



COMMENTS ON IGWG DRAFT GLOBAL STRATEGY

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) welcomes this opportunity to contribute the views of the global R&D-based pharmaceutical industry concerning the draft global strategy addressing the important relations among public health, innovation and intellectual property rights. Indeed, it is vital that the Intergovernmental Working Group's (IGWG) recommendations encourage innovation to treat, prevent and cure the diseases that disproportionately affect developing countries, including via the constructive use of intellectual property rights to promote such innovation. In particular, the incentives to be proposed by the IGWG should be effective, market-based incentives which complement, not weaken, the existing system of global pharmaceutical R&D led by the R&D-based pharmaceutical industry.

PROMOTING R&D INTO DISEASES THAT DISPROPORTIONATELY AFFECT DEVELOPING COUNTRIES

Overall, it is vital that the IGWG remain 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)

In light of this mandate and definition, it is not appropriate that the draft Global Strategy prepared by the Secretariat includes R&D on "Type I" diseases. As the Secretariat itself defines, Type I diseases are *not* diseases which "disproportionately affect developing countries", but are rather "... incident in both rich and poor countries, with large numbers of vulnerable populations in each." Thus, the expansion by the draft Strategy into Type I diseases goes beyond the mandate given to the IGWG in the WHA Resolution.

In practical terms, it must be noted that R&D into diseases which affect industrialized and developing countries alike ("Type I" diseases) is strong and ongoing. Indeed, market incentives are stimulating the development of literally hundreds of compounds to treat such Type I diseases. Given that R&D into such Type I diseases are already strongly covered, the IGWG should focus on promoting more R&D into areas which are not benefiting from strong R&D efforts, i.e., the Type II and particularly Type III diseases. Indeed, the importance of focusing on Type II and Type III diseases is emphasized in the resolution text itself, as noted above.

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.

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 into diseases, and centers devoted entirely to R&D for Type II and III diseases is available from IFPMA (Mario Ottiglio, m.ottiglio@ifpma.org) and will be submitted to the IGWG public hearing as a separate document.

With regard to such research, it is very surprising that the role of the Tropical Disease Research Program (TDR), headquartered in WHO, is only mentioned in a footnote in the Strategy paper. Given TDR's excellent record for thirty years of promoting R&D into diseases of poor countries and its success in bringing together research partners (including industry), it is very regrettable that the strategy does not include suggestions on how to support and expand TDR's resources and activities. Please see the TDR web site (<http://www.who.int/tdr/>) for more information on their activities and successes.

Another element in the Global Strategy which is under-represented concerns promoting South-South collaboration on R&D for diseases which disproportionately affect developing countries, which is briefly mentioned in paragraph 14 and para. 15 (4.2.a). Leading emerging markets can certainly share their expertise and experience with other developing countries and joint research efforts concerning diseases and conditions of mutual concern among developing countries should be encouraged. WHO can play an important role in this process by using its convening power to bring together researchers from developing countries who are working on priority diseases which disproportionately affect developing countries. As noted above, the TDR program has much success and experience in bringing together such researchers. It would be a mistake to assume that all R&D has to be done in the industrialized country (“North”). Certain leading emerging markets are already developing stronger R&D capacities, and many developing countries have rich biodiversity and genetic resources which could be the basis for further research.

SPECIFIC CONSTRUCTIVE INCENTIVES TO PROMOTE R&D

It is also important that the IGWG focus on promoting policies that support and complement existing market mechanisms which promote R&D, particularly for encouraging R&D by researchers in developing countries to address diseases disproportionately affect developing countries. Such incentives and policies include:

Advance Market Commitments (AMCs)

- AMCs are an innovative market-based ‘pull’ mechanism designed to accelerate research and development of pharmaceuticals, particularly vaccines, for diseases that affect the poorest countries, and to increase access to these products when they become available. AMCs represent legally-binding undertakings by donor governments and organizations to subsidize future purchases by developing countries of vaccines that are not yet available.
- The first AMC was launched on 9 February 2007 with commitments totaling \$1.5 billion from five countries (Canada, Italy, Norway, Russia, and the UK) and the Bill & Melinda Gates Foundation. The AMC targets pneumococcal disease, which is a major cause of pneumonia and meningitis and is responsible for 1.6 million deaths each year, and is focused in particular on the development of vaccines to prevent strains prevalent in developing countries.
- Qualifying drugs and vaccines must meet developing countries’ needs sufficiently to justify their acquisition. This approach provides drugs and vaccine developers with a potential ‘market’ to target, thereby stimulating research and competition. Mirroring market-based systems, manufacturers must develop safe and effective products that are in demand by the end-users to be successful. Once appropriate drugs and vaccines have been developed, AMCs will underwrite a portion of developing country purchases, up to a pre-agreed price and for a specific period, thereby ensuring access.
- Through this mechanism AMCs can help establish the stable market conditions that support investment in drugs and vaccines that are particularly relevant to the developing world. With markets established through AMCs open to all manufacturers, individual developers can use sound market-based principles to decide whether to make the significant investments required to develop, scale-up and produce safe and effective drugs and vaccines. Importantly for donors, AMC payments will be based on success, and only made once suitable products are developed and purchased by qualifying countries.
- As market-based mechanisms, AMCs should complement other initiatives, particularly “push” interventions, such as public funding of research through academia and public-private partnerships. The combination of AMCs with upfront R&D funding should increase the probability that new, safer, more effective products will result.

