

Comments on IGWG Draft Global Strategy

German Association of research-based pharmaceutical manufacturers (VFA)

As the representative of research-based pharmaceutical and biopharmaceutical companies in Germany, VFA welcomes the opportunity to comment on the draft plan of action prepared by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG).

Remit of the IGWG and nexus to the VFA and its membership

According to the draft report which is subject of these comments, the central motivation for founding the IGWG was “the growing burden of diseases and conditions that disproportionately affect developing countries, particularly women and children”. The draft report identifies „reducing the very high incidence of communicable diseases in those countries” as an “overriding priority”. Given this remit, one of the central tasks of the IGWG is described as finding ways “of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries ...”.

The VFA-membership consists of those pharmaceutical companies who invented and developed the vast majority of the existing pharmaceuticals. The research-based pharmaceutical industry may be the primary addressee of such funding and incentive mechanisms the IGWG tries to develop, as it would be up to its companies to create and develop such new medicines. Many of our members are already active in such indications. 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. We welcome constructive, workable and partnerships-based attempts to induce more research and development in Type II and III diseases.

The new mechanisms discussed and implemented by the IGWG should therefore be able to make the development of new drugs for diseases primarily affecting developing countries (“Type II and III diseases”) more attractive for companies active in the sector of R&D in pharmaceuticals. Ideally, more companies should be motivated to participate in such R&D activities. In this context, particular emphasis should be put on pharmaceutical companies in emerging economies, e.g., Brazil, India and others, which could be motivated to enter the R&D business in diseases that affect their own countries. If the IGWG creates workable and efficient incentive mechanisms, it would be a great accomplishment and highly appreciated by the research-based pharmaceutical manufacturers.

The existing incentive for R&D in new drugs

For diseases affecting both developed and developing countries (“Type I diseases”), the incentive for pursuing such research and development activities is market-based. Through the system of patent protection a refinancing of the considerable investments in such R&D is possible. This system is working very well and is producing a steady stream of new drugs each year.

This given, and for reasons of efficient use of resources, it is vital that the IGWG remains focused on its mandate as set in resolution WHA resolution 59.24:

“...such strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, **essential health research and development relevant to diseases that disproportionately affect developing countries**, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;” (emphasis added)

Thus, references to Type I diseases in the draft strategy should be eliminated so as to not distract the IGWG from focusing on its mandate as given by the WHA. In particular, the references to Type I diseases in paragraphs 6, 8, 9 (1.1a), 9(1.4b), 10, and 16, as well as in the footnotes, should be eliminated.

Need to avoid counterproductive proposals

It was outlined above that the existing patent system is effective as an incentive for the development of new drugs against diseases prevalent both in developed and developing countries. IGWG should avoid any attempts to weaken this system.

The proposed actions in para. 17(5.2) and statements in para. 19 regarding TRIPS "flexibilities", are particularly problematic in this context. While the flexibilities in TRIPS (usually meaning compulsory licensing and parallel trade) indeed exist, it is not proven that "TRIPS flexibilities" will actually promote public health. In fact, compulsory licensing can disincentivize the development and introduction of innovative products into markets and also reduce incentives for investing into R&D, which would not improve public health.

Furthermore, the use of these "flexibilities" will not lead to further R&D, which is, as discussed above, the mandate of IGWG. Thus, the IGWG devoting undue attention to TRIPS flexibilities is not appropriate in terms of the IGWG mandate and in terms of supporting measures which would actually promote R&D. Furthermore, with regard to so-called "TRIPS Plus" elements of free trade agreements, it is not within WHO's competence to advise on trade policy, including FTAs. It is up to the countries themselves, and if any organization would have the right to give recommendations regarding FTAs and TRIPS, it would be WTO or WIPO, not WHO.

The mandate of the IGWG and the complex problem of access to medicines

VFA welcomes that some parts of the draft report do address elements of the complex issue of access to medicines. VFA much appreciates that improving health systems in poor countries is being identified as one of the key issues. When it comes to the availability of medicines, it must be noted that patents, in fact, are a key issue for access. The reality is that without patents as the core incentive mechanism there would hardly be any medicines available at all.

It is a sad truth as well that medicines remain unavailable to a huge number of people as they are not able to pay for them. Obviously, people who have to make a living on one or two dollars per day are simply not able to pay for medicines. For these people, solidarity-based public support mechanisms must be created. It must also be noted, however, that it is not even possible to achieve universal access to medicines which are being donated or offered at cost. The MECTIZAN donation program against river blindness, which this year has its 20th anniversary, or the COARTEM-program against Malaria are important examples for this fact. Both programs are led and implemented by the WHO, so the described background is absolutely clear.

