
Elements of a global strategy and plan of action

1. This document is designed as a basis for discussion by the Intergovernmental Working Group when considering provisional agenda item 2. It suggests some possible elements of a draft global strategy and plan of action, but does not attempt to treat each one comprehensively. The suggestions need to be evaluated from the viewpoint of their technical and political feasibility.
2. The issues at hand are complex and the number of partners involved is large; progress therefore will require a collective effort. Wider consultation is also needed, in order to consider the contributions of all stakeholders, so that their inputs can be channelled towards achievement of a common goal: an enhanced and sustainable basis for research and development relevant to the health needs of developing countries.
3. A global strategy and plan of action should provide a medium-term framework for all partners, and include setting of clear objectives and priorities and a realistic estimation of the financing needed. The process should determine specific activities aligned to strategic objectives, well-defined, measurable targets, the implementers, the time frame, and the cost.
4. Based on the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health,¹ and founded on an evidence-based, data-driven approach, the global strategy and plan of action, might include the following elements:
 - prioritizing research and development needs
 - promoting research and development
 - building innovation capacity
 - improving delivery and access
 - ensuring sustainable financing mechanisms
 - establishing monitoring and reporting systems.
5. **Prioritizing research and developments needs.** As a first step, the plan of action will need to set out ways to identify gaps in research on diseases that disproportionately affect developing countries. A significant improvement in the understanding of the determinants of disease is essential to drive research on new products in a sustainable fashion. This is closely linked to the need for

¹ See document A/PHI/IGWG/1/2.

developed and developing countries to prioritize innovation in a coordinated way. The plan of action should encourage countries to define explicit strategies for research and development, to devote a growing proportion of their budget for health research and development to research objectives in developing countries, and to provide support for establishing, implementing or strengthening the latter's programmes for health research.

Areas for action:

- identify gaps in current coverage of research in Type II and Type III Diseases¹
- expand prioritization to include neglected diseases, as well as HIV/AIDS, malaria and tuberculosis
- set research priorities in developing countries so as to address public health needs and implement public health policy
- conduct research on affordable and technologically appropriate products to combat Type I diseases in developing countries¹
- improve accessibility of compound libraries for identification of potential compounds

6. **Promoting research and development.** The plan of action should also identify gaps in the discovery, development and delivery of products for diseases affecting developing countries. Product development brings together several sectors of society, so the promotion of research and development should take account of their needs and objectives.

Areas for action:

- devote a larger proportion of the health research and development budget of developed countries to the health needs of developing countries
- provide support for national health-research programmes through appropriate political action and long-term funding in developing countries
- set up a forum to enable more organized coordination and sharing of information
- promote discovery science in order to identify, validate and build up a sustainable portfolio of new products, whose development is facilitated through appropriate legal arrangements permitting unrestricted access to drug leads identified through the screening of compound libraries for diseases relevant to the public health needs of developing countries
- promote early-stage drug research and development in developing countries (including basic research, lead identification, lead optimization and pre-clinical trials).

¹ Type I diseases are prevalent in both rich and poor countries, with large numbers of vulnerable population in each; Type II diseases are prevalent in both rich and poor countries, but with a substantial proportion of the cases in poor countries; Type III diseases are those overwhelmingly or exclusively prevalent in developing countries

7. **Building innovative capacity.** Developing innovative capacity requires an approach that interconnects education, intellectual property and technology transfer. The innovation cycle in low-income countries is generally not self-sustaining, and they depend upon the products of innovation designed to meet needs of developed countries. Ways to overcome this difficulty could include framing of patenting and licensing policies that maximize access to innovations for development of products of relevance to the public health needs of developing countries, and support for developing countries to consider legislation containing research exemptions in order to foster health-related research and innovation.

Areas for action:

- provide support for development of innovative capacity through investment by developing countries in human resources and the knowledge base, especially in tertiary education
- intensify North–South or South–South partnerships and networks to support capacity building
- strengthen education and training in research and development, including management of intellectual property
- promote transfer of technology and production in developing countries through action by developed countries and pharmaceutical companies
- strengthen product regulatory capacity in developing countries, including improvement of ethical-review standards and clinical-trials capacity
- promote patent pools of upstream technologies or other mechanisms to promote innovation of products for priority diseases in developing countries
- document and disseminate best practices in innovation observed in developing countries.

8. **Improving delivery and access.** Governments need to invest appropriately if existing and new products are to be made available and accessible to those in need. Improved delivery, access and appropriate use could be addressed by encouraging governments to invest in the health-delivery infrastructure and in financing the purchase of medicines and vaccines through insurance, to institute mechanisms to regulate the quality, safety and efficacy of medicines and other products, and to adopt measures to promote competition and ensure that pricing of medicines is consistent with public-health policies.

Areas for action:

- support product introduction in developing countries through improved regulation at national and international levels
- accelerate regulatory approval of products with potential utility
- conduct operational studies to maximize the value and use of new products in high disease-burden settings with inadequate health services
- implement national and international disease-control policies reflecting impact-evidence of new products

- frame policies emphasizing affordable innovations adapted to realities of health-care delivery in developing countries
- enact legislation in developing countries for application of the flexibilities provided for in the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- establish a database on patent status in a country of a given product, and document and disseminate the information
- encourage manufacturing in developing countries that complies with good manufacturing practices
- devise ways to curb counterfeiting of medicines and technology.

9. **Ensuring sustainable financing mechanisms.** Action is needed that generates additional and sustainable financing for research and development in order to address the health needs of developing countries, and engages governments in this process. A plan of action could include steps to secure such financing for developing and making accessible products to combat diseases that disproportionately affect developing countries, for underpinning public-private partnerships and local research and development institutions, and for boosting resources channeled to research organizations in developing countries in both the public and private sectors.

Areas for action:

- estimate financing requirements of the plan of action
- channel more funds to research organizations in developing countries in both the public and private sector
- continue to support public-private partnerships and research and development institutions in developing countries and assess their performances
- establish a funding mechanism for research and development for neglected diseases.

10. **Establishing monitoring and reporting systems.** WHO should continue to monitor from a public-health perspective the impact of intellectual property rights and other factors on the development of new products, and on access to medicines and other health-care products in developing countries. Systems need to be established that can monitor the impact on innovation and on access to medicines and other health-care products of TRIPS and of the Doha Declaration on the TRIPS Agreement and Public Health; to measure performance and progress towards objectives contained in the plan of action; and to monitor and evaluate relevant programmes.

Areas for action:

- monitor impact on innovation and on access to medicines and other health-care products of TRIPS and of the Doha Declaration on the TRIPS Agreement and Public Health
- measure performance and progress towards objectives and targets of the plan of action
- report regularly on progress.

11. Each of the above areas for action is in itself a major challenge. The elements can be elaborated on to identify current activities and future directions, as the Intergovernmental Working Group determines the work required, sets priorities, and identifies the main actors responsible for implementation.

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