

**Comments of PhRMA on the Draft Global Strategy and Plan of Action of the  
Intergovernmental Working Group on  
Public Health, Innovation and Intellectual Property**

**I. Introduction**

As a representative of research-based biopharmaceutical companies, PhRMA welcomes this opportunity to comment on the draft plan of action prepared by Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). Many aspects of the plan could be usefully pursued by the IGWG. These include: identifying gaps in R&D for Type II and III diseases; developing concrete plans to address gaps; providing technological development capacity building; promoting effective cooperation between public and private sector research entities; and identifying and promoting complementary incentive mechanisms to existing intellectual property tools. The plan should promote cooperation, not compulsion, and should use methodologies based on objective evidence.

Several other proposals in the IGWG draft plan should not, in our view, be pursued. Fundamentally we believe these proposals will divert focus away from diseases that disproportionately affect developing countries; are unproven and potentially damaging to the existing R&D activity; are unlikely to work; or are politically infeasible. These include: placing Type I diseases in the scope of work; compelling contributions to patent pools; promoting an open-source research paradigm for the development of pharmaceutical products; imposing limits on the terms of bilateral treaties of Member States; expanding work into areas that are under the mandates of other international organizations; pursuing an R&D treaty; mandating open compound libraries.

**II. General Observations on the Scope and Mandate of the Work Program**

**A. Ensuring a Proper Focus and Scope for the Work Program is Essential to Achieve Tangible Progress**

The central motivation for the IGWG, and the necessary focus of its program of action, is “the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children.” As clarified in various discussions, these are problems caused by communicable diseases within the developing world which do not also affect significant populations of individuals in the industrialized world.

The existing rights-based incentive programs have consistently delivered new medicines to address Type I diseases, which benefit patients in both industrialized and developing countries. Type I diseases should therefore not be in the work program. Moreover, these commercial incentives, in conjunction with public sector and other non-commercial initiatives, foster a robust environment for research and development activities in both developed and developing countries.

**B. Objective Evidence Should be Used to Identify Gaps in R&D**

The mandate of Element 1 of the Proposed Work Program calls for identifying gaps in research and development activities for Type II and Type III diseases. This element of the work program is a critical first step that could provide a comprehensive picture of existing and future research programs underway in both developing and developed countries. This element of the work program should catalog and explain the work being done in the public sector, by private companies, by public-private partnerships (PPP), and non-profit organizations. The IGWG also should strive to identify gaps from multiple perspectives, including by disease type, by treatment approach for particular diseases (e.g., drug as well as non-drug based interventions), and by both individual country and region.

In pursuing this element, objective evidence must be collected and used. A prioritization of needs that is not driven by sound evidence and science will divert limited resources and create redundancies with ongoing research and development activities.

### **C. The Work Program Should Promote Cooperation, Not Compulsion**

The track record of the pharmaceutical industry in research and development of new medicines demonstrates that cooperative and incentive based mechanisms are effective in promoting research and development activities. Under the existing rights-based system, private companies have developed: all 22 of the antiretroviral drugs available today for treating AIDS with many more in pipeline and treatments for certain tropical diseases affecting the poorest populations, such as leprosy, onchocerciasis, and lymphatic filiarisis. The R&D based industry is continuing to look for new cures for diseases that disproportionately affect developing countries on their own and through partnerships. Current pipeline projects include: TB: 17 medicines; 2 vaccines; Malaria: 18 medicines; 2 vaccines; other tropical diseases: 8 medicines; 2 vaccines.

Sustaining additional R&D on Type II and Type III diseases will require programs that promote continued cooperation among the private sector, the academic community, the public sector, and non-governmental organizations. The experience of the past decade, in particular, shows that cooperation among these different sectors is not only possible but is efficient and effective in developing well-focused research and development programs.

The IGWG should therefore focus its work on successful and proven models such as the WHO Tropical Disease Research (TDR) program, the Global Alliance of TB Drug Development, the Medicines for Malaria Venture (MMV) and other innovative programs that promote R&D for diseases disproportionately affecting the developing world. Successful new solutions will build upon models such as these that best leverage commercial incentives, such as intellectual property protection and focused non-commercial incentives and support.

By contrast, measures that seek to coerce or dictate conditions on private companies, academic institutions or non-profit research institutions, are generally ineffective in promoting collaborations needed to sustain R&D efforts. The IGWG should therefore promote and improve incentive based measures and strategies that foster cooperation among stakeholders, rather than measures that seek to coerce or compel conduct.

