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

Planning for an open-ended meeting of Member States to discuss progress

Report by the Director-General

1. In May 2013, the Health Assembly adopted resolution WHA66.22 on follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, in which the Director-General was requested, inter alia, to convene another open-ended meeting of Member States 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 research and development, 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.¹

2. The Regional Committee for South-East Asia at its sixty-eighth session, in its review of the draft provisional agenda of the 138th session of the Executive Board, endorsed through decision SEA/RC68(3) a proposal made by India to include “Follow-up of Consultative Expert Working Group” as an agenda item for that session. It was further suggested that the Board’s session be used as an opportunity “to review progress on the follow-up of the report on the Consultative Expert Working Group on Research and Development: Financing and Coordination, and prepare for the open-ended meeting in a transparent and inclusive manner, including by identifying priority issues and finalizing the agenda and modalities of the open-ended meeting well in advance. This would enable focused and result-oriented discussions during the open-ended meeting.”

3. Through resolution WHA66.22, the Health Assembly endorsed a “strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health research and development, in line with the global strategy and plan of action on public health, innovation and intellectual property, as a step toward achieving the goal of development and delivery of affordable, effective and safe health products for which existing market mechanisms fail to provide incentives for health research and development; and agreeing to develop the strategic workplan further, through the broad engagement of public and private entities, academia and civil society”. The resolution also urged Member States “to strengthen health research and development capacities, increasing

¹ Document A66/23 (http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_23-en.pdf, accessed 30 November 2015).

investments in health research and development for diseases disproportionately affecting developing countries”.

4. The resolution also requested the Director-General to support Member States in their endeavours to establish or strengthen health research and development capacities and monitor relevant information on health research and development. More specifically, the Health Assembly requested the Director-General, among other things:

(a) to establish a global health research and development observatory within WHO’s Secretariat in order to monitor and analyse relevant information on health research and development with a view to contributing to the identification of gaps and opportunities for health research and development and defining priorities;

(b) to facilitate the implementation of a few demonstration health research and development projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken;

(c) to review existing mechanisms in order to assess their suitability to perform the coordination function of health research and development;

(d) to explore and evaluate existing mechanisms for contributions to health research and development 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 monitor their effectiveness independently.

GLOBAL HEALTH RESEARCH AND DEVELOPMENT OBSERVATORY

5. Work towards the establishment of a global observatory on health research and development is well underway with the launch of its first phase scheduled for January 2016.¹ The first phase includes collecting and collating available data on funding for health research and development, health products in the pipeline, clinical trials and research publications. In the subsequent phases, the observatory’s functions and remit will continue to be broadened as it receives additional resources, data and analyses. Besides the online portal, key outputs of the observatory will be the development of planned and on-demand analyses of health research and development gaps, highlights of key findings from the data collected and contributions to priority-setting mechanisms as part of the coordination function of health research and development.

HEALTH RESEARCH AND DEVELOPMENT DEMONSTRATION PROJECTS

6. Through a process recommended in decision WHA66(12) (2013), the following six demonstration projects have been selected:

(a) the visceral leishmaniasis global research and development and access initiative (proponents: Drugs for Neglected Diseases initiative and United States Food and Drug Administration);

¹ www.who.int/research-observatory (accessed 30 November 2015).

- (b) exploiting the pathogen box: an international open-source collaboration to accelerate drug development in addressing diseases of poverty (proponent: Medicines for Malaria Venture);
- (c) development of easy to use and affordable biomarkers as diagnostics for types II and III diseases (proponents: African Network for Drugs and Diagnostics Innovation, China Tropical Diseases Drugs and Diagnostics Innovation Network et al.);
- (d) development of a vaccine against schistosomiasis based on the recombinant Sm14, a member of the fatty acid-binding protein: controlling transmission of a disease of poverty (proponent: Oswaldo Cruz Foundation, Brazil);
- (e) multiplexed point-of-care test for acute febrile illness (proponent: Translational Health Science and Technology Institute, India);
- (f) demonstration of the potential of a single-dose malaria cure of artemether-lumefantrine through reformulation in a nano-based drug delivery system (proponent: Council for Science and Industrial Research, South Africa).