It is also widely known that 95% of the drugs listed in WHO's model list of essential medicines are patent free. Access to them, however, is far from being the rule in most developing countries. India, where more than 20.000 generic companies produce all kinds of medicines patented elsewhere, is far from being able to grant access to those copy products to all Indian patients. The underlying reasons for these facts are manifold and complex and the object of the work of numerous institutions, organisations, governments, civil society and private enterprises. It is a challenge for governments and societies of all countries to find solidarity-based support systems which are able to grant access to healthcare for everyone. The research-based pharmaceutical industry is a partner for all governments and civil society groups who want to cooperate with us.

Nevertheless, in some instances trade issues do contribute to the accessibility of drugs. It is widely acknowledged that taxes and tariffs on the import of drugs do add to drug costs and should be abolished. It is appropriate to discuss such cases at those organisations that have been created for them, which is the WTO and the WIPO. The same applies to all kinds of questions in connection with the protection of intellectual property rights.

IGWG should focus on its mandate and strive to create new additional incentives for more R&D in new drugs in areas where these are necessary. It would be counterproductive to mix the two topics. IGWG should ask for the support of WTO and WIPO for any trade- and IP-related issues.

Need for additional incentives for Type II and III diseases

A market-based mechanism to fund R&D is rarely applicable for these types of diseases, because a refinancing of R&D investments via patent protected market exclusivity for a limited span of time often fails due to the lack of purchasing power in the poor countries of the developing world.

It must be noted that the development of new drugs in Type II and III diseases is equally risky and expensive. This means that such R&D basically has to be organised in the same way as pharmaceutical research in other areas, meaning a normal portfolio management with several candidates for one indication, as it must be expected that the majority of compounds to be developed will fail during the development phase which normally extends over about ten years. There is no doubt that it is not possible to enforce such a process, nor is it possible to predict which compounds will finally "survive" the development process.

It is equally obvious that, as market refinancing is impossible, a different way of funding must be found. The core of the proposals made in the draft report consists of public funding mechanisms of different kinds. While this is welcomed by the VFA, the sources for such additional public funding still have to be found. This may be a key task of the IGWG. Another key task of the IGWG may be to identify priorities, i. e., gaps in the current R&D pipeline for communicable diseases prevalent predominantly in the developing world.

To achieve its aims, the IGWG should 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. Ideally, some members of the IGWG would, after thorough analysis, make concrete offers to pharmaceutical companies to join cooperative projects (PPPs).

Identification of priorities

WHO can play an important role in identifying research gaps among Type II and III diseases, building upon existing research such as the recent "Priority Diseases for Europe and the World" study and the joint IFPMA/WHO Paper on "R&D for Neglected Diseases" from 2001. Convening scientific experts to review ongoing research and to note where further research is needed would be an important contribution which the WHO Secretariat could make towards the success of the IGWG process. The sections of the Global Strategy which support such mapping exercises should thus be supported. The R&D-based industry is already conducting many research projects into Type II and III diseases. An updated survey of ongoing R&D projects on such diseases, as well as a summary description of companies' research centers devoted entirely to R&D for Type II and III diseases is available from IFPMA (m.ottiglio@ifpma.org) and will be submitted to the IGWG as a separate document by IFPMA.

The draft report's proposals for new incentives

New incentives that should be pursued:

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 exclusivity 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.

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.

New incentives that should NOT be pursued

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 in the context of pre-competitive basic research. These are not traditional patent pools, however and do not justify assumptions that patent pools are workable.

Voluntary patent pools are conceptually grounded on two 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 present for pharmaceutical products and related technology. In the case of patents on a specific product, for instance, there will be only one patent owner with a clear position relative to the patented product. There is no need for an intermediary between the patent owner and the entity wishing to license the patent to produce a copy of the drug product.

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.

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 bilaterally between countries, the involvement of the IGWG in this area is improper.

An independent Research & Development Treaty is not warranted

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. At a minimum it should not be considered until gaps in R&D are identified.

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. A more specific example that should be examined is the USAID program, begun in the 1980s to develop a new Malaria vaccine. While this program was allocated \$60 million and did work for more than two decades, the envisioned vaccine never materialized.
- 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.

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.

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.

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.