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 products[1] 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 diseases[1]; *(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.

30. The actions to be taken to promote research and development are as follows:

(2.1)[1] supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area *(consensus)*

(a) promote cooperation between private and public sectors on research and development (consensus)

(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding (consensus)

(c) support governments in establishing health-related innovation in developing countries (consensus)

(2.2) promoting upstream research and product development in developing countries (*consensus)*

(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products; (consensus)

(For inclusion in final report, in reference to 2.2(a): Colombia considers that the concept of discovery science is the knowledge concerned with the physical world and its phenomena, which does not include the open source methods as they correspond to a particular way of licensing of a right in the copyright field. Furthermore, Colombia considers that the choice of a particular way of licensing of a right corresponds to the rightholders and not to the Governments)

(b) Promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries; (consensus)

(c) identify incentives and barriers, including IP-related provisions, at different levels – national, regional and international - that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools; (consensus)

(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases; (consensus)

(e) support early-stage drug research and development in developing countries; (consensus)

[1] The chapeau and 2.1(a) have been moved to Element 7. The remaining text has been renumbered accordingly.

(f)[1] *build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries; (consensus)*

[(g) [promote the generation, [transfer, [acquisition] and voluntary sharing] /[acquisition and voluntary sharing], of new knowledge and technologies, consistent with [national law and] international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries]

(2.3) improving cooperation, participation and coordination of health and biomedical research and development *(consensus)*

(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources (consensus)

(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities. (consensus)[2]

(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, a essential health and biomedical R&D treaty. (consensus)

(d) support active participation of developing countries in building technological capacity. (consensus)

(e) promote the active participation of developing countries in the innovation process. (consensus)

(2.4) Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries. *(consensus)*

(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centers, especially in developing countries. (consensus)

(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts. (consensus)

(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries (consensus)

---

[1] Subparagraph 2.3(f) has been moved to Element 5. The remaining text has been renumbered accordingly.

[2] The key stakeholder for 2.4 (b) would be WHO.

(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms (consensus)

[(e) consider the incorporation of research exemptions in legislation of developing countries to address public health needs, consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on TRIPS and Public Health.]

(2.5) Establish and strengthen national and regional coordinating bodies on research and development

(a) develop and coordinate a research and development agenda (consensus)

(b) facilitate the dissemination and use of research and development outcomes (consensus)

Element 3. Building and improving innovative capacity

31. There is a need to frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine. *(consensus)*

32. The actions to be taken to build and improve innovative capacity are as follows: *(consensus)*

(3.1) building capacity of developing countries to meet research and development needs for health products *(consensus)*

(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health. (consensus)

(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries. (consensus)

(c) strengthen health surveillance and information systems. (consensus)

(3.2) Framing, developing and supporting effective policies that promote the development of capacities for health innovation *(consensus)*

(a) establish and strengthen regulatory capacity in developing countries. (consensus)

(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans. (consensus)

(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries.(consensus)

(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin,, taking into account the work of WHO and other relevant organizations. (consensus)

(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries *(consensus)*

(a) develop successful health innovation models in developing innovative capacity (consensus)

(b) intensify North–South and South–South partnerships and networks to support capacity building (consensus)

(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries (consensus).

(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments *(consensus)*

(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine.(consensus)

(b) encourage and promote policies on innovation in the field of traditional medicine including [increasing access to prior art to improve the quality of patents]/[creating ways to prevent its inappropriate use].

(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards (consensus)

(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine (consensus)

(e) promote South-South collaboration in traditional medicine (consensus)

(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation. (consensus)

(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation (*consensus*)

(a) encourage the establishment of award schemes for health-related innovation; (consensus)

(b) encourage recognition of innovation for purposes of career advancement for health researchers. (**consensus**)

Element 4. Transfer of technology

33. North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7 of the TRIPS Agreement states that the protection and the enforcement of intellectual property rights should contribute to the promotion of technological innovation and 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 the balance of rights and obligations. *(consensus)*

34. The actions to be taken in relation to this element are as follows:

(4.1) promoting transfer of technology and the production of health products in developing countries *(consensus)*

(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries. (consensus)

[(b) [provide [guidance] on what [appropriate] technologies are [most] needed to facilitate local health research and production in developing countries[, including [but not limited] to establish and update a reference list of technologies]]

(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate. (consensus)

(d) deleted by consensus

(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development *(consensus)*

(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry; (consensus)

(b) deleted by consensus

(c) facilitate local and regional networks for collaboration on research and development and transfer of technology; (consensus)

