

EFPIA Comments on

Draft global strategy and plan of action on public health, innovation and intellectual property

EFPIA appreciates the opportunity to comment on the “Draft global strategy and plan of action on public health, innovation and intellectual property” (A/PHI/IGWG/2/2) released by the World Health Organisation on 31st July. EFPIA believes the Intergovernmental Working Group has a real opportunity to complement existing innovation incentives and funding sources and increase the relevance of global research for the developing world

EFPIA's member companies continue to innovate and develop new medicines: the research-based industry developed 90% of the innovative drugs on the WHO Essential Medicines List. It supplies a high percentage of all ARVs used to treat patients in developing countries and supports major research centres and treatment programmes in the developing world.

The Remit

Resolution 59.24 provides the remit for IGWG. The preamble of the Resolution provides context for the work of the Group and in particular in describing the “gap” which the proposed global strategy and plan of action (GSPA) would fill. It suggests the central need is for

“A 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;”

The WHO membership want quick results since they encourage the IGWG to give “particular attention to needs-driven research and other potential areas for early implementation”. This clear signal should be read in the light of other parts of the resolution which lay out the need for political and financial engagement on the part of all WHO member states. This is a partnership in which the IGWG contribution can only go so far. By calling on members to engage in their domestic policies, the secretariat clearly recognize the limits of what can be done at the multilateral level. The “basis” must be one that encourages and gives guidance to the engagement of different stakeholders in addressing common problems, rather than seeking to force compliance.

The Resolution refers to both communicable and non-communicable diseases, while the draft report elaborates on this in the focus section,

“The focus of the strategy will be on diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or

unaffordable. The Commission highlighted the need to focus on Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.”

The inclusion of the question of affordability changes substantially the focus of the Working Group. It touches on questions of the competitiveness of supply, but also on questions of the responsibility of government to use redistributive fiscal mechanisms to ensure access to healthcare and on the needs of the large part of the global population for whom all medicines are unaffordable. EFPIA’s suggestion is that this element of the IGWG discussion could be progressed in terms of an examination of the reasons for the lack of accessibility of the medicines on the WHO’s Essential Drug List. The better distribution and use of these medicines would directly address the problems referred to in IGWG’s remit and would undoubtedly generate more widely-relevant conclusions.

Defining the disease scope of the IGWG exercise has proved contentious, just as it has in other previous debates related to access to medicines. The draft report makes a careful distinction. In relation to Type II and III diseases, the focus is to identify and address research “gaps”. These diseases respond weakly or not at all to the incentives which drive the development of treatments for type I diseases and it is clear that the “basis” must have a financial element if it is to effectively address type II/III diseases.

In relation to type I diseases, the focus is on the “needs of developing countries”. In EFPIA’s understanding, it is assumed that new medicines for these diseases will emerge, but there are questions about whether the formulations developed will be appropriate for the developing world. From the industry’s perspective, companies routinely develop a range of formulations of new medicines and these respond to the needs of different groups of patients. Although all progress in the developing world is contingent on fixing the basic accessibility question, it is clearly important to examine how best to address this important and neglected population and how action in this area should be integrated with the capabilities of the developing countries. However, the strategy in relation to type I diseases should be distinct from that for type II/III.

There is scope for the IGWG to be more ambitious on the important role that intellectual property plays in economic development. Conversely, EFPIA sees a real danger that by sustaining the current debate focused on means of confiscating IP rights, IGWG will stifle debate about how the incentive system can be made more relevant to the developing world. EFPIA sees no long-term gain in the appropriation model and believes insufficient attention is paid to the benefits that may accrue to emerging or developing countries through the adoption of robust domestic IP systems. As a result, emerging or developing countries are not given the opportunity to make informed and coherent choices about the domestic IP system that they want to adopt as opposed to that which others want them to adopt.

Our industry recognizes that, in order to address the health needs of developing countries, there may indeed be space for initiatives that complement, but do not replace or weaken, IP protections. However, we believe recommendations relating to IP rights should take place within the **appropriate designated international forums such as the WTO or**

World Intellectual Property Organization, per international agreements designating them the appropriate forums for discussions on intellectual property matters. In particular, the recent creation of the new Committee on Development and Intellectual Property at WIPO and the adoption of a list 45 proposals as part of the WIPO development agenda provide a forum for this activity. The logical course for IGWG would be to “export” these proposals to more expert fora.

Comments by section

In the following section, we specify the proposals in the draft report that should form the content of the final report

Element 1 Prioritising Research and Development

- (1.1) and (1.2) are important elements of the final GSPA. The “ gap analysis” should be a continuous process, encouraging stakeholder engagement. Consideration will have to given to how it should be linked to the programmes of neglected diseases research of other governmental and non-governmental funders. Access to compound libraries should only be on a voluntary basis.
- EFPIA see the value of (1.3) and (1.4), but has doubts as to whether WHO has a useful role in this type of activity.

