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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 resolution WHA66.22 the Health Assembly endorsed a strategic work plan to improve monitoring and coordination of 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, and agreed to its further development through the broad engagement of public and private entities, academia and civil society.

2. The Health Assembly also requested the Director-General, inter alia to: (1) establish a global health research and development observatory within the Secretariat in order to monitor and analyse relevant information on health research and development; (2) review existing mechanisms in order to assess their suitability to perform the coordination function of health research and development; and (3) explore and evaluate existing mechanisms for financial contributions to health research and development and, if there is no suitable mechanism, to develop a proposal for effective mechanisms, and a plan to monitor their effectiveness independently.

3. This report describes the work done to date in response to these requests.

GLOBAL HEALTH RESEARCH AND DEVELOPMENT OBSERVATORY

4. The Global Health Research and Development Observatory will build on existing sources of information, while recognizing the considerable gaps that exist in the capacity of many countries to produce data of this kind. Success will rely on establishing effective networks and supporting Member States to both contribute to and gain benefit from an observatory.[1] The information and data available at the Global Observatory would enable users to:

- analyse data on financing for global health research and development;
- produce analyses to inform the management of national research and development portfolios;

[1] The challenges in establishing an observatory were set out in a recent paper in The Lancet: Røttingen J-A, Regmi S, Eide M, Young AJ, Viergever RF, Årdal C et al. Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory? The Lancet. 2013; 382:1286–1307. doi:10.1016/S0140-6736(13)61046-6).

- identify research and development priorities at national, regional and global levels;
- benchmark activities, for instance between countries; and
- monitor and evaluate trends against national, regional and global strategies.

5. The Secretariat has started the process of establishing the Global Observatory.[1] It ran an informal workshop in February 2013, followed by an exercise to map stakeholders.[2] Specific activities have included the creation of a product pipeline database and exploration of ways to exploit the systems and networks of a database on Africa-based research funders. A review of published health research and development priorities that have been identified through WHO's technical programmes is being synthesized into a searchable database, as one way of providing a systematic overview. Member States and the Secretariat are organizing regional and global consultations in order to define more precisely the scope of the Global Observatory and the flow of information between national, regional and global observatories. The Secretariat is holding a public briefing at WHO headquarters on 6 December 2013 on the actions taken to date.

REVIEW OF THE SUITABILITY OF EXISTING MECHANISMS TO COORDINATE HEALTH