

SIXTY-SIXTH WORLD HEALTH ASSEMBLY Provisional agenda item 17.2

A66/23 11 March 2013

Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Report by the Director-General

1. The attached documents EB132/21 and EB132/21 Add.1 were considered by the Executive Board at its 132nd session in January 2013. The Board noted the report of the open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination¹ and agreed that the comments made thereon by Member States would be brought to the attention of the Health Assembly.²

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to consider the report of the open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination and the draft resolution recommended by the open-ended meeting of Member States, bearing in mind the financial and administrative implications of its adoption for the Secretariat.³

¹ See document EB132/21, Annex.

 $^{^{2}}$ See the summary record of the eleventh meeting of the Executive Board at its 132nd session, section 2.

³ Document EB132/21 Add.1.



EXECUTIVE BOARD 132nd session Provisional agenda item 10.2

EB132/21 7 December 2012

Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Report by the Director-General

The Director-General has the honour to transmit to the 132nd session of the Executive Board the report of the open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (see Annex), which met in Geneva from 26 to 28 November 2012, including a draft resolution, agreed by consensus.

ANNEX

REPORT OF THE OPEN-ENDED MEETING OF MEMBER STATES ON THE FOLLOW-UP OF THE REPORT OF THE CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION, GENEVA, 26–28 NOVEMBER 2012¹

1. The open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) met from 26 to 28 November 2012 in Geneva and was chaired by Dr Viroj Tangcharoensathien (Thailand). The session was attended by representatives from 81 Member States, and one regional economic integration organization.

2. Member States decided to open the morning session of 26 November 2012 to nongovernmental organizations (NGOs) in official relations with WHO and intergovernmental organizations (IGOs), and also to invite The Wellcome Trust, the Bill & Melinda Gates Foundation and the South Centre.

3. Member States considered the outcomes of the national and regional consultations and the regional committee meetings on the CEWG report,² and the analysis and feasibility of the recommendations proposed by the CEWG, taking into account related studies. Member States also considered the report of the Secretariat on proposals and options relating to (1) research coordination, (2) financing and (3) monitoring of R&D expenditures.³

4. The appended draft resolution was agreed by consensus.

5. The Director-General was requested to submit this report and attached draft resolution to the Sixty-sixth World Health Assembly, through the Executive Board at its 132nd session, for its consideration.

6. The open-ended meeting of Member States strongly recommends that the Executive Board considers this report and its attached draft resolution with a view to recommending the adoption of the resolution by the World Health Assembly without reopening it.

¹ Document A/CEWG/4.

² Documents A/CEWG/2 and A/CEWG/2 Add.1.

³ Document A/CEWG/3.

Appendix

DRAFT RESOLUTION

Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

The Sixty-sixth World Health Assembly,

PP1 Having considered the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination;¹

PP2 Recalling resolution WHA65.22, which requested the Director-General, inter alia, to hold an open-ended meeting of Member States² to thoroughly analyse the report and the feasibility of the recommendations proposed by the Consultative Expert Working Group, and taking into account discussions during regional committee meetings and regional and national consultations;

PP3 Further recalling the global strategy and plan of action on public health, innovation and intellectual property and its aims to promote innovation, build capacity, improve access and mobilize resources³ to address diseases that disproportionately affect developing countries as well as resolutions WHA59.24, WHA63.21 and WHA63.28;

PP4 Recognizing the urgency in addressing the health needs of developing countries and the related inequities in the current research landscape due to recognized market failures and the need for enhancing investments in health R&D related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases;⁴

PP5 Acknowledging the need for improving monitoring of health R&D resource flows, and identification of gaps in health R&D, better coordination of health R&D, and priority-setting based on the public health needs of developing countries;

PP6 Acknowledging also that the provision of additional information on disease burden, research opportunities, the potential health impact, and estimations of the resources needed to develop new health products and make them accessible to the poor in developing countries can provide an important basis for advocacy for additional financing;

PP7 Recognizing the importance of securing sustainable financing mechanisms for health R&D to develop and deliver health products⁵ to address the health needs of developing countries;

¹ Documents A65/24; Annex and A65/24 Corr.1.

