

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

Report by the Director-General

1. In January 2017, an earlier version of this report was considered and noted by the Executive Board at its 140th session.¹ In response to comments made, and to take account of latest developments, the Secretariat has adjusted the text in the following areas: paragraphs 5, 6, 9, 11 and 17–19 of the report; paragraphs 4 and 8 and Table 2 of Annex 1; and paragraphs 8 and 11 of Annex 2.

2. In resolution WHA69.23 (2016), the Health Assembly requested the Director-General to expedite the full implementation of the strategic workplan endorsed in resolution WHA66.22 (2013). Resolution WHA69.23 includes the following elements:

- development of WHO's Global Observatory on Health Research and Development;²
- full implementation of the strategic workplan;
- establishment of an Expert Committee on Health Research and Development to provide technical advice on the prioritization of health research and development;
- exploration of the feasibility of a voluntary pooled fund to support research and development for Type III and Type II diseases and specific research and development needs of developing countries in relation to Type I diseases.

3. More specifically, the Health Assembly in resolution WHA69.23 requested the Director-General to submit to the Seventieth World Health Assembly, through the Executive Board at its 140th session, two texts: terms of reference and a costed workplan for the Global Observatory on Health Research and Development; and a proposal with goals and an operational plan for a voluntary pooled fund to support research and development for Type III and Type II diseases and specific research and development needs of developing countries in relation to Type I diseases.

4. The terms of reference and a costed workplan of the Global Observatory on Health Research and Development are submitted in Annex 1.

¹ Document EB140/21; see also the summary records of the Executive Board at its 140th session, eleventh meeting.

² Available at: <http://www.who.int/research-observatory/en/> (accessed 13 February 2017).

5. The proposal for a voluntary pooled fund is contained in Annex 2. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases has developed an operational plan for a voluntary pooled fund to support health research and development, which contains further details including two case studies on the operationalization of the fund in relation to two diseases.¹ The Secretariat also undertook a study that presents possible financing options that could be used to feed the voluntary pooled fund as requested in resolution WHA69.23.²

6. In response to resolution WHA69.23 the Executive Board at its 140th session also noted the terms of reference for the Expert Committee on Health Research and Development as set out in document EB140/22.³

Global Observatory on Health Research and Development

7. The Global Observatory on Health Research and Development aims “to consolidate, monitor and analyse relevant information on health research and development needs of developing countries, with a view to contributing to the identification and the definition of gaps and opportunities for health research and development priorities”.⁴

8. In January 2016, a demonstration version of the Global Observatory was published online which incorporated data on: funding for health research and development (from Policy Cures Research’s Grant Finder survey⁵); health products that are under development (from four data sources); clinical trials (from the WHO International Clinical Trials Registry Platform); research publications (from PubMed); gross domestic expenditures on health research and development by country (from UNESCO, OECD, La Red de Indicadores de Ciencia y Tecnología – Iberoamericana e Interamericana and Eurostat) and other relevant country-level macroeconomic data such as total health expenditures (from WHO’s global health expenditures database) and burden of disease (from the Global Health Observatory).

9. Following consideration of feedback from users, the Global Observatory on Health Research and Development was released on 19 January 2017. It includes new elements, such as indicators for monitoring activities in and resources for health research and development, comprehensive analyses of data on health research and development by disease, comparative analyses of health research and development activities between countries and across diseases, and a section on classifications and standards, as a first step towards harmonization of future data collection efforts. The Observatory will continue to be expanded and updated as new resources and information become available.

¹ http://www.who.int/phi/implementation/research/Draft_OperationalPlan_for_a_VoluntaryPooledFundSupportHealthResearchDevelopment.pdf?ua=1 (accessed 13 February 2017).

² http://www.who.int/phi/implementation/research/DraftOptions_for_SustainableFundingVoluntaryPooledFundSupportHealthResearchDevelopment.pdf?ua=1 (accessed 13 February 2017).

³ See the summary records of the Executive Board at its 140th session, eleventh meeting.

⁴ Resolution WHA69.23, eighth preambular paragraph, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R23-en.pdf (accessed 13 February 2017).

⁵ <http://www.policycuresresearch.org/g-finder/> (accessed 13 February 2017).

HEALTH RESEARCH AND DEVELOPMENT DEMONSTRATION PROJECTS

10. Based on resolution WHA66.22, the following six demonstration projects were finally 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);
 - (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, Chinese Network for Drugs and Diagnostics Innovation et al.);
 - (d) development of a vaccine against schistosomiasis based on the recombinant Sm14, a member of the fatty acid-binding protein family: 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).

