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Agenda item 18

FOLLOW-UP OF THE REPORT OF THE CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION

Note for the Programme Subcommittee

Executive Summary

1. By its resolution WHA65.22 entitled Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, the World Health Assembly considered, during its Sixty-fifth session held from 21-26 May 2012, the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) in documents A65/24; Annex and A65/24 Corr.1.

2. Resolution WHA65.22 requests the Director-General to hold an open-ended Member States[1] meeting to analyze thoroughly the report and the feasibility of the recommendations proposed by the CEWG, taking into account, as appropriate, related studies. The meeting will also take into account the results from national consultations and Regional Committee discussions and develop proposals or options relating to (a) research coordination, (b) financing and (c) monitoring of R&D expenditures[2], to be presented under a substantive item dedicated to the follow-up of the CEWG report at the Sixty-sixth World Health Assembly, through the Executive Board at its one-hundred and thirty-second session.

3. This information note is intended to summarize the contents of documents A65/24 and A65/24 Corr.1 and resolution WHA65.22 which are herewith submitted for your views and comments.

[1] And, where applicable, regional economic integration organizations.
[2] As defined in the Global strategy and plan of action on public health, innovation and intellectual property.

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BACKGROUND

1. The high price of patented health products impedes access to health products in low-and-middle income countries such as those in the WHO African Region. This situation is aggravated by the current international and national rules on Intellectual Property Rights (IPRs) especially the stringent intellectual property protections in the pharmaceutical market. It has been observed over the years that research and development in health products related to diseases which disproportionately affect developing countries is grossly inadequate.[3]

2. In May 2003, the World Health Organization (WHO) tasked an independent Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to analyze the relationship between intellectual property rights, innovation and public health. The CIPIH report concluded that intellectual property rights provide important incentives for the development of new medicines and medical technology but noted that they do not provide an effective incentive when patient populations are small or poor.[4]

3. Based on the CIPIH recommendations, the Fifty-ninth World Health Assembly adopted resolution WHA59.24[5] which established the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property Rights (PHI). The IGWG was tasked to draw up a global strategy and plan of action (GSPA) aimed at, *inter alia*, securing an enhanced and sustainable basis for needs-driven, essential health R&D relevant to diseases that disproportionately affect developing countries. The Sixty-first World Health Assembly, through resolution WHA61.21,[6] adopted the GSPA.

4. A report submitted by an Expert Working Group, EWG, (established under resolution WHA61.21) on Research and Development: Coordination and Financing was judged to have excluded important submissions that came from wide consultations. The Sixty-third World Health Assembly, in 2010, adopted resolution WHA63.28 wherein the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) was established with the principal task of deepening the analysis and taking forward the work done by the EWG.

5. The underlying mandate for both expert groups was the objective set out in the GSPA-PHI report, i.e. "to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases".

6. The scope of the CEWG mandate also centered on element 2 (Promoting research and development) and element 7 (Promoting sustainable financing mechanisms) of the GSPA-PHI. It also consisted in: taking forward the work and deepening the analysis of the EWG; and examining additional submissions and proposals on R&D financing and coordination.

7. The Sixty-fifth World Health Assembly through resolution WHA65.22,[7] among other things, requests regional committees to discuss at their 2012 meetings the report of the CEWG in

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3 G-Finder Report 2011.

4 Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, April 2006.

5 WHA59.24; Public health, innovation, essential health research and intellectual property rights; 27 May 2006.

6 WHO, World Health Assembly Resolution WHA61.21, Global Strategy and Plan of Action on public health, innovation and intellectual property. In: Sixty-first World Health Assembly, Geneva, 24 May 2008. Geneva, World Health Organization.

7 WHA65.22: Follow-up of the Consultative Expert Working Group on Research and Development: Financing and Coordination.

the context of the implementation of the global strategy and plan of action on public health, innovation and intellectual property in order to contribute to concrete proposals and actions.

8. This information document is prepared to update Member States on the progress made by the Consultative Expert Working Group on Research and Development: Financing and Coordination, and to request the Regional Committee to discuss documents A65/24 and A65/24 Corr.1.within the context of the GSPA-PHI.

PROGRESS MADE

9. The Fifty-ninth session of the Regional Committee for Africa endorsed a document elaborating on the regional perspective to implement the global strategy and plan of action. The document outlines issues and challenges and proposes actions to enhance the implementation of the GSPA-PHI.

10. In addition to the participation of African experts in the CEWG, a Regional consultation was organized on 27 August 2011 in Abidjan, Côte d'Ivoire, to provide the African Regional input into the proposals made by the CEWG. The consultation examined the appropriateness of the different R&D financing approaches proposed and the feasibility of their implementation in the WHO African Region.

11. The report of the CEWG presented to the Sixty-fifth World Health Assembly explains the manner in which the committee worked, the criteria used for the analysis of the proposals, the results of the analysis, and recommendations for consideration by Member States.

12. The proposals assessment process consisted in analyzing of 109 proposals inherited from the EWG. They had been reduced to 91 and grouped under 22 thematic proposals which had been reviewed by the EWG. These proposals were finally reduced to 15 groups.