² And, where applicable, regional economic integration organizations.

³ See resolutions WHA61.21 and WHA62.16.

⁴ In the context of this resolution health R&D shall refer to health 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.

⁵ The term "health products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

PP8 Recalling the global strategy and plan of action on public health, innovation and intellectual property, which refers to a range of incentive schemes for health R&D, with one objective being the de-linkage of the cost of R&D from the price of health products;

PP9 Recognizing the interlinkage of monitoring, coordination and financing of health R&D as well as the importance of predictability and sustainability of the resources required to enhance health R&D;

PP10 Reaffirming the importance of facilitation of technology transfer on mutually agreed terms between developed and developing countries as well as among developing countries as appropriate;

PP11 Underscoring that health R&D should be needs-driven and evidence-based, and be guided by the following core principles: affordability, effectiveness, efficiency and equity; and it should be considered as a shared responsibility;

PP12 Realizing the need for improving priority-setting and transparent decision-making processes based on the public health needs of developing countries;

PP13 Noting the important role of the public and private sectors in promoting innovation and developing new health products,

1. ENDORSES the following strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health R&D, in line with the global strategy and plan of action on public health, innovation and intellectual property, as a step towards achieving the goal of development and delivery of affordable, effective, safe and quality health products, in which existing market mechanisms fail to provide incentives for health R&D; and agrees to develop further the strategic workplan through broad engagement of public and private entities, academia and civil society;

2. URGES Member States:¹

(1) to strengthen health R&D capacities and to increase investments in health R&D for diseases disproportionately affecting developing countries;

(2) to promote capacity building, transfer of technology on mutually agreed terms, production of health products in developing countries, and health R&D and access to health products in developing countries through investments and sustainable collaboration;

(3) to establish or strengthen national health R&D observatories or equivalent functions for tracking and monitoring of relevant information on health R&D, in line with agreed norms and standards as established in subparagraph 4(1) below, and to contribute to the work of a global health R&D observatory;

(4) to promote coordination of health R&D at national, regional and global levels in order to maximize synergies;

¹ And, where applicable, regional economic integration organizations.

(5) to identify projects, as part of the strategic workplan, through regional consultations and broad engagement of relevant stakeholders, to address research gaps, ensure effective coordination at all levels, and secure resource needs for implementation in order to develop and deliver health products;

(6) to continue consultation, at national as well as at regional and global levels, including through the governing bodies of WHO, on specific aspects related to coordination, priority setting and financing of health R&D;

(7) to contribute to coordinated and sustainable financing mechanisms for health R&D, through voluntary contributions for activities at country, regional and global levels, in particular for monitoring, including a global health R&D observatory;

3. CALLS upon all stakeholders, including the private sector, academic institutions and nongovernmental organizations, to share relevant information on health R&D with WHO in order to contribute to a global health R&D observatory and to contribute to the financing mechanisms;

4. **REQUESTS** the Director-General:

(1) to develop norms and standards for classification of health R&D, building on existing sources, in consultation with Member States and relevant stakeholders, in order to systematically collect and collate information;

(2) to support Member States in their endeavour to establish or strengthen health R&D capacities and monitor relevant information on health R&D;

(3) to establish a global health R&D observatory within WHO's Secretariat in order to monitor and analyse relevant information on health R&D, building on national and regional observatories (or equivalent functions) and existing data collection mechanisms with a view to contributing to the identification of gaps and opportunities for health R&D and defining priorities in consultation with Member States, as well as, in collaboration with other relevant stakeholders, as appropriate, in order to support coordinated actions;

(4) to facilitate through regional consultations and broad engagement of relevant stakeholders the implementation of a few health R&D demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken;

