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 Executive Board at its 136th session noted an earlier version of this report, which has been updated in the light of comments made during the Board’s discussion (see in particular paragraph 12 and the Figure illustrating the proposed governance structure of the pooled fund).

2. In decision WHA67(15), the Sixty-seventh World 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 towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases. This report describes the establishment of such a fund, under the management of the Special Programme, as well as its relationship with the Global Health Research and Development Observatory and the future coordination mechanism.

3. In resolution WHA66.22 on follow up of the report of the Consultative Expert Working Group, the Sixty-sixth World Health Assembly requested the Director-General to facilitate through regional consultations and broad engagement of relevant stakeholders the implementation of a few health research and development demonstration projects for which immediate action can be taken. Although the demonstration projects are independent of the possible creation of a pooled fund, they, together with the budget line established by the Special Programme for Research and Training in Tropical Diseases to accommodate their funding, as well as the Global Observatory, could provide the nucleus for the development of the fund. WHO and the Special Programme for Research and Training in Tropical Diseases will work in collaboration to maximize the opportunities to use the demonstration projects to inform the development of the final research and development fund.

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1 See summary record of the Executive Board at its 136th session, ninth meeting.
2 See document WHA67/2014/REC/1 for the decision.
4 The report on the intermediate evaluation of the demonstration projects is contained in document A68/34 Add.1.
A POOLED FUND FOR GLOBAL HEALTH RESEARCH AND DEVELOPMENT

4. In resolution WHA66.22, the Health Assembly recognized the interlinkage of monitoring, coordination and financing of health research and development. That interlinkage will inform the scope of the fund, which would finance research and development projects to address priority research gaps as identified by the Global Observatory and the future coordination mechanism. A functional research and development observatory and a coordination mechanism are essential to ensuring that the fund meets the Health Assembly’s expectations. The fund will be managed by the Special Programme, and the Global Observatory and the coordination mechanism will be managed by the Secretariat. The focus of the fund would be the development of effective and affordable health technologies related to type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases, taking into account the principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination, namely delinkage of the delivery price from research and development costs, the use of open knowledge innovation, and licensing for access.1 The contractual arrangements for the funding of projects will ensure that any future health technologies financed through the fund will be accessible to those in need. Arrangements could include clauses on at-cost or preferential pricing, non-exclusive licensing agreements or licences to WHO or the Special Programme.

5. The priorities of the fund would be informed by the analysis of the research landscape provided by the Global Observatory. General priority areas would be recommended by the coordination mechanism. WHO is currently examining options for such a mechanism.

6. The Health Assembly, on the recommendation of the Programme, Budget and Administration Committee of the Executive Board, would decide on the allocation of the research and development fund to be apportioned to support research and development projects and to support the Global Observatory and the coordination mechanism.

MANAGEMENT OF THE FUND WITHIN THE SPECIAL PROGRAMME FOR RESEARCH AND TRAINING IN TROPICAL DISEASES

7. The Joint Coordinating Board of the Special Programme for Research and Training in Tropical Diseases will be responsible for the oversight of the funding mechanism under the Special Programme’s management. It will report on its activities to the Health Assembly every two years. The Joint Coordinating Board is made up of 28 members nominated by Member States. The structure provides a balance of representatives of donor countries, representatives of disease-endemic countries, the cosponsors of the Special Programme and civil society. The new functions of the Joint Coordinating Board would require a review of the number of its annual meetings and membership of its governing bodies and subcommittees. Management of conflicts of interest for members is through the process approved by the Joint Coordinating Board at its 37th annual session in June 2014.2

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2 See the report of the 37th session of the Joint Coordinating Board (available at http://www.who.int/tdr/about/governance/jcb/jcb37_report.pdf?ua=1, accessed 16 October 2014).
8. A new scientific working group would be established within the Special Programme under the governance of its Joint Coordinating Board. The scientific working group’s role would be to prepare and manage regular calls for research and development project proposals focusing on priority needs in line with WHO’s global strategy and plan of action on public health, innovation and intellectual property. Its work would be based on scientific criteria and informed by the priorities identified by the Global Observatory and the recommendations of the coordination mechanism. Its tasks would include reviewing the submitted research and development projects, overseeing monitoring, and reporting on implementation. The Joint Coordinating Board would approve the final selection of projects as submitted by the scientific working group. The membership of the scientific working group would reflect the scientific disciplines required, experience of product development, gender balance and representation of disease-endemic countries, taking into account the expanded scope of diseases from the Special Programme’s current mandate. Management of conflicts of interest for members of the scientific working group would follow WHO’s current policy for expert committees.

