

World Health Organization
Second Public Hearing on Public Health, Innovation and Intellectual Property
Request for Comments

**Comments – Draft Global Strategy and Plan of Action
(A/PHI/IGWG/2/2 of July 31, 2007)**

Specific Comments on the Global Strategy and Plan of Action

Resolution 59.24, which established the IGWG process and called for the development of the medium-term global strategy and plan of action, called on WHO Member States to examine the “needs-driven, essential health research and development needs” of developing countries, and to identify ways to carry forward such research and development on an enhanced and sustained basis. The resolution noted the particular need to focus on the challenges of AIDS, tuberculosis and malaria, but also other communicable diseases, that disproportionately affect the health situations of developing countries. In this statement, Novartis would like to review briefly the contributions it has made to the objectives outlined in Resolution 59.24. With reference to the draft global strategy and plan of action, Novartis is providing a number of observations and comments that it urges the IGWG participants to take into account as they continue refining the specific approaches to be adopted.

Element 1 – Prioritizing research and development needs

The mandate of Element 1 is to identify gaps in research and development activities for Type II and Type III diseases. We urge the IGWG to examine existing and future research programs underway in all countries and in both the private and public sectors, in order to ensure that existing R&D is not duplicated and that the real gaps are addressed.

In connection with this element, it is worthwhile to review the work that is now ongoing at the Novartis Institute for Tropical Diseases (NITD) and consider how it can best complement the longer-term Plan of Action. Activities related to the Novartis Institute for Tropical Diseases (NITD):

- The NITD was established in January 2003 as a public-private partnership between Novartis and the Singapore Economic Development Board (EDB). It has concentrated research efforts initially on dengue fever, tuberculosis and malaria, although it is anticipated that research would encompass additional diseases in the future. The Institute’s activities include target discovery, screen development, compound optimization and preparation for clinical testing.
- The NITD coordinates with a number of other research organizations and stakeholders in conducting its work: the WHO, health ministries, the Stop TB Partnership, the Drugs for Neglected Diseases Initiative, the Global Alliance for TB Drug Development, Medecins Sans Frontieres, the Grand Challenges for Global Health Foundation of the National Institute of Health, and the Pediatric Dengue Vaccine Initiative.
- Tuberculosis: The NITD uses technologies such as high-throughput screening and crystallography/NMR studies to develop small molecule compounds as potential treatments for multi-drug-resistant TB. The NITD, Imperial College and other collaborators have received a grant from the Grand Challenges for Global Health Initiative (and funded by the Bill and Melinda Gates Foundation and Wellcome Trust) to undertake new work in discovering new targets for latent and persistent TB infection. The NITD has teamed with

the Hasanuddin University and the Eijkman Institute in Indonesia to carry out clinical research into dengue fever, tuberculosis and malaria.

- Malaria: The NITD received a grant from the Medicines for Malaria Venture, the Singapore EDB and the Wellcome Trust to discover next-generation vaccines for the treatment of malaria. The focus of the effort is to develop a one-dose cure for *P. falciparum* and a curative modality for *P. vivax*. The NITD oversees the program and conducts research jointly with the Genomics Institute of the Novartis Research Foundation, the Swiss Tropical Institute, and the Biomedical Primate Research Center.
- Dengue fever: The NITD, together with the Environmental Health Institute, the Genome Institute of Singapore, the SingHealth Group, the National Healthcare Group, and the Temasek Life Science Laboratory, founded the Singapore Dengue Consortium in 2003. The aim of the project is to characterize viral- and host-specific factors responsible for the onset of the disease and to develop small molecule interfering compounds. Work is proceeding on annotating clinical data and patient histories to allow for improved surveillance and understanding of genetic variations among serotypes. The project is also correlating viral genetic markers with the disease's clinical severity.

Element 2 – Promoting research and development

- As noted in the preceding section, Novartis has voluntarily teamed with numerous research bodies and experts in developed as well as developing countries in carrying out drug discovery and drug R&D operations.
- Our experience demonstrates that contractual arrangements among the participating organizations have worked well as a means for sharing technology and intellectual property rights during the discovery process. Alternative approaches such as “patent pools” or “open access,” as used in the software sector, on a voluntary basis, are not appropriate for use in the pharmaceutical sector. Patent pools aggregate complementary and overlapping patents held by many different parties on a given technology. Cross-licensing arrangements then allow all participants to benefit from access to the patents covered by the pool. The pharmaceutical sector consists of patent holders that have exclusive rights to a given drug for a time-limited period within a given jurisdiction. There is no “general technology” to be shared without infringing the patent holder's rights.
- If patent pools become mandatory, they will lead to legal uncertainty for innovators. This will lead to insecurity that will discourage, rather than promote, investments in R&D.
- The Novartis Institute for Tropical Diseases (NITD) has opened its annotated compound library to other participants within these networks, as they become part of the larger Novartis research “family.” This is an arrangement that has worked well for Novartis and for collaborators.