Strengthening Public Private sector Partnerships (PPPs)

- PPPs are projects funded and run through a partnership of government and one or more private sector companies.
- PPPs have proven to be effective means of bringing public-sector, academic and private-sector research institutions together to contribute their respective expertise and strengths.
- Finding sustainable and sufficient funding for such PPPs has been a significant challenge – more funds from bilateral and multilateral donors are needed.
- Governments and multilateral donors should implement policies which strengthen PPPs, including through promoting funding to PPPs.
- Examples of very successful PPPs; TB Alliance, MMV (in R&D); Mectizan Donation Program, International Trachoma Initiative, Global Alliance to Eliminate L.F. (access to health). For further examples, partnerships’ brochure are available on IFPMA Website at the following links:
 - HIV/AIDS: <http://www.ifpma.org/documents/NR7702/HIV%20A5.pdf>

- Malaria: <http://www.ifpma.org/documents/NR7703/MALARIA%20A5.pdf>
- Tuberculosis: <http://www.ifpma.org/documents/NR7704/TUBERCULOSIS%20A5.pdf>
- Tropical Diseases: <http://www.ifpma.org/documents/NR7705/TROPICAL%20DISEASES%20A5.pdf>

Expanded Funding Mechanisms

- Expanded Funding Mechanisms, similar to the Global Fund to Fight AIDS, Tuberculosis and Malaria, should be considered to ensure that necessary funds are available to countries and communities to purchase new and existing drugs for diseases which predominantly affect developing countries.
- As in the case of the Global Fund to Fight AIDS, Tuberculosis and Malaria, expanded funding mechanisms create a market, attracting more companies and creating more volume. This leads to the possibility of lowering per unit prices.

Tropical Disease Acts in industrialized countries

- Similar in spirit to the US, EU or other national “Orphan Drug Acts”, a Tropical Diseases Drug Act there could be a legislative package intended to provide a favorable framework of incentives to increase R&D for drugs targeting diseases of the developing world.
- Such a package would 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, a Tropical Diseases Drug Act represents a comprehensive and potentially stand-alone measure. They 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.

SPECIFIC ACTIONS TO PROMOTE PROVED ACCESS

According to WHO estimates, one third of the world population does not have regular access to essential medicines, despite such drugs being inexpensive and, for circa 95% of them, being off patent throughout the world. A significant number of developing countries have not yet adopted disease control and management policies recommended by WHO, and advocacy efforts focusing on the newest medicines rather than essential medicines.

Companies have made substantial contributions to global efforts, on individual and partnership bases to improve access to and use of needed medicines. These include working in R&D public private partnerships, preferential pricing policies, community investment activities and innovative solutions such as voluntary licensing. More detailed information about partnerships concerning HIV/AIDS, malaria, tuberculosis, and tropical diseases are available on the IFPMA website at the link: <http://www.ifpma.org/News/Publications.aspx>

However, these efforts can only be successful if effective government policies and priorities are set correctly to make sustainable access to quality medicines a reality. Governments should draw up different policies in order to contain factors affecting the access to health with measures such as:

- Continuing to increase global financing and improving access to medicines, building on the examples of the GAVI and the GFATM;
- Reducing taxes on both imported and domestically produced drugs avoiding inflating the price of drugs that are mainly free of patent or donated and relieving poor people from paying additional money for potential free drugs;
- Securing distribution systems so that heavily discounted or donated medicines from industry are not “parallel traded” out of the countries that are in most need to other regions and countries;
- Investing in infrastructure such as, hospitals, medical personnel training, building communication roads and facilities (electricity, small airports, etc.);
- Encouraging disease prevention programs;

Generic companies also have a role to play in improving access. There is a fundamental truth about tackling disease in the developing world – we need new medicines and vaccines. We do not yet have a cure for AIDS. We do not have a vaccine for AIDS. Existing medicines are less and less effective as resistance to them grows. Intellectual property protection is of critical importance to promoting strong and sustainable innovation for new medicines and vaccines. Deficiencies in access to health can be addressed through simple and focused policies by governments. Progress in

improving access to medicines can only be achieved through unequivocal commitment of all related stakeholders – governments, international community, donors, responsible civil society organizations and private sector.