11. In 2015, the Ad-hoc Committee for the Demonstration Projects/Global Health R&D Observatory¹ reviewed the workplans and budget proposals for five demonstration projects – (a) to (e) – as well as those of the Global Observatory on Health Research and Development, and recommended allocation of funding for the first year of implementation of those five demonstration projects and the Observatory. Letters of agreement were signed and funds were disbursed for demonstration projects (a) to (c) in 2015 and for demonstration project (d) in September 2016, using all available funds. The fifth demonstration project (e) was approved for funding by the Ad-hoc Committee and the letter of agreement was signed with funds disbursed in March 2017. The Global Observatory on Health Research and Development has not received any funding so far. The sixth demonstration project (f) was only recognized as a demonstration project in April 2016 and will receive funding subject to approval by the Ad-hoc Committee. A meeting of stakeholders for this demonstration project was held on 27 February 2017 in Geneva.

LINKING MONITORING, COORDINATION AND FINANCING OF HEALTH RESEARCH AND DEVELOPMENT

12. In resolution WHA69.23, the Health Assembly requested a description of how the Global Observatory on Health Research and Development, the proposed Expert Committee on Health Research and Development and the Scientific Working Group of a voluntary pooled fund would work together in terms of specific disease examples.

¹ See http://www.who.int/phi/news/adhoc_committee/en/ (accessed 13 February 2017).

13. The role of the Global Observatory on Health Research and Development is to provide the fundamental data needed to prioritize decisions on research and development. Such analyses would include data on the unaddressed public health needs for new products, ongoing research and development activities (such as products in the pipeline and clinical trials), investments, gaps, list of approved products, patents, and any established priorities for research and development for the diseases and conditions within its scope.

14. The analyses produced by Global Observatory on Health Research and Development will be used by the Expert Committee on Health Research and Development to recommend priority areas for research and development of specific health products and technologies; for example, the need for an innovative vaccine against pulmonary tuberculosis in adults, a condition that accounts for most cases of tuberculosis worldwide, or an accurate and specific, easy-to-use diagnostic tool that can be used in rural health settings.

15. The Scientific Working Group of the proposed pooled fund would then operationalize the priorities established by the Expert Committee by defining the detailed product characteristics. The interaction of this system is illustrated in the recent report on Health product research and development fund: a proposal for financing and operation.¹

PROMOTING AND ADVOCATING FOR SUSTAINABLE AND INNOVATIVE FINANCING

16. In resolution WHA69.23 the Health Assembly also requested the Director-General to promote and advocate sustainable and innovative financing for all aspects of the strategic workplan and to consider its inclusion in WHO financing dialogues.

17. The estimated total financial requirement over the period 2014–2017 for the implementation of the demonstration projects and establishment of the Global Observatory is US\$ 85 million.² As at 20 January 2017, a total of US\$ 2.52 million over the four years had been contributed or pledged by France, Germany, Switzerland, the United States of America and the European Commission to the Global Observatory. A total of US\$ 10.49 million had been contributed by Brazil, Germany, India, Norway, South Africa and Switzerland to the voluntary fund designated for demonstration projects. This includes US\$ 1.20 million that has been contributed or pledged by Norway and Switzerland as matching grants for contributions from developing countries on the basis of half a dollar for each dollar contributed, and US\$ 1.40 million of Swiss matching funds are still available, pending developing country contributions.

18. In total, US\$ 70.59 million is required for all the selected demonstration projects to be completed as proposed and to finalize the development of the Observatory.

19. Given the importance of the subject matter, the specific nature of research and development funding in comparison to the funding of emergencies and other parts of WHO's Twelfth General Programme of Work, the Secretariat is exploring the possibility of organizing a specific high-level

¹ Figure 4.1 in Health product research and development fund: a proposal for financing and operation. Geneva: World Health Organization on behalf of the Special Programme for Research and Training in Tropical Diseases; 2016, available at: http://www.who.int/tdr/publications/r_d_report/en/ (accessed 13 February 2017).

² See document A69/40, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_40-en.pdf (accessed 13 February 2017).

event in 2017 with the purpose of promoting increased investment into research and development funding in areas where the current investment levels are insufficient to meet global public health needs. The Secretariat is undertaking further fundraising for the demonstration projects and full development of the Global Observatory.

