



**EUROPE**

**Regional Committee for Europe  
Fifty-seventh session**

**Belgrade, Serbia, 17–20 September 2007**

---

Provisional agenda item 10(b)

EUR/RC57/Inf.Doc./1  
13 September 2007  
74108  
ORIGINAL: ENGLISH

**Public health, innovation and intellectual property**

This document contains the draft report of a consultation meeting with Member States and stakeholder organizations in the WHO European Region on public health, innovation and intellectual property. The meeting was held at the WHO Regional Office for Europe in Copenhagen on 27 and 28 August 2007, in preparation for the second session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, to be held at WHO headquarters in Geneva on 5–10 November 2007.

Participants in the Copenhagen meeting asked for this report to be submitted to the Regional Committee for information.



1. As follow-up to the World Health Assembly's resolution WHA59.24, the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) was convened by WHO headquarters on 4–8 December 2006, in order to open discussions on the best ways to boost research into medicines and other health products for diseases disproportionately affecting the poor, and the relationship between intellectual property and public health. Resolution WHA 59.24, which followed an independent report by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), took stock of the fact that current medical research and development (R&D) often does not address the needs of developing countries and that, even when products exist, poor populations struggle to access them (see <http://www.who.int/intellectualproperty/en/>).

2. The World Health Assembly also discussed the topic in May 2007 and adopted resolution WHA60.30 on public health, innovation and intellectual property, urging Member States and WHO to give strong support to this intergovernmental process.

3. Following the first session of the IGWG in December 2006, the Executive Board discussed the report of the meeting, and regional consultation meetings were held with the Member States to provide further input into the global strategy and the plan of action (GSPOA). The WHO Regional Office for Europe organized two subregional consultations with Member States, in Moscow on 26 and 27 April and in Istanbul on 30 April and 1 May 2007. The European Commission also organized a coordination meeting with member countries of the European Union in Brussels on 2 April. These meetings provided an opportunity to discuss with Member States the progress of the IGWG to date, to review the working document for the GSPOA and to identify further issues that needed to be included in the GSPOA from a European perspective. The subregional meetings suggested that every country should establish national interministerial coordination mechanisms, and that countries should focus specifically on what they could contribute to the process and how they could benefit from the GSPOA.

4. In order to prepare the countries for the second session of the IGWG on 5–10 November 2007, and to obtain additional input for the GSPOA being prepared by the WHO Secretariat, the WHO Regional Office for Europe organized a consultation meeting for all European countries in Copenhagen on 27–28 August 2007. The meeting brought together representatives of all WHO European Member States, largely from ministries of health, foreign affairs, development cooperation and trade, as well as experts from patent offices and the research community, and representatives of the European Commission. In addition, all the major stakeholders were invited, and the meeting benefited from the presence of experts from the Organisation for Economic Co-operation and Development (OECD) and the World Intellectual Property Organization (WIPO), as well as from the community of nongovernmental organizations (NGOs) and the pharmaceutical industry.

5. The participants discussed the eight areas for action in the GSPOA,<sup>a</sup> making general comments on the overall content and format, and specific comments on each of the elements. Delegations in general welcomed the GSPOA as a comprehensive and balanced document, and a good starting point for the discussions in November. Most countries had not had the opportunity for internal governmental discussions, so their comments did not represent official government positions. It was suggested by a number of countries that the plan needed to have fewer and well defined priorities, and that several of the elements and areas for action could be merged. Monitoring of implementation of the action plan and its achievements was considered to be of vital importance, but it was stressed that there should be fewer and better measurable indicators, and there should be a proper balance between qualitative and quantitative indicators. Member States welcomed the glossary of terms, and the WHO Secretariat would post this on the internet and keep it updated; Member States were invited to contribute additional terms.

6. The scope of the strategy should not be limited to research on specific diseases; it should also identify R&D gaps in terms of all health needs. With regard to the range of countries covered in the strategy, it was suggested that some actions in the GSPOA should be specific to developing countries,

---

<sup>a</sup> *Draft global strategy and plan of action on public health, innovation and intellectual property*. Geneva, World Health Organization, 2007 (document A/PHI/IGWG/2/2, [http://www.who.int/gb/phi/E/index\\_E.html](http://www.who.int/gb/phi/E/index_E.html), accessed 13 September 2007).

while others should cover all countries. The strategy should also explicitly link to the Millennium Development Goals. The GSPOA should clearly reflect where there is a commitment to action (by governments and countries and WHO) and where it invites others to act (e.g. international organizations, NGOs, academia, public–private partnerships (PPPs), charitable foundations, etc.). It was also suggested to differentiate the lead body for action from the lead body for monitoring.

7. Member States indicated that they needed to have an estimate of the cost of implementing the GSPOA, as well as proposals for means of financing. Action to secure sustainable financing should be a key priority of the strategy, and industrialized countries should devote a larger proportion of their health R&D budgets to the health needs of developing countries, while developing countries should devote a larger part of their GDP to health and to strengthening their health systems. Member States also requested the Secretariat to identify where GSPOA actions are covered by other agreements and initiatives (such as the Lisbon goals as related to European Union R&D funding for developing countries; the WHO Special Programme for Research and Training in Tropical Disease, and the 2004 WHO Priority Medicines project).

8. On Element 1 of the GSPOA, “Prioritizing research and development needs”, participants suggested that this element or some the actions described in it should be merged with element 2 on promoting R&D and with actions from element 8 on monitoring, and they commented that the scope of the strategy should be expanded to include Type I diseases (those incident in both rich and poor countries, with large numbers of vulnerable populations in each).

