

2 May 2008

Draft global strategy on public health, innovation and intellectual property

The context

1. In resolution WHA59.24 the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important for WHO Member States and the WHO Secretariat to recognize and better address the increasing prevalence of noncommunicable diseases in those countries. *(consensus)*
2. Currently, 4.8 billion people live in developing countries, representing 80% of the world population. Of this number, 2.7 billion, representing 43% of the world population live on less than US\$ 2 a day. Communicable diseases account for 50% of the developing countries burden of disease. Furthermore, poverty, among other factors, directly affects the acquisition of health products¹ and medical devices, especially in developing countries. *(consensus)*
3. Governments, the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices. More efforts should be made to avoid suffering and reduce preventable mortality and to meet the health-related Millennium Development Goals [and to implement obligations arising under human rights treaties with provisions relevant to health] / [and to implement health-related provisions contained in the international human rights instruments].
4. [Proposals should be developed for health-needs driven research and development that include a range of incentive mechanisms, including also addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.] *(consensus pending decision by the USA)*
5. Advances in biomedical science have provided opportunities to develop new, affordable, safe and effective health products and medical devices, particularly those that meet public health needs. Urgent efforts should be made to make these advances more affordable, accessible and widely available in developing countries. *(consensus)*
6. [The CIPIH Report provides an effective analysis of the problems and makes recommendations that form a basis of future actions.]

¹ The term "health products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

7. Intellectual property rights are an important incentive for the development of new health-care products. This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain. *(consensus)*

8. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent Members from taking measures to protect public health. The declaration, while reiterating commitment to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all. *(consensus)*

9. Article 7 of the TRIPS agreement states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation into the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”. *(consensus)*

10. The Universal Declaration of Human Rights provides that “everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”. *(consensus)*

11. [The high prices of medicines impede access to treatment which require a new thinking on the mechanisms to support innovation.]

12. International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face [institutional, policy, legal, financial and manufacturing] obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance.

The aim

13. The aim of this global strategy on public health, innovation and intellectual property is to provide a medium-term framework based on the recommendations of the CIPIH, [with a focus on Type II and Type III diseases and the needs of developing countries in relation to Type I diseases]. The strategy and the plan of action shall 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.

14. The elements of the global strategy, which are designed to promote innovation, build capacity, improve access and mobilize resources, will: *(consensus)*

a) Provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels; *(consensus)*

- b) Promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases¹; (*consensus except for footnote*)
- c) Build and improve innovative capacity for research and development, particularly in developing countries; (*consensus*)
- d) Improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries; (*consensus*)
- e) Encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to [health products]/[medicines] for all, as well as explore and implement, where appropriate, [innovative]/ [alternative] incentive schemes for R&D [to complement the existing ones];
- f) Improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access; (*consensus*)
- g) Secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries; (*consensus*)
- h) Develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems. (*consensus*)

The focus (deleted) (pending consensus)

The principles

15. The WHO Constitution states that “the objective of WHO shall be the attainment by all peoples of the highest possible level of health”. Accordingly, WHO shall play a strategic and pro-active role in contributing to pursue the agenda on “public health, innovation and intellectual property”, within its mandate and its constitutional objectives. To achieve this, WHO, including the regional and country offices, shall strengthen institutional competencies and programmes to implement this strategy and plan of action as well as the existing mandates given by relevant WHA resolutions. (*consensus pending decision by the USA*)

¹ [The Commission on Macroeconomics and Health as referred to in the CIPIH report, specifies the definitions of Type I, II and III diseases, and the specific diseases on which this draft strategy focuses, are as followed: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. The strategy will focus on the Type I diseases which are increasingly prevalence in developing countries, for example, diabetes, cardiovascular diseases and cancer. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. For the purposes of the Strategy, the focus is on HIV/AIDS and TB. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. For the purpose of the strategy, the focus is on the nine neglected infectious diseases that disproportionately affect poor and marginalized population, prioritized by the UNICEF/ UNDP/ World Bank/ WHO Special Programme for Research and training in Tropical Diseases: Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis and human African trypanosomiasis. Nevertheless, Member States can either expand or narrow the list of diseases as appropriate.] (will be revisited)

16. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. *(consensus)*

17. [The right of everyone to the enjoyment of the highest attainable standard of physical and mental health is recognized as a fundamental human right in the international Human Rights instruments, in particular, in the International Covenant on Economic, Social and Cultural Rights Article 12.1.]