Element 2 Promoting Research and Development

- In general, this section contains proposals over which WHO has little direct influence. (2.1) and (2.2) could be considered as conditions for a successful innovation culture. Statements of this sort could be progressively advanced over the medium term, but the track record of governmental compliance with research or healthcare spending commitments is mixed at best.
- (2.3) and (2.4) contain a series of contradictory proposals, including two very radical proposals to develop a new innovation model (“open source” and the “R&D Treaty”). Both proposals have received some public support, but both remain completely untested in the context of pharmaceutical R&D. Their further evaluation also requires a level of expertise concerning innovation systems which does not exist in WHO. As such, these proposals are a distraction from the objectives of IGWG. In EFPIA’s view, they should not be advanced.

Element 3 Building and improving innovative capacity

EFPIA supports all the proposals made in this section, which we see as key to the ability of developing countries to participate in the innovation process, as well as to progress access to healthcare.

Element 4 Transfer of Technology

EFPIA considers this section to be similar in its content to element 2. The goal of technology transfer has to be embedded in a country’s overall economic development

strategy. There has been no substantive debate about the adequacy of existing technology transfer mechanisms in IGWG and it is questionable whether IGWG is the best forum for discussion of such a complex issue. This is particularly notable in the reference to TRIPS in (4.2(d)). At a minimum, a debate in WHO may cut across what is already being done in bilateral development collaborations. EFPIA also regrets that no space could be found in the Draft Report to express the simple facts that technology transfer is dependent on the quality of legal infrastructure in the receiving country and that it is only successful if carried out voluntarily.

(4.3(a)) calls for the ‘promotion’ of patent pools. It is premature to call for their promotion when their usefulness in biomedical R&D is completely unproven and open to significant doubt. EFPIA does not wish to close down debate, but it must be noted that the proposals so far put forward are quite unlike existing patent pools. They are based on compulsory licensing, have significant potential to distort competition and may deter innovation. There is some positive experience of the voluntary sharing of intellectual property in the pre-competitive arena, but the concepts now being advanced deal with final products and raise quite different issues. As was the case with the R&D Treaty and the use of Open Source, a workable proposal that will expand the quantity and quality of available medicines has not yet been made and little benefit will be gained from prolonging these discussions in the context of a strategy and plan of action.

Element 5 Management of Intellectual Property

EFPIA sees no role for WHO in the provision of guidance on intellectual property. It has been clearly shown that the most critical causes of deficiencies in access to medicines do not relate to intellectual property. It is therefore of great concern that IGWG should consider this a core role for WHO, particularly in the light of the significant global challenges for which WHO is the acknowledged leading UN organisation.

We support elements of (5.3(a) and (b)). However, in considering ‘complementary incentive schemes’, care must be taken not to damage the existing IP-based system which has led to the development of the vast majority of essential medicines available today. We suggest that the rest of this section could be deleted in its entirety without weakening the value of the final report. Aside from being outside the competence of WHO, elements of this section are legally-contentious. EFPIA recognises that WHO members will continue to review the effect of different types of supra-national legislation, including IP, on health, but this does not require an explicit mandate from IGWG. WHO’s needs for guidance on IP can be achieved through reference to more expert organisations.

Element 6 Improving Delivery and Access

Element 6 contains many proposals that can only be met by National Governments. EFPIA strongly supports most of them as being entirely consistent with improvements in the supply of medicines. The proposals also contain useful links as for example between the proposal on operational studies (6.2(b)) and the broader thrust of the IGWG report to systematically identify “gaps” in existing innovation efforts. However, blanket calls for

local manufacture in developing countries (6.3(a)), oversimplifies the complex global pharmaceutical supply chain and fails to acknowledge the many other barriers to access. In many countries, local manufacture would not improve access, would introduce unsustainable complexity and could lead to higher costs or lower quality. For most developing countries access will be best improved by investment in healthcare infrastructure not in production capacity.

EFPIA notes the proposals in (6.3). We strongly support (6.3 (c)), an obvious step in reducing the cost of medicines, whose adoption will be an acid test of the genuine commitment of some countries. In general, in this section, EFPIA detects a deficiency in reasoning. The draft report does not reflect real challenges. It highlights post-patent market access, but many countries do not have adequate access to generic medicines, hence generic penetration is less important than sustainable supply. In other countries, generics are routinely tolerated when they are neither legal nor comparably validated. It is this that IGWG should focus on.

Regarding pricing, many of EFPIA's member companies already have policies in place concerning the prices they offer in the developing world. This is particularly the case for HIV/AIDS medicines. These policies work on the basis of local affordability. It is a necessary condition of such policies that the needs-based price differentiation they offer is matched by a respect of such differentiation by Governments. In practice, this is hard to achieve and, although it would be unrealistic to expect compliance from Governments, it could be usefully re-emphasised in the final report.

Element 7 Ensuring Sustainable Financing Mechanisms

This is an extremely important section. EFPIA supports all the proposals made. The section should also include a proposal to quantify the future financial needs of Type II/II research and development. EFPIA regards the financial deficit facing the existing research bodies as the single most serious problem facing IGWG.

Achieving success

EFPIA calls on the delegates to the IGWG to work together with key stakeholders to advance medical research and development and establish sustainable long-term financing for diseases that disproportionately affect the developing world.

EFPIA intends to remain fully engaged in the IGWG and to give whatever support it can to bring it to a successful conclusion.

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