fluctuate according to its applicability to the project concerned, the issue it is addressing, and community/country/people it is aimed at serving. Therefore, there is no "one size fits all" formula or approach to objectively assess projects without the context of the specific R&D needs of developing countries the project is trying to address. A ranking approach may act against the objective of requiring stakeholders to provide rationale for their preferences, and may not be responsive to the need to identify complementary incentives for R&D in developing countries.

<sup>1</sup> Source: US Food and Drug Administration. See New Drug Approvals in 2008, PhRMA.

<sup>2</sup> See Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA61.21, 24 May 2008.

With respect to the criteria for proposals, we would suggest streamlining the number of evaluation criteria by grouping certain criteria together. For example, key groupings might include broader headings such as: Impact, Acceptability, Feasibility, Sustainability, Ethical Considerations, and Multi-Stakeholder Approaches.

Supportability: We would read “acceptability” (current criteria #9) under the term Supportability as among the most important criteria against which R&D proposals should be evaluated. It is particularly important for R&D proposals to be considered in relation to how relevant they are to various stakeholders. Proposals that have widespread consensus and support would be the most likely to succeed and thus should be considered by the EWG. This notion is also implied in the concept of product development partnerships and in broader category of public-private partnerships. Suitability (current criteria #2) and prior experience (current criteria #10) could also be combined under the broader supportability heading in terms of measuring whether a proposal targets key stakeholders and allocates funds appropriately. Support, experience, and leverage of expertise are critical when attempting to implement new mechanisms and the ability to draw on the past experience of key stakeholders is a key step towards possible success.

Sustainability: Sustainability is another key criterion against which R&D financing proposals should be evaluated. We would suggest combining concepts including risk management (current criteria #6), long-term functioning (current criteria #11), automaticity (current criteria #12), scalability (current criteria #13), and time to implement (current criteria #14). Sustainability is critical to ensuring that mechanisms, once launched, continue to be supported as part of systematic, long-term frameworks. This is particularly true for public-private partnerships, for example, which over time have transformed the pipeline of R&D projects for diseases of the developing world. Furthermore, a sustainable proposal is one that fosters continued innovation. A key factor for innovation is the existence of an enabling framework which stimulates the creation of new technologies. Serving this goal, sound intellectual property protection, including patents and data exclusivity, is one of the key factors to guarantee sustainability.

Feasibility: Under feasibility, we would suggest combining criteria including funding (currently noted as criteria #1, “revenue related”), costs (current criteria #3), efficiency (current criteria #4), and technical feasibility (current criteria #8). These criteria should take into account the overall relationship between a proposal’s intended goals and transaction costs, and evaluate the extent to which a proposal can be implemented to maximize R&D. Technical feasibility should be an important consideration given potentially significant legal, regulatory or other barriers that may need to be addressed to successfully implement and carry out key R&D initiatives in developing countries.

Impact: We view impact (currently criteria #5) or the degree to which a proposal directs R&D toward developing country needs as another crucial criterion. Given the stated goal of identifying incentives for R&D into diseases that disproportionately affect the developing world, it is critical to measure the extent to which various proposals support long-term innovation and facilitate continued delivery of medicines for such diseases. As such, proposals could be evaluated based on their ability to address the specific needs of developing countries and influence health outcomes from diseases primarily affecting the developing world.

Governance: Another broad grouping of criteria could fall under governance. This grouping, referring to good governance practices, could combine accountability (current criteria #15), governance and ownership (current criteria #16), and transparency (current criteria #17). At a high-level, it is important to consider the extent to which both fundraiser and recipient are accountable for maintaining the functioning of the overall R&D mechanism to ensure key outcomes. Transparency is also central to enhancing overall support for certain R&D mechanisms, particularly with regard to how funding and allocation decisions are made. Furthermore, we reinforce the importance of consistent monitoring of progress and allocation of funding to ensure that the R&D activity/project has an impact and is sustainable. Any proposal which allocated substantial resources to diseases that disproportionately affect developing countries will need to include mechanisms to ensure accountability and monitoring.

Multi-Stakeholder Approaches: Lastly, we would suggest adding a broad criteria heading, which emphasizes the need for R&D proposals to represent multi-stakeholder approaches. This grouping could include the degree to which proposals complement or conflict with each other (taking into account current criteria #7 “positive/negative interactions”), as well as how various proposals for R&D financing support public-private partnerships, and stakeholders with instructional and field experience are partnered with to most effectively use expertise.