(d) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights; (consensus)

(e) promote the necessary training to increase absorptive capacity for technology transfer; (consensus)

(4.3) Develop possible new mechanisms to promote transfer of and access to key health-related technologies (*consensus*)

(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices (consensus)

(b) [consider [and if feasible develop]] additional [voluntary] effective, sustainable and complementary [or alternative] mechanisms [including appropriate patenting and licensing policies] to promote innovation of [and access to] products [of relevance to public health needs of developing countries]/[for priority diseases in developing countries]/ [for diseases that disproportionately affect developing countries]] [, for instance, licensing guidelines and policies that promote humanitarian and access objectives.]

(c) [encourage appropriate patenting and licensing policies that maximize access to innovations for development of products of relevance to the public health needs of developing countries]

or

delete subparagraph (c) or move to element 5

Element 5. Application and Management of intellectual property to contribute to innovation and promote public health (consensus)

35. The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific R&D needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health. *(consensus)*

36. The actions to be taken in relation to this element are as follows: *(consensus)*

(5.1) *Support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries (consensus)*

(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and that is consistent with the provisions in the TRIPS Agreement and instruments related to that agreement and meets the specific R&D [and access] needs of developing countries (consensus pending consideration by Suriname)

(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries (consensus)

(c) [to compile, maintain and update user-friendly global databases on the status of health-related patents and facilitate widespread access to the databases, in particular by

developing countries and to strengthen national capacities of analysis and the quality of patents] [1]

(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs. (consensus)

*(e) to strengthen education and training, [*inter alia *of patent examiners], in the [granting], application and management of intellectual property, from a public health perspective [taking into account] / [in line with] [the Doha Declaration on the TRIPS agreement and Public Health] including use of [flexibilities] / [provisions] contained in the TRIPS Agreement*[2] *[and instruments related to that agreement] / [, including those recognized by the Doha Declaration on the TRIPS agreement and Public Health and the WTO decision of 30 August 2003].*

(f) [developing countries should be encouraged to develop Traditional Knowledge digital library]

or

[WHO to encourage Member States to use traditional knowledge digital libraries for their patent examination procedures in order to prevent misappropriation of traditional knowledge]

or

[[encourage] / [consider[, where appropriate]], [if feasible and appropriate], the [voluntary] development of health-related traditional knowledge digital libraries [which can be used if desired], and their use [in patent examination] / [to help prevent misappropriation of traditional knowledge] [, while appropriately protecting [the confidentiality of] the knowledge in these libraries]/[taking into account the relevant international instruments including those concerning traditional knowledge and the rights of indigenous peoples]

[Encourage the development of possible new mechanisms, including development of digital libraries, to prevent misappropriation of health-related traditional knowledge, taking into account the relevant international instruments including those concerning traditional knowledge and the rights of indigenous peoples]

(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs (consensus)

STOP 1 May 21h00

(h) [establish measures to avoid unethical experiments involving human beings as a requirement for registration of medicines and technologies]

(i) [to create a Coordination Committee among WHO, WIPO and WTO for looking at solutions on the issue of public health and intellectual property]

---

[1] Key stakeholders for (c) would be WHO and WIPO.

[2] Key stakeholders for (e) would be WHO, WTO, WIPO, UNCTAD and UNIDO.

(5.2) **[To provide as appropriate, upon request, in collaboration with other competent international organizations, technical support to countries that intend to make use of the provisions contained in the agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities as recognized by the Doha Ministerial Declarations on the TRIPS agreement and Public Health.]**

or

[To provide as appropriate, upon request, in collaboration with other competent international organizations technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products [and also to information on their safety and efficacy] and to implement the Doha Ministerial Declarations on the TRIPS agreement and Public Health and other WTO instruments.]

*(a) **consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement), including those recognized by the Doha Declaration on TRIPS agreement and Public Health and the WTO decision of 30 August 2003 (consensus)***

(b) [avoid the incorporation of TRIPS-plus measures in any trade agreements and in national legislation that may have negative impact on access to health products or treatments in developing countries]

or

[delete subparagraph (b)]

(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003. (consensus)

(d) [consider taking necessary legislative steps in countries with manufacturing capacity to allow compulsory licensing for exporting pharmaceutical products[1] to countries with insufficient or no manufacturing capacity with the aim of facilitating access consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003]

[delete subparagraph(d)]

or

*[(d) [take necessary]/**[facilitate]/[encourage]** legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent*

[1] to revisit consistencies in the future deliberations, *cf* health products

with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health]

Pro memoria refer to 6.3(d)

(e) [support incorporation of appropriate provisions in the relevant international agreements to prevent misappropriation of health-related traditional knowledge]

or

[support where appropriate legislative and other measures at national and international levels to prevent misappropriation of health-related traditional knowledge]

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to type I diseases (*consensus*)

(a) explore and, where appropriate, promote a range of incentive schemes for research and development [including also addressing, where appropriate, the linkage between the cost of research and development and the price of medicines] / [including those that separate the incentives for innovation from the prices of health-care products, for example, the prize fund model], and review existing innovative financing mechanisms.