18. [The objectives of public health and the interests of trade should be appropriately balanced and coordinated.]

or

[The right to health takes precedence over commercial interests.]

19. The promotion of technological innovation and the transfer of technology should be pursued by all states and supported by intellectual property rights. *(consensus)*

20. Intellectual Property Rights do not and should not prevent Member States from taking measures to protect public health. *(consensus)*

21. International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health. *(consensus)*

22. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health. *(consensus)*

23. Research and development of developed countries should better reflect the health needs of developing countries. *(consensus)*

24. The Global Strategy and the Plan of Action should promote the development of health products and medical devices needed by Member States, especially developing countries, that are:

- (i) developed in an ethical manner;
- (ii) available in sufficient quantities;
- (iii) effective, safe and of good quality;
- (iv) affordable and accessible;
- (v) used in a rational way;

(consensus)

25. Intellectual Property Rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain. *(consensus)*

26. Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution

chains and procurement practices to minimize costs that could adversely influence the price of these products and devices. (*consensus*)

START 1 May

The elements

Element 1. Prioritizing research and development needs

27. Health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases need to be identified urgently. A better understanding of the developing countries health needs, and their determinants is essential to drive sustainable research and development on new and existing products. (*consensus*)

28. The actions to be taken to prioritize research and development needs are as follows:

(1.1) map global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries;¹ (*consensus*)

(a) *develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases (consensus)*

(b) *disseminate information on identified gaps, and evaluate their consequences on public health. (consensus)*

(c) *provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs (consensus)*

(1.2)² formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels:

(a) *set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments (consensus)*

(b) *conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries (consensus)*

(c) *include research and development needs on health systems in a prioritized strategy (consensus)*

¹ It was noted that WHO should act as the lead stakeholder for 1.1.

² Language from sub-element 1.2 has been moved to sub-element 2.3; language from sub-element 1.3 has been moved to sub-element 2.4. The remaining text has been renumbered accordingly.

(d)¹ urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health needs. (consensus)

(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).² (consensus)

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples. (consensus)

(a) set research priorities in traditional medicine; (consensus)

(b) supporting developing countries to build their capacity in research and development in traditional medicine; (consensus)

(c) promote international cooperation and the ethical conduct of research; (consensus)

(d) support South-South cooperation in information exchange and research activities; (consensus)

(e) support early-stage drug research and development in traditional medicine systems in developing countries. (consensus)

Element 2. Promoting research and development

29. There are many determinants of innovation capacity. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential. (consensus)³

¹ Language from sub-element 1.4(d) has been moved to sub-element 2.5.

² Language from proposed new (g) has been moved to Element 3 (*build capacity in health R&D and local production within developing countries through strategies that: promote access to knowledge, tools, and the technology necessary for innovation; ensure effective coordination and building of networks; ensure appropriate and sustainable financing; and training of human resources necessary to build the appropriate regulatory capacity in developing countries*).

³ The following sentence and accompanying footnote has been moved to Element 7: In this context, developing countries should consider the appropriate level of investment necessary to strengthen research and research capacity. FN: Participants in the High-Level Ministerial Meeting on Health Research for Disease Control and Development (Accra, 15-17 June 2006) committed themselves to meeting the recommendation by the Commission for Health Research for Development in 1990 that developing countries should invest at least 2% of the national health budget on research and on research capacity strengthening.