(5) to review existing mechanisms to assess their suitability to perform the coordination function of health R&D;

(6) to explore and evaluate existing mechanisms for contributions to health R&D and, if there is no suitable mechanism, to develop a proposal for effective mechanisms, including pooling resources and voluntary contributions, as well as a plan to independently monitor their effectiveness;

(7) to convene another open-ended meeting of Member States¹ prior to the Sixty-ninth World Health Assembly in May 2016, in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health R&D, taking into account all relevant analyses and reports, including the analysis of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination;

(8) to report on the review of existing coordination mechanisms (referred to in subparagraph 4(5) above), as well as on the evaluation of existing mechanisms for contributions to health R&D (referred to in subparagraph 4(6) above) to the Sixty-seventh World Health Assembly, through the Executive Board at its 134th session; to report on the implementation of health R&D demonstration projects (referred to in subparagraph 4(4) above) to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session; and to transmit the report of the open-ended meeting of Member States to the Sixty-ninth World Health Assembly.

¹ And, where applicable, regional economic integration organizations.



EXECUTIVE BOARD 132nd session Provisional agenda item 10.2 EB132/21 Add.1 18 January 2013

Report on financial and administrative implications for the Secretariat of resolutions proposed for adoption by the Executive Board or Health Assembly

1. Resolution: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

2. Linkage to the Programme budget 2012–2013 (see document A64/7 http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_7-en.pdf)

Strategic objective(s): 11

Organization-wide expected result(s): 11.1

How would this resolution contribute to the achievement of the Organization-wide expected result(s)?

Access to essential medicines and medical technologies is a fundamental pillar of national health policies. Research and development of new medicines and technologies for effectively tackling the diseases that disproportionally affect developing countries is critical to improving access. It is also very important that new technologies, when developed, are affordable. Currently, spending on research and development is insufficient, and even when new medicines are developed they are not affordable. After discussions and consultations among Member States on the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, this resolution will implement further steps aimed at enhancing sustainable funding for research and development and ensuring that the resulting products and technologies are accessible.

Does the programme budget already include the products or services requested in this resolution? (Yes/no) No.

3. Estimated cost and staffing implications in relation to the Programme budget

(a) Total cost

Indicate (i) the lifespan of the resolution during which the Secretariat's activities would be required for implementation and (ii) the cost of those activities (estimated to the nearest US\$ 10 000).

- (i) three years (covering the period June 2013–May 2016)
- (ii) Total US\$ 10.7 million (staff: US\$ 2.7 million; activities: US\$ 8 million). This amount does not include the total cost of one activity that will require two additional years to be fully implemented (with an additional cost of US\$ 4 million for staff and activities).

	(b)	Cost for the biennium 2012–2013
		Indicate how much of the cost indicated in 3 (a) is for the biennium 2012–2013 (estimated to the nearest US\$ 10 000).
		Total US\$ 1.47 million (staff: US\$ 270 000; activities: US\$ 1.2 million).
		Indicate at which levels of the Organization the costs would be incurred, identifying specific regions where relevant.
		Headquarters and regional offices.
		Is the estimated cost fully included within the approved Programme budget 2012–2013? (Yes/no)
		No.
		If "no", indicate how much is not included.
		US\$ 1.47 million.
	(c)	Staffing implications
		Could the resolution be implemented by existing staff? (Yes/no)
		No.
		If "no" indicate how many additional staff – full-time equivalents – would be required, identifying specific regions and noting the necessary skills profile(s), where relevant.
		Headquarters level: one staff member at grade P.5 and two staff members at grade P.4.
4.	Funding	
	Is the estimated cost for the biennium 2012–2013 indicated in 3 (b) fully funded? (Yes/no)	
	No.	
	If "no", indicate the funding gap and how the funds would be mobilized (provide details of expected source(s) of funds).	

US\$ 1.47 million; source(s) of funds: to be identified.

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