(b) ~~[expand]~~/[consider if appropriate and affordable the use of] the advance-market commitment approach [~~based on a participatory approach~~] (move to Element 7.1)

(c) [assess the impact of data-exclusivity on access to medicines]

or

[delete subparagraph (c)] (move to Element 5.2)

(d) [developing countries should adopt or effectively implement policies in order to prevent or correct anti-competitive practices related to the use of patents for health products, including the use of pro-competitive measures available under the intellectual property law]

(e) deleted by consensus

[(f) consider measures to ensure the strict application of the patentability criteria in order to obtain the best interpretation for public health as stated in paragraph 4 of the Doha Declaration on TRIPS and public health]

or

[delete (f)]

[(g) avoid restrictions for the use of or reliance on undisclosed test data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS][1]

or

[delete (g)]

Text to be considered with Element 5

2.3(f) deleted by consensus

3.2(d) deleted by consensus

Element 6. Improving delivery and access (consensus)

37. Support for and strengthening of health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system. *(consensus)*

38. International [and bilateral] agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements[, and the ones contained in the TRIPS agreement and reaffirmed in the Doha Declaration,] that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

39. The actions to be taken to improve delivery and access are as follows: *(consensus)*

(6.1) encourage increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system *(consensus)*

(a) *invest in developing health-delivery infrastructure and ensure financing of [essential] health products.*

(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, making full use of the transitional period until 2016[2] [, if necessary]

(c) prioritize health care in national agendas (consensus)

(d) encourage national health authorities to improve national management capacities [in order] / [with a view] to [guarantee] / [improve] / [increase] delivery and access to

[1] It was agreed to move sub-element 5.4 to sub-element 5.1.

[2] In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

medicines and other health products with quality, efficacy, safety and affordability [and to develop strategies to promote rational use of medicines]

(e) increase investment in human resource development in the health sector (consensus)

(f) develop effective country poverty reduction strategies that contain clear health objectives (consensus)

[(g) encourage pooled procurement mechanisms in developing countries]

(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices *(consensus)*

(a) [develop and] strengthen [[medicines] / [drugs] regulatory authority] capacity to monitor the quality, safety and efficacy of [priority] health products [and services], and [accelerate] / [prioritize] the regulatory approval of [strategic] [life-saving] products [with potential utility] [for national public health programs] [while maintaining quality and respecting ethical review standards]

(b) [conduct]/ [promote] operational studies to maximize the [therapeutic] value and use of new[and existing] products [and treatments in health systems] [in high disease-burden settings with inadequate health services]

(c) [develop and] implement national and international disease-control policies [that are based on evidence that use of new and existing products has an impact]/ [that make use of innovative medicines based on scientific evidence of efficacy, safety and comparative costs with regard to therapeutical and economical advantages offered by existing products that are used rationally for such diseases]

(d) comply with good manufacturing practices for safety standards, efficacy and quality of health products (consensus)

(e) strengthen the WHO pre-qualification programme (consensus)

(f) [develop and strengthen, where appropriate, legislation, enhance regulatory, surveillance and other appropriate measures to prohibit the production, trade and sale of counterfeit drugs, substandard drugs in order to address the public health consequences of such products.]

or

[To minimize the risks to public health resulting from the use of drugs which have been counterfeited[1], adulterated, or have expired through health promotion, surveillance and health regulation.]

[1] WHO Secretariat defines counterfeit drugs as follows (p. 192): Drugs which are deliberately and fraudulently mislabelled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines and may include products with the correct ingredients but fake packaging, with wrong ingredients, without active ingredients or with insufficient active ingredients.

(g) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals.(consensus)

(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs *consensus)*

(a) [support the production and introduction of generic versions, in particular of essential medicines [and vaccines], in developing countries, through the development of national legislation and/or policies that encourage generic production and entry [including inter alia Regulatory Approval Exception or Bolar Provision,] and which are consistent with relevant international instruments, including intellectual property agreements].