13. The following criteria were used for the evaluation of the proposals: public health impact, efficiency, technical feasibility, financial feasibility, intellectual property, delinking, access, governance and capacity building. The criteria were well met by the following proposals: global framework on research and development; direct grants to companies; patent pools; pooled funds; open approaches to research and development and innovation; milestone prizes and end prizes. The criteria were less well-met by: purchase or procurement agreement; priority review voucher; green intellectual property, health impact fund, orphan drug registration, tax breaks for companies, transferrable intellectual property rights. The following were not relevant to the CEWG mandate: removal of data exclusivity and regulatory harmonization.

14. The CEWG report makes the following comments on financing: traditional financing mechanisms based on direct or indirect taxation are more likely to succeed than a complex landscape of uncoordinated voluntary or innovative initiatives; countries should consider, at national level, what tax options might be appropriate to them as a means of raising revenue to devote to health and health R&D, and also what can be done together in a coordinated fashion.

15. With regard to governments' funding for R&D, the CEWG noted the following: most African countries do not meet the Abuja target of allocating 15% of government budget to health; no developing country has met the 2% target for health research; developed countries on average meet or exceed both these targets and spend on average about 0.15% of GDP on health research; developed countries have not met the 5% target for health research as a proportion of development assistance for health.

16. The report recommends the following on financing: all countries should commit to spend at least 0.01% of GDP on government-funded R&E devoted to meeting the health needs of developing countries in relation to the types of R&D defined in their mandate; most of the funding should be used within each individual country; 20%–50% of funds raised for health R&D addressing the needs of developing countries should be channelled through a pooled mechanism; developing countries with a potential research capacity should aim to commit 0.05%–0.1% of GDP for health research of all kinds; developed countries should aim to commit 0.15% to 0.2% of GDP to government-funded health research of all kinds.

17. The following challenges for research coordination were noted in the report: need to review research capacity building initiatives for coherence and effectiveness; lack of a standard mechanism to record, classify and compare health research funding on a global basis; lack of access to, and availability of information on, financing flows; a plethora of funders and research organizations, each taking decisions independently and with overlapping objectives but separate governance arrangements; need to associate coordination with a funding mechanism (i.e. pooled funding) to increase effectiveness.

18. The following recommendations regarding coordination were made: creation of a global R&D observatory to monitor financial flows to R&D, the R&D pipeline, learning lessons; the need to set up advisory mechanisms made up of institutions and funders and an advisory committee; WHO to play a central role in improving coordination to be considered as part of the WHO reform process.

19. The CEWG recommended the institution of a global binding instrument to ensure implementation of the recommendations provided above. The instrument would operate as follows: preparation of a global framework that combines the different elements and recommendations in a concerted manner; conventions to be used as a means by which countries enter into agreements with legal force to achieve common goals; conventions can have funding provisions attached to them; propose an international Convention on Global Health R&D under Article 19: "The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization.

20. The principles of the global binding instrument proposed by the CEWG are: under the auspices of the WHO (Article 19); delinking of the cost of R&D and the price of the product; involvement of all governments in setting priorities, coordinating and funding R&D efforts; a funding mechanism to ensure the sustainable financing of all activities under the convention; a supplementary instrument to the IPR-based incentive system (not a replacement); WHO Member States to decide on the institutional mechanism and *modus operandi* of the instrument.

21. The key CEWG recommendations are: **Principles**: affordable products can best be achieved through free open market competition requiring the delinking of R&D costs and prices of products; **Approaches to R&D**: more efficient and collaborative through sharing of results, Open knowledge innovation, equitable licensing and patent pools; **Financing mechanisms**: need to double existing public investments to US$ 6 billion annually; all countries should commit to spend at least 0.01% of GDP on government-funded R&D devoted to meeting the health needs of developing countries related to product development; **Pooling resources**: 20%–50% of funds raised for health R&D addressing the needs of developing countries should be channelled through a pooled mechanism to improve efficiency and coordination; **Funding allocation**: should require appropriate open licensing or use of public domain, whether through conditional grants or prizes; **Strengthening research and development capacity and technology transfer**: address the capacity needs of academic and public research organizations in developing countries, utilise direct grants to companies in developing countries; **Coordination**: establish a Global Health

R&D Observatory and relevant advisory mechanisms under the auspices of WHO; **Implementation through a binding global instrument for R&D and innovation for health**: formal negotiations on an International Convention on Global Health R&D should be initiated, a convention will complement the current IPR-based incentive system.

NEXT STEPS

22. Resolution WHA65.22 urges Member States to, *inter alia*, "hold national level consultations among all relevant stakeholders, in order to discuss the CEWG report and other relevant analyses, resulting in concrete proposals and actions; to participate actively in the meetings at regional and global level referred to in this resolution".

23. The results of consultations from Member States will be useful in the discussions related to the CEWG report at the sixty-second session of the Regional Committee. Resolution WHA65.22 as well as documents A65/24 and A65/24 Corr.1 are hereby submitted for your review and comments.