7. The above-mentioned projects are at different levels of implementation, except project (f), from South Africa, which is nearing finalization of a proposal for expert review. The Ad-hoc Committee for the Demonstration Projects/Global Health Research and Development Observatory¹ has been established, to which demonstration projects' proponents submit their financial requirements. After reviewing technical workplans and budgets for the first year, the Committee at its meeting in Geneva on 19 June 2015 recommended allocation of funding for three projects to date. Letters of agreement have been signed and money has been disbursed. The funding requirements from the other two selected projects have been received, and pledged contributions are awaited from some Member States before disbursements can be made.

BUDGET LINE FOR DEMONSTRATION PROJECTS AND THE GLOBAL HEALTH RESEARCH AND DEVELOPMENT OBSERVATORY

8. As reported by the Director-General to the Executive Board at its 134th session in January 2014,² a budget line for the demonstration projects and the observatory was established outside WHO's Programme budget and has been managed by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. The estimated total financial requirement for implementation of these two activities for four years 2014–2017 is US\$ 85 million. Member States were contacted to contribute to this voluntary fund and to date US\$ 7.65 million have been contributed or pledged by Brazil, India, Norway, South Africa and Switzerland. Switzerland has also pledged US\$ 2 million and Norway about US\$ 500 000 as matching grants for contributions from low- and middle-income Member States on the basis of half a dollar for each dollar, up to these earmarked amounts. The implementation rate of funds received to date has been 97%, but the current gap for the remaining period until the end of 2017 stands at US\$ 75 million. There have been some direct contributions for the observatory from France, Switzerland and the United States of America.

¹ http://www.who.int/phi/news/adhoc_committee/en/ (accessed 30 November 2105).

² Document A68/34.

EXPLORATION OF FINANCING MECHANISM FOR CONTRIBUTIONS TO HEALTH RESEARCH AND DEVELOPMENT

9. In decision WHA67(15), adopted in May 2014, the Health Assembly requested the Director-General to further explore with the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases the possibility of hosting a pooled fund for voluntary contributions toward research and development for type III and II diseases and the specific research and development needs of developing countries in relation to type I diseases. Subsequently, the Special Programme has undertaken an extensive consultation with stakeholders from the public and private health product development sectors, including industry, civil society and the donor community.¹ The conclusion of this exercise is that, subject to the availability of new funding, the Special Programme can adapt the mechanisms it has in place to accommodate a new financial mechanism, certainly within the early start-up phase. This would integrate with WHO's plans for a coordinating group and the priorities it would identify through data from the newly established global observatory on health research and development. The Special Programme will publish in advance of the open-ended meeting a detailed analysis of several aspects that contribute to the design of a new financial mechanism.

PLANNING FOR THE OPEN-ENDED MEETING OF MEMBER STATES

10. In consultation with Member States, it is proposed to hold the open-ended meeting of the Member States requested in resolution WHA66.22 on 7–9 March 2016 at WHO headquarters. The Secretariat will prepare a detailed progress report on the implementation of resolution WHA66.22 which will be made available well in advance of the meeting.

11. The Secretariat has drafted an outline provisional agenda for the open-ended meeting (see Annex) for consideration and discussion by the Board at its 138th session.

ACTION BY THE EXECUTIVE BOARD

12. The Board is invited to consider the report and provide guidance on the drafted outline provisional agenda, the nomination of the Chairman and Vice-Chairman, and the participation of non-State actors, and on future steps.

¹ A full report will be available at: <http://www.who.int/tdr/en/>. This work was supported by a 2 million Swiss francs designated award from the Swiss Agency for Development and Cooperation .

ANNEX

**DRAFT OUTLINE OF PROVISIONAL AGENDA
FOR THE OPEN-ENDED MEETING**

Geneva, 7-9 March 2016

Opening session

Opening remarks by the Director-General

Election of the Chairman and Vice-Chairman of the meeting

First session

Presentation by the Secretariat on the progress in implementing resolution WHA66.22

Member States' comments on the progress made

Statements by non-State actors (to be confirmed)

Second session

Secretariat presentations on progress in the development of the global observatory on health research and development, in implementation of health research and development demonstration projects, and in exploring financing mechanism for contributions to health research and development

Member States' comments and discussion

Third session

Member States' discussion

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