## **II. Elements of the Work Program that Should Be Pursued**

### **A. Identification and Updating of Gaps in R&D for Type II and III Diseases**

Any large scale work program aimed at promoting research and development activities will face a number of challenges. These include finite financial resources, available human resources (i.e., adequately trained research scientists, medical personnel, etc.), and adequate political will. Compounding this problem is the inherent uncertainty involved in scientific research and development activities. More often than not, scientific research ends without a “solution” to the problem that motivated the research and development activities. An AIDS vaccine, for instance has been pursued vigorously for years but scientific obstacles have not been surmountable to date.

Recognizing this, an important element of the IGWG work program must be the correct identification of existing gaps in R&D programs for Type II and III diseases. The accurate identification of gaps with objective evidence will enable these cross-cutting research initiatives to be developed and supported. It will help ensure that priority is given to diseases for which existing commercial or non-commercial R&D programs are insufficient. The identification of gaps should be a continuing element of the work program so that adjustments can be made as R&D successes occur.

## **B. Scientific Capacity Building in Developing Countries**

The IGWG could usefully support efforts to promote appropriate types of technological capacity building programs within developing countries as part of its work program without overlapping programs of other international organizations or national governments. Technological capacity building can be promoted by supporting basic research in the life sciences at academic research institutions, applied research programs and clinical research. The experiences gained from programs of regulatory agencies from industrialized nations working with regulatory agencies and organizations in developing nations should be evaluated carefully as a constructive way of promoting specific types of capacity building. The European Agency for the Evaluation of Medicinal Products (EMA), for instance, has worked successfully to support regulatory approval programs within developing nations. These programs provide hands-on technical training to officials of regulatory agencies in developing nations, thereby providing tangible experiences in technology transfer.

Promoting the creation of public and private organizations that will actually carry out research and development activities in developing countries implicates many distinct types of issues and activities, many of which are outside the mandate of the IGWG. For example, promoting the establishment of local research facilities depends on a range of practical considerations, only some of which relate to the mandate of the WHO. Any research institution (commercially or non-commercially motivated) will have to assess the capacity of the local economy to support its practical needs (e.g., available adequately trained scientists and other specialized employees, the predictability and transparency of local regulations, etc). Additional considerations exist for commercially-motivated entities, including the transparency and predictability of the business environment and a variety of legal policies (e.g., intellectual property, taxation, product liability, etc).

## **C. Promoting Effective Cooperation Between Public and Private Sector Research Entities Should be a High Priority**

The IGWG has identified public-private partnerships as one mechanism to promote research and development to address issues associated with Type II and III diseases. The breadth and diversity of existing public-private partnerships demonstrates that these programs represent the most tangible and effective means of achieving the R&D objectives of the IGWG. The IGWG should thus promote public-private partnerships as a primary means of addressing gaps it identifies as part of its work program. It should also document and study the experiences of existing public-private partnerships, including the specific skills and value added by the different participants (e.g. the unique ability of industry to develop new drugs; licensing intellectual property skills). The IGWG can also study issues associated with licensing intellectual property rights, structuring efficient research partnerships, inducing participation of different stakeholders, and sharing information.

## **D. Identify and Promote Complementary Incentive Mechanisms to Intellectual Property Systems**

The IGWG should, as part of its work program, identify new incentive mechanisms that will complement existing commercial incentives, such as those provided by intellectual property systems. Examples include:

Advance market commitments. These incentives provide a defined “market” through contractual commitments of governments, international organizations or NGO’s to procure specified quantities of products. In principle, advance market commitments have substantial merit, at least in some instances as stimulants for new R&D. Practical questions will have to be assessed using experiences gained under these programs.

Specialized market mechanisms. Market exclusivity mechanisms such as orphan drug exclusivity available in the United States and Europe should be studied to assess their relevance and viability for promoting new R&D activities focused on Type II and Type III diseases. While not specifically

identified in the IGWG work program, specialized market exclusivity mechanisms have proven successful in stimulating R&D for diseases that do not have patient populations sufficient to provide a commercial incentive for new drug development. Other regulatory approaches to spinning R&D might be possible.

Research and development tax incentives. Tax incentives can provide an indirect commercial incentive for entities to engage in specified types of collaborative research and development projects. Tax incentives, however, are probably most viable where they can be transferred to an entity that will ultimately realize revenues from sales of a product. Cross-border research and development programs also present new issues that will have to be evaluated. The IGWG should explore whether these types of mechanisms can complement other types of incentives directed at commercial entities.