Again, while these category headings are not exhaustive, they provide some guidance to help better group core criteria against which R&D financing proposals may be evaluated by the EWG. Those proposals that demonstrate significant impact/outcomes for identifying incentives for R&D into diseases that disproportionately affect the developing world, which are relevant to key stakeholders, and which can be undertaken in a manner that minimizes transaction costs, yet maximizes R&D for diseases impacting the developing world, should be supported.

### **Inventory of Proposals**

Based on the inventory of proposals collated by the EWG, it is evident that the inventory reflects a range of stakeholder interests. These mechanisms should not be viewed as stand alone solutions, but rather as complementary mechanisms to existing rights regimes incentives for stimulating further R&D, including intellectual property. In particular, we would like to comment on several key mechanisms, including, public-private partnerships, “orphan drug” legislation, patent pools, prizes, and advance market commitments.

- Product Development Partnerships are models in which companies provide the R&D, technology, manufacturing and distribution expertise with contributions from public sector partners. This model leverages the respective strengths of each partner, and is a crucial link in the process of bringing new discoveries to patients, particularly for those few diseases that affect neglected populations. These proposals appear to have attributes that should be evaluated against all of the evaluation criteria discussed.
- “Orphan Drug”-type mechanisms 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. By providing a series of “push/pull” mechanisms, this model represents a valid and potentially stand-alone approach. These proposals appear to have attributes that should be evaluated against of the evaluation criteria found under Impact, Sustainability, Feasibility, and Governance.
- The Advance Market Commitment (AMC) approach may help to replicate market forces, in that it makes money available only if companies succeed in producing the desired product. Research-based biopharmaceutical companies around the world have the necessary know-how, and the AMC’s innovative financial incentive could encourage them to take on the risk associated with bringing new medicines and treatments from the laboratory to the poorest countries that need them. These proposals appear to have attributes that should be evaluated against all of the evaluation criteria discussed.
- 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.”<sup>3</sup> They may not accurately be called financing mechanisms, but can be mechanisms which facilitate transactions. We are aware of several definitions of mechanisms termed “patent pools,” some of which have different objectives. We urge the EWG 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. These proposals appear to have

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<sup>3</sup> 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.”

attributes that should be evaluated against the evaluation criteria Multi-Stakeholder, Impact, and Governance.

- Prizes are funds that create rewards for development of new products, which would be paid in a lump sum once a product obtains necessary marketing approval. Prizes should be structured to sustainably complement current IP systems and should be conceived on a voluntary basis. 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. These proposals appear to have attributes that should be evaluated against the evaluation criteria Sustainability, Supportability, Impact, and Governance.

### **Evaluation Framework**

Lastly, regarding the EWG's framework approach, the research-based biopharmaceutical industry views it as important to examine a broad range of incentives to foster R&D into diseases affecting the developing world. In examining the range of R&D mechanisms identified as part of the overall inventory, it is important to prioritize those proposals that track closely with the criteria outlined above (particularly impact, supportability, feasibility, and sustainability) to ensure that R&D proposals meet the specific needs of developing countries, while at the same time contributing to long-term, strategic approaches to support innovation and foster medical advances to help patients.

One of the main objectives and assets of the Global Strategy and Plan of Action was a call for promoting and prioritizing R&D for diseases where additional efforts are needed. By evaluating various R&D financing mechanisms according to the criteria, the EWG has an unprecedented opportunity to prioritize those proposals that would have the greatest impact on fostering R&D in the developing world and improving health outcomes more generally. For example, proposals that focus on Type III diseases, and in particular, on diseases for which little research is currently underway, could perhaps be more impactful in meeting the needs of countries in the developing world<sup>4</sup>. Further, given that certain proposals such as an R&D treaty and the Health Impact Fund are applicable to all diseases (public) and in all phases except for R&D infrastructure, it would be useful to incorporate the criteria outlined above into the framework approach to better prioritize and more readily assess competing proposals against their stated purpose.

We continue to support the Expert Working Group's efforts to examine current financing and coordination of R&D, and proposals for new and innovative sources of funding to stimulate R&D. The research-based biopharmaceutical industry stands ready to serve as an active stakeholder in assisting with evaluation of R&D financing mechanisms to better address the needs of the developing world.

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<sup>4</sup> On this issue, see IFPMA presentation to Expert Working Group, 12 January 2009, [http://www.ifpma.org/fileadmin/pdfs/2009\\_01\\_16\\_IFPMA\\_DG-EWG\\_120109\\_FINAL.pdf](http://www.ifpma.org/fileadmin/pdfs/2009_01_16_IFPMA_DG-EWG_120109_FINAL.pdf).