Element 3 – Building and improving innovative capacity

- The experience of pharmaceutical companies like Novartis demonstrates that cooperation and proper incentives are the best means of promoting R&D activities.
- Effective programs will be those that promote cooperation among the private sector, the public sector, academia, and non-governmental organizations.
- The NITD opens up 30 positions to students on a regular basis, creating opportunities for scientists and technicians to receive training and practical education on research into tropical diseases.
- Novartis' development of the artemisinin-based anti-malaria drug Coartem is another example of collaboration with researchers in developing countries, in this case in China.

- Novartis has expanded its investment in research operations in China and over the next years will be carrying out additional research and testing activities at these facilities.

Element 4 – Transfer of technology

- The IGWG should support efforts to promote appropriate capacity building and technology transfer. The focus should be on practical concerns, such as exploring incentive mechanisms to facilitate tech transfer.
- Market-based solutions in this area are preferable to, and will be more enduring than, government-mandated approaches. Transfer of technology issues are best dealt with through voluntary, market-driven arrangements among parties wishing to enter into cooperation with one another.
- Successful public-private partnerships (PPPs) will find appropriate means for sharing technology and spreading knowledge among collaborators through networks of contractual arrangements.

Element 5 – Management of intellectual property

- Novartis is supportive of capacity building efforts to help developing countries with the management of intellectual property, provided that the activities undertaken include more training of patent examiners, better information technology systems to support patent and trademark office operations and increase transparency, and more education and training of officials and the public as to the importance of patents in encouraging innovation.
- Novartis does not support the IGWG undertaking activities or making recommendations in areas that would impinge on the work of the World Trade Organization or World Intellectual Property Organization. Accordingly, any references to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to the flexibilities for developing countries outlined under the TRIPS and Health decision, or to operational aspects of intellectual property rights under the jurisdiction of WIPO should be clearly outside the scope of work for the IGWG and for the WHO.
- Similarly, free trade agreements are undertaken at the discretion of particular Member States and are not a matter which is appropriate for IGWG or WHO examination.
- The search for alternative funding mechanisms for medicines to treat diseases prevalent in developing countries is a laudable goal. Some PPPs are making progress in identifying promising treatments, and the hope is that many of these will be on the market by 2012.
- Given the very considerable costs of bringing new drugs to market, however, any alternative funding models would need to meet a test for sustainability. Some of the models suggested, the prize model for example, would not be able to meet this test. Pharmaceutical product development costs on the order of hundreds of millions of dollars. In order to make a prize, or other model, attractive for innovators, substantial financial resources must be offered. It can take twelve years or more to develop a new medicine, with significant investments during that period. If the prize or other incentive is diverted by its sponsors to other needs in the meantime, the investment by researchers will not be rewarded. Any uncertainty regarding the security of the prize funds will thus discourage participation.

Element 6 – Improving delivery and access

- Novartis supports efforts aimed at improving health infrastructure in developing countries, including efforts to regulate the safety, quality and efficacy of medicines in these markets. The problems caused by poor quality and counterfeit medicines are adding to the challenges posed by HIV/AIDS and malaria in developing countries.

- Poor quality medicines have contributed to patients developing high levels of resistance and to the consequent need for second-line HIV/AIDS treatments.
- Novartis believes that the TRIPS flexibilities under the Doha Declaration on TRIPS and Public Health, and the Decision adopted in August 2003 governing procedures for exporting medicines to developing countries that have no domestic manufacturing capacity to produce the needed drugs, are workable. They should be allowed to operate. The case of Rwanda notifying the WTO Secretariat in July 2007 of its intention to import 260,000 packs of TriAvir from the Canadian manufacturer over the next two years is an example of how these procedures can be implemented.

Element 7 – Ensuring sustainable financing mechanisms

- Novartis supports efforts to identify key resource gaps in researching and developing medicines to fight diseases that are disproportionately affecting developing countries. Tracking progress of the many projects now underway would be helpful in rationalizing research efforts and avoiding duplication.
- Novartis would also support work to identify best practices of PPPs and to facilitate their operations in developing countries where possible. Such efforts should be voluntary in nature and encourage, but not mandate, collaboration among various interested parties.

Element 8 – Establishing monitoring and reporting systems

- Novartis finds that this element of the action plan is overly interventionist in approach and tone, assuming as it does that intellectual property rights form the major barrier to access by developing countries to essential medicines. Instead, Novartis would favor a country-by-country assessment of the major impediments within Member States to access to medicines, including existing health infrastructure, adequacy of trained personnel, and other factors.
- Novartis believes that the global strategy and plan of action attempts to overlay a “one-size-fits-all” approach to the access to medicines issue when, in fact, the situation will vary from country to country.
- Novartis looks forward to continuing its collaborative work with WHO in treating malaria and leprosy, and in furthering its research efforts on dengue fever, tuberculosis and other tropical diseases through the NITD.
- The IGWG can perform a valuable service by focusing attention on the health needs of developing country Member States and on creating informational tools that will make it easier for PPPs to collaborate, identify resource needs and for governments and the private sector to work together toward common goals. Novartis hopes that the global strategy and plan of action can be fine-tuned so that it better addresses such needs.

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