### **III. Measures in the Proposed Work Program that Should Not Be Pursued**

#### **A. Patent Pools**

The work program includes a call for work on “patent pools” concerning “upstream and downstream technologies.” This aspect of the work program is unlikely to provide any practical benefits in promoting the objective of increasing R&D activities for Type II and Type III diseases.

Voluntary collaborations among rights-holders in the bio-pharmaceutical industry can work, particularly in the context of pre-competitive basic research. These are not traditional patent pools, but they do indicate that voluntary arrangements can be made.

Voluntary patent pools are conceptually grounded on three principles that are not applicable to research and development of pharmaceutical technologies:

- First, identical products (or products that comply with a public standard) are being made by many different entities;
- Second, an unworkably large number of different entities own patents on different features or elements of the same product; and
- Third, the complexity of securing licenses on all necessary patents is time-consuming, inefficient and must be repeated many times.

These circumstances are not ordinarily present for pharmaceutical products and related technology. Unlike voluntary patent pools used in other industries, proposals relating to patent pools for pharmaceutical technologies that have been circulated are built upon a model of compulsory licenses. That is destructive of the cooperative and collaborative approach needed to make R&D enterprises successful.

#### **B. Free Trade Agreement Standards Are Not an Appropriate Topic for the IGWG**

The review of standards being negotiated in bilateral and regional free trade agreements is not related to the work program of the IGWG. This element is not directed to the objective of promoting new and additional research and development activities. Moreover, because these agreements are negotiated between countries, the involvement of the IGWG in this area is improper.

#### **C. Duplication of the Work of the WTO and WIPO Wastes Valuable Resources and Should Be Avoided**

Several areas of the work program call for work on topics that are the direct responsibility of the WIPO and the WTO. The WHO presently participates in the work being done on IP standards by both of these institutions, and should continue to provide input to these other institutions. Creating a new

and independent program of work on implementing WTO or WIPO standards is not justified or necessary.

**D. An Independent Research & Development Treaty is Not Warranted and Would Not be Effective**

The IGWG should not undertake the establishment of a new treaty directed to research and development because the need for it has not been established.

Moreover, this proposal is premised on several faulty assumptions. 1) It assumes that government-funded R&D for new drugs will result in innovation equal or better to what we see today under the current patent system, but for a lesser cost. This concept has been proven wrong in a number of real-world examples. As a general matter, the record of government funded R&D under the former Soviet Union was not impressive. 2) It assumes that Member states will be willing and able to tax their citizens to fund this system on an ongoing basis, whether or not Members face budget shortfalls or national emergencies. Further, this plan fails to consider how these budget commitments would be enforced to ensure that “free riders” do not cause its ultimate demise. 3) Finally, the proposal fails to address the very real world reality that such a system would create disputes within contributing states regarding where funds are being allocated and spent.

**E. Proprietary Data of Companies in Compound Libraries and Comparable Collections Should be Respected Rather Than Eliminated**

A number of companies currently permit use of their compound libraries in R&D collaborations with public partnerships. Ways of expanding such voluntary collaborations could be explored. The call for free and unrestricted sharing of compound libraries owned by private entities, however, undercut the positive and constructive voluntary collaborations needed for success. The long term effect of eliminating private rights in compound libraries would erode the private sector’s ability to build and use compound libraries.

**F. An Open-Source Research Paradigm is Already Used in Some Areas of Basic Pre-Commercial Research, but is not practical for Research and the Development Stages**

The IGWG draft plan does not define exactly what is meant by “open-source research paradigm”. However, relationships under which entities agree to reciprocal access to each other’s basic research results under defined terms, already within academia and industry in some early, basic research.

However, the call for an open source model of R&D for the development of specific pharmaceutical products is not practical. Such a model eliminates the economic incentives to develop specific products. If all will be able to freely make the final product, there is no incentive to invest the large sums needed for the early development stages when the chances of success are limited or unknown. Prize systems, which are sometimes also mentioned, might have a role to play if they are in addition to the IP based system, especially in academia. As a replacement for the IP system prizes would not incentivize the private sector as they are too uncertain. They may in fact limit R&D as the “winner take all” approach would disincentivise follow-on innovation which often delivers better products than the first-in-class.

Comparing the use of an open source model in the software industry to that within the pharmaceutical industry is comparing apples to oranges. The open source model is inefficient and ineffective when substantial investments of capital and human resources are a necessary precondition to research programs. This is precisely the type of research and development environment that exists for development of medicines. Investments in capital resources (e.g., reagents, equipment, physical facilities, information technologies, etc) are necessary in R&D in the biotechnology and pharmaceutical sector and cannot be secured by an “open source” model.