(b) [frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices]

(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products [and medical devices] and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access.

[(d) Deleted – with cross-ref to para 5.2(d) white paper no.1, 29 April 2008

(e) [encourage pharmaceutical companies to adopt transparent, consistent and equitable pricing policies, aiming to reduce prices for developing countries and increase access to quality, safe and affordable medicines.]

or

[encourage pharmaceutical companies to continue or adopt new policies and practices that increase [sustainable and equitable] access by developing countries to safe, effective and affordable medicines]

(f) [stimulate the development of policies by developing countries to monitor pricing, enable policies for reduction of prices, and strengthen WHO's work on pharmaceutical pricing].

and

(g) delete on consensus (duplicate of para 5.2(a))

(h) delete on consensus (ref to para 6.3(a))

(i) delete on consensus (ref to para 6.3(a))

(g) deletion pending successful para 6.3(a)

(h) [to encourage the WHO and other UN bodies to support policies that contributes to the entry of generic products into the market]

(i) delete on consensus (ref to para 6.3(a))

(j) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval.

(move to under para 6.2)(consensus)

(k) deleted on consensus (ref to para 6.2(e) – consensus text)

[(g) adopt or effectively implement competition policies in order to prevent or remedy anti-competitive practices related to the use of medicinal patents, including the use of measures that favour competition available under intellectual property law]

(cross ref to potential duplication with para 5.3(d))

6.4 Increase information among policy makers, users, doctors and pharmacists regarding generic products. (*consensus*)

Move to para 6.3

Element 7. Promoting sustainable financing mechanisms (consensus)

40. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by this strategy need to be identified and analysed. *(consensus)*

41. It is important to make maximum use of and complement as appropriate and feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation. *(consensus)*

42. The actions to be taken to promote sustainable financing mechanisms are as follows: *(consensus)*

(7.1) [endeavour to secure adequate and sustainable financing for research and development, and improve coordination, [where feasible and appropriate,] / [whenever most necessary] in the existing global health R&D funding architecture in order to address the health needs of developing countries]

[(a) [Establish an ad-hoc expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative models of financing for R&D related to [diseases and conditions that disproportionately affect developing countries]/ [Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases]

(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA 58.34. (consensus)

(c) create a database of possible sources of financing for R & D. (consensus)

(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices. *(consensus)*

(a) document and disseminate best practices in public-private and product development partnerships (consensus)

(b) develop tools to periodically assess performance of public-private and product development partnerships (consensus)

(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries (consensus)

[(7.3) Setting up a global R&D fund to address the identified R&D gaps in Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.

(a) of this fund, money will be earmarked and provided for research in the form of grants for R&D for these diseases in advance, as well as prize/rewards for path-breaking research after it is accomplished.

(b) of this fund, money will be earmarked and provided to buy out patents to ensure that health products are made available at affordable prices in developing countries.

(c) financing for this fund will come from contributions by countries, donors, industry and taxing of international financial transactions as agreed to by Member States.

(d) an operational mechanism will be set up for this fund as agreed to by Member States.]

or

delete proposed 7.3

[(7.4) increasing funding for research and development that focuses on the health needs of developing countries]

[(a) Urge [developed countries to] consider [voluntary] [allocation of a [progressive]/[an appropriate] percentage of their [health ODA] budget to health research needs of developing countries]

Element 8. Establishing monitoring and reporting systems

43. Systems should be established to monitor performance and progress of this strategy. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years. *(consensus)*

44. Steps to be taken will include:

(8.1) measuring performance and progress towards objectives contained in the plan of action *(consensus)*

(a) establish systems to monitor performance and progress of the implementation of each element of the Global Strategy and Plan of Action (consensus)

[(8.2) monitoring the [factors]/[incentives and barriers] [, including intellectual property rights,] that could affect innovation and access to medicines and other health products]

(a) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries (consensus)

[(b) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission's report, on the [innovation and] development of, and access to, health care products, and to report thereon to the Health Assembly][1] (adapted from WHA 59.24, paragraph 4 subparagraph 5)

[(c) monitor and report the impact *of [new] / [innovative and alternative] / [incentive] mechanisms on innovation and access to health products and medical devices]*

[(d) monitor and] / [report on] investment in research and development to address the health needs of developing countries.]

Note: Box on "A Global Responsibility for Action" forwarded to the Plan of Action Drafting Group

= = =

[1] Key stakeholders for subparagraph (b) would be WHO in collaboration with WIPO and WTO.