IMPORTANCE OF IMPROVING HEALTHCARE SYSTEMS AND DRUG QUALITY

As several delegations have noted in their verbal and written submissions to the IGWG, it is important that populations be able to access medicines which result from R&D efforts. Furthermore, the quality of these medicines is a very important consideration to ensure that patient needs and public health priorities are indeed met. For these reasons, the IGWG should particularly support the efforts suggested in paragraph 20(6.2) to strengthen developing countries' mechanisms to regulate the quality, safety and efficacy of medicines and other health products. Furthermore, the encouragement of developing countries to invest in their health-care infrastructure (para. 20(6.1)) and to eliminate tariffs and taxes on health care products (para. 20(6.3.c)) should also be supported as well.

CONCERNS ABOUT CERTAIN ELEMENTS OF THE DRAFT STRATEGY

As noted above, there are many good elements in the draft Strategy for Members to consider as concrete and constructive actions to encourage WHO Members to promote R&D into diseases that disproportionately affect developing countries. Also, as noted above, certain areas, such as the role of TDR and the potential for effective “south-south” collaboration, need to have more emphasis.

There are also other elements currently in the draft strategy which detract from its overall effectiveness by diverting the IGWG's time and resources into areas which are beyond its mandate or indeed beyond that of WHO. In particular, these elements concern the interpretation of international trade and intellectual property legal regimes, such as the WTO TRIPS Agreement. Given that there are two well-established international organizations, the WIPO and WTO, who have extensive programs and expertise in advising countries regarding the implementation of such international agreements, it is surprising that the draft Strategy seeks to give WHO a similar role. Such duplication of effort is at best redundant and at worst will create a set of possibly conflicting advice to resource-poor developing countries that need such advice most. A particularly clear example of such redundancy is shown in para 15 (4.2.d), which calls on the IGWG to promote compliance with Art.66.2 of TRIPS. In reality, members' compliance under this article is already reviewed at regular meetings of the WTO TRIPS Council. An additional review by WHO is superfluous. Similarly, calls on WHO to help countries to “manage intellectual property” (para.16) and the actions outlined in para 17 (5.1.and 5.2) are within the mandate of WTO and WIPO. These organizations, and not WHO, have the capacity and experience to assist countries in building national capacities in intellectual property management. WHO can contribute its expertise to the initiatives of these bodies in these areas, but should not be taking the leading role which is indicated in these sections of the draft strategy.

The proposed actions in para 17(5.2) and statements in para 19 regarding TRIPS “flexibilities”, are particularly problematic. 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 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 really 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.

Further problematic aspects of the draft Strategy concern the attention given in para 17 (5.3) to “complementary incentive regimes” for R&D. It is important that the draft Strategy emphasizes that such measures should be “complementary” in nature. The implication is that such measures cannot replace the current, market-based system for promoting R&D and this implication is important to keep in mind. While some specific disease areas of R&D could benefit from increased, complementary incentives, the overall system, based on IPRs, is not “broken” and should not be weakened.

With regard to the specific points raised in para 17(5.3):

(5.3) exploring and promoting complementary incentive schemes for research and development

(a) explore and implement complementary incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products (for example, the prize fund model)

(b) expand the advance-market commitment approach

(c) assess the impact of data-exclusivity regulations

(d) examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use.

Regarding (a): it is inappropriate to cite "for example, the prize fund models" specifically. Prize models are an unproven and probably ineffective means of promoting R&D into pharmaceutical products. At best, they could give some incentives in limited circumstances when offered on a voluntary basis.

Regarding (b): Expanding the advance-market approach would be a constructive incentive for promoting R&D.

Regarding (c) and (d): These points refer to Art. 39 in TRIPS. It is not within WHO's mandate to assess TRIPS i.e. rules in WTO-agreements. By mentioning data exclusivity in this context, WHO implies that data exclusivity is as potentially blocking R&D and access to medicines. However, in reality, such data exclusivity can promote adaptive innovation of pharmaceutical products and also help incentivize the introduction of innovative medicines into markets.

CONCLUSIONS

The IGWG Draft Global Strategy and Plan of Action could be an important opportunity for WHO and its Member States to propose concrete and constructive initiatives to increase and strengthen R&D for diseases that disproportionately affect developing countries; i.e., Type II and III diseases. Such initiatives would include:

- increasing resources for the TDR program;
- strengthening existing PPPs addressing Type II and III diseases;
- mapping remaining research gaps concerning Type II and III diseases and proposing constructive market-based incentives to address those gaps, such as advance market commitments;
- incentives to promote R&D into Type II and III diseases by researchers and companies in developing countries and "south-south" collaboration.

Further constructive recommendations in the draft Strategy include measures to improve developing countries' capacities in promoting drug quality, as well as urging countries to eliminate taxes and tariffs on health products.

We would add that in the area of capacity building it would be important to build developing countries' capacity to develop and use the emerged global IP system. This system would benefit countries in the development of new drugs and vaccines for Type II and Type III diseases.