9. A secretariat would be established within the Special Programme to support the work of the scientific working group, manage calls for proposals, monitor implementation of the selected projects and prepare reports. The Figure illustrates the suggested governance of the pooled fund.

**Figure. Proposed governance structure of the voluntary pooled fund**

**FUNDING**

10. The premise for the establishment of a pooled fund and the Global Observatory depends on the availability of new funds. The Joint Coordinating Board of the Special Programme for Research and Training in Tropical Diseases has stated that the Special Programme’s involvement depends on the identification of new funds and not a reallocation of the Special Programme’s existing or future resources. It stated that fundraising should be the responsibility of WHO. There are different ways to
organize the financing of such a mechanism by voluntary means. An earlier assessment by the Secretariat describes in more detail how different existing mechanisms are financed.¹

(i) Some organizations rely on ad hoc voluntary contributions, including the Special Programme for Research and Training in Tropical Diseases and the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, as well as most product-development partnerships. The disadvantage of such a mechanism is that funding is difficult to predict.

(ii) Other organizations use a replenishment model, in which each donor independently fixes its contribution in the form of a pledge. Pledges are public, legally non-binding statements on planned contributions. Contributions are voluntary as donors themselves fix the amount of pledges, but such a mechanism provides for some planning security as pledges span a certain time period. Examples of this model are the Global Fund to Fight AIDS, Tuberculosis and Malaria, the International Drug Purchase Facility (UNITAID) and the GAVI Alliance, with the latter using additional innovative financing mechanisms.

11. Countries may want to consider implementing innovative funding mechanisms at national or regional levels to raise financial resources and to ensure a sustainable flow of funding. The pooled fund should also be able to accept voluntary, preferably unspecified funding by non-State actors such as philanthropic foundations following WHO’s rules on acceptance of donations. The Special Programme for Research and Training in Tropical Diseases will ensure appropriate management of conflicts of interest in subsequent decisions on the allocation of funds, in other words that such contributions have no impact on the process of selection of projects.

FINANCIAL MANAGEMENT OF THE FUND

12. There are two main options for the financial management of the fund account (receiving donations and making payments). If the fund is held directly by the Special Programme for Research and Training in Tropical Diseases, the current arrangement is for WHO to implement an administrative charge that covers costs associated with the administration of the Special Programme’s designated funds. Alternatively, the fund could be held as a trust fund account by a third party, for example, the World Bank, which is a cosponsor of the Special Programme for Research and Training in Tropical Diseases. The third party trustee would disburse funding on the Joint Coordinating Board’s instruction, in line with the Health Assembly’s recommendation regarding the division of the research and development fund. It would invest the funds according to the trustee’s investment strategy and report on financial management to the Joint Coordinating Board. WHO has positive experience with both models. However, following internal discussions, it is suggested that the fund be held directly by the Special Programme for Research and Training in Tropical Diseases. This option is more efficient as it avoids an additional layer of administration and the need to coordinate the relationship with the trustee. Under this model, assets will be invested by WHO on behalf of the fund and in agreement with WHO’s investment strategy. Consistent with the Secretariat’s policy on programme support costs, 13% will be charged to cover administrative and management costs. The budget ceiling allocated to

¹ See the report by the Secretariat on 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 (document A/CEWG/3) and the related fact sheets on funding and research mechanisms (http://www.who.int/phi/2-funding_mechanism_factsheets_6nov12.pdf?ua=1, accessed 13 October 2014).
Special Programme for Research and Training in Tropical Diseases would need to be adjusted accordingly.

**ACTION BY THE HEALTH ASSEMBLY**

13. The Health Assembly is invited to note the report and to consider the establishment of a pooled fund for voluntary contributions towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases to be hosted by the Special Programme for Research and Training in Tropical Diseases.