9. On Element 2, “Promoting research and development”, participants discussed the need to define what a medical R&D treaty would be and what possible elements could be included in it (specific action 2.4(c)), to differentiate between securing sustainable financing and innovative financing mechanisms, and to include in this element specific actions on health systems research.

10. On Element 3, “Building and improving innovative capacity”, the delegates made the following suggestions: to merge this with element 4 on transfer of technology; to include concrete actions to reduce the risk of migration (3.2(c)), highlighting the need to formulate national human resources plan (3.2(b)); to include references to ethics and the role of ethical committees; and to include a reference to prequalification of manufacturers by WHO (it was noted that this is currently an indicator for specific action 6.2(d)). Regulatory issues could also be merged with element 6 and needed stronger indicators. Finally, delegates proposed including a section on traditional medicines and developing new methodology for constructing a framework for evidence-based traditional medicine.

11. On Element 4, “Transfer of technology”, it was suggested that a distinction should be made between issues related to patents, R&D and production, and their different legal frameworks; that the proposed models for patent pools (optional or compulsory) and the effectiveness of each should be clarified, and other possible models considered (specific action 4.3(a)); and that the expression “priority diseases in developing countries” in specific action 4.3(b) should be defined and the terms in the GSPOA used in a consistent way.

12. On Element 5, “Management of intellectual property”, the participants felt a general need to strengthen the scope and wording of this element. The proposed actions in the IGWG process were all in line with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and reference should be made to the Doha Ministerial Declaration on the TRIPS Agreement and Public Health. It was suggested that ministries of health should have increased capacity to engage in issues related to intellectual property rights and to secure greater recognition of health needs therein. The wording “upon request” in sub-element 5.2 (referring to WHO providing support for application of TRIPS flexibilities) was debated, but it was noted that this wording is taken directly from resolution WHA60.30. Participants also suggested reconsidering the choice and focus of indicators, including stronger indicators for specific actions 5.3(a) on incentive schemes and 5.3(c) on assessing the impact of data exclusivity regulations. They proposed that a wider range of incentive schemes (including prize funds) should be covered, beyond advance-market commitments.

13. The wording of specific action 5.3(a) should follow that in operative paragraph 3(4) of resolution WHA60.30: "... incentive mechanisms including also addressing the linkage between the cost of R&D and the price of medicines, vaccines, diagnostics and other health-care products". Member States also indicated that the mandates of other international organizations in this area need to be recognized.

14. With regard to data protection/data exclusivity it was suggested that, apart from possible adverse effects on competition among generics, this could also be beneficial for developing the use made of traditional knowledge (which cannot be patented). It was also suggested that the discussion about intellectual property should be connected with the human rights approach to public health.

15. On Element 6, "Improving delivery and access", participants stressed the importance of this component and wanted to strengthen the formulation of sub-element 6.1 and to refer to "health systems" rather than "health-delivery infrastructure", as the former is broader and includes regulatory systems. It was emphasized that all countries (including developing countries) should invest more in improving delivery of and access to medicines; a specific reference was made to existing international commitments on this subject, and it was suggested a specific indicator on this should be included. Specific action 6.1(c), on prioritizing health care in national agendas, was felt to be so important that it should be moved to the top of the GSPOA (see also the report of the CIPIH, section 4.10). Delegates also suggested strengthening the wording on good manufacturing practices (GMP) to promote good quality, referring to "combating counterfeit drugs" instead of "minimizing their public health consequences", and including actions on the rational use of medicines. Many participants support the reduction of taxes and tariffs, especially for "essential medicines", in specific action 6.3(c) and wanted to include a global indicator on WHO's work on monitoring pharmaceutical pricing.

16. On Element 7, "Ensuring sustainable financing mechanisms", participants emphasized the critical importance of this aspect and suggested that the role of WHO in this element should be more clearly defined as either leading activities, monitoring actions, or being the key implementer. The strategy should also have a resource mobilization plan and must be more specific on resource needs. While it was acknowledged that there is currently a strong focus in the action plan on PPPs and their potential benefits/threats, it was felt that the plan needs better tools and indicators to assess such partnerships. It was also suggested that public funding in R&D should be increased and steps taken to ensure that R&D addresses public health priorities and has a critical mass to achieve results. The increasing role of charitable foundations and new funding bodies was highlighted. The commitment by partners should be explicitly stated in the document, and it was felt to be especially important to engage investment funds and financial markets in these discussions, with a focus on advancing the cause of public health.

17. Element 8, on "Establishing monitoring and reporting systems", on the one hand focuses on monitoring progress in implementing the action plan, and on the other hand specifically monitors the evolution of health needs, the flows of R&D funding, and the impact of intellectual property and innovation. In general, the delegates suggested that all indicators should be reviewed to ensure that they are specific, measurable, meaningful and valid. It was suggested that action under sub-element 8.2 should be linked not just to intellectual property but to other elements in the GSPOA (especially health systems). With regard to the output of element 8 (database, reports), the Secretariat plans to publish an updated monitoring report and welcomes suggestions on how to do this.

18. In his concluding comments, the Vice-Chairman of the IGWG stressed the need for all countries to discuss the GSPOA with their governments and prepare for the second session of the IGWG. He encouraged all Member States to participate in that forthcoming session and to establish national interministerial coordination mechanisms on this. In conclusion, he thanked the delegates for their active and constructive contributions, and he encouraged all those involved to express their views on the web-based public hearing that was running from 15 August to 30 September 2007 ([http://www.who.int/phi/public\\_hearings/second/en/index.html](http://www.who.int/phi/public_hearings/second/en/index.html)).