Promoting policy coherence

20. The Health Assembly in resolution WHA69.23 additionally requested the Director-General to promote policy coherence within the Organization. The Secretariat thus ensures that key principles agreed with respect to research and development as a follow-up to the report of the Consultative Expert Working Group are also applied in its other areas of engagement, namely in new initiatives such as the Research and Development Blueprint to foster research and development preparedness for infectious diseases with epidemic potential, or the Global Antibiotic Research and Development Partnership, a joint venture by WHO and the Drugs for Neglected Diseases *initiative*.

ACTION BY THE HEALTH ASSEMBLY

21. The Health Assembly is invited to note the report and to provide guidance on future strategic directions.

ANNEX 1

**TERMS OF REFERENCE OF THE GLOBAL OBSERVATORY ON
HEALTH RESEARCH AND DEVELOPMENT****GOAL AND SCOPE**

1. The establishment of a Global Observatory on Health Research and Development was mandated by the Sixty-sixth World Health Assembly in resolution WHA66.22 (2013). In May 2016, the Sixty-ninth World Health Assembly in resolution WHA69.23 recognized the central role of the Global Observatory on Health Research and Development and re-emphasized its overall goal “to consolidate, monitor and analyse relevant information on health research and development needs of developing countries”. The Global Observatory will do so by “building on national and regional observatories (or equivalent functions) and existing data collection mechanisms, with a view to contributing to the identification and the definition of gaps and opportunities for health research and development priorities, and supporting coordinated actions on health research and development.”
2. The scope of data and analyses covered by the Global Observatory on Health Research and Development will prioritize information on “Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases, as well as needs for information on potential areas where market failures exist, and also on antimicrobial resistance and on emerging infectious diseases likely to cause major epidemics.”
3. The Global Observatory on Health Research and Development functions as a centralized and comprehensive source of information and analyses on global health research and development activities, building on existing data and reports from a wide range of data sources and gathering new information, where needed and feasible, with the aim of enabling decisions on priorities in research and development.
4. WHO’s Global Observatory on Health Research and Development has the following terms of reference:
 - (a) to produce comprehensive analyses and syntheses of existing data and information on health research and development for specific health conditions (for example, tuberculosis, malaria and leishmaniasis) in order to identify gaps and opportunities for health research and development and to facilitate coordination in setting priorities for new investments;
 - (b) to monitor and report on global trends related to health research and development, including investments in health research and development and capacity for health research at national level; registered clinical trials and health technologies that are under development (the research and development pipeline); as well as approved medicines;
 - (c) to benchmark and compare health research and development activities across countries and health conditions; for example, comparing investments in health research and development across countries and health conditions with indicators such as burden of disease, gross domestic product, gross domestic expenditures on health, and expenditures on other types of research;

(d) to contribute to improving data collection and sharing standards by making available classifications and terminologies it uses as a step towards consensus building and better harmonization of future data-collection efforts;

(e) to make all data and analyses available to the general public in a web portal;

(f) to conduct comprehensive analysis and syntheses of data based on the advice of the Expert Committee on Health Research and Development.

5. To ensure adequate expert input into the Global Observatory's technical areas of work and analyses, the Secretariat will work closely with its technical departments and their established expert groups and committees in order to develop and/or review analyses and syntheses produced by the Global Observatory. The comprehensive analyses will be produced in close collaboration with experts in the respective subject areas and supported by the Global Observatory's data.

6. In addition, the Secretariat will also seek regular user feedback on the Global Observatory's structure and outputs from national policy-makers, academia, WHO's technical experts and other international governmental organizations and global partnerships, WHO regional offices, civil society and industry stakeholders to continue improving the Observatory's functionality and usability in future versions.

7. The analyses and data provided by the Global Observatory will constitute a major resource for the work of the Expert Committee on Health Research and Development, which aims at providing technical advice to the Director-General on priorities for health research and development.

WORKPLAN AND BUDGET FOR THE GLOBAL OBSERVATORY ON HEALTH RESEARCH AND DEVELOPMENT

8. The estimated costs for continued development of the Global Observatory for the period 2016–2019 are shown in Table 1. Table 2 shows available funds for the two bienniums 2016–2017 and 2018–2019 and the funding gaps. The estimated total net cost for 2016–2019 is US\$ 6.3 million. The total net earmarked funds received or pledged (as of 20 January 2017) are US\$ 1.77 million (net of programme support costs) for 2016–2017. Taking into account the allocated WHO programme budget funds from assessed contributions, the total gross funding gap for 2016–2017 is US\$ 0.32 million. Without additional financial contributions, the total funding gap is estimated at US\$ 2.05 million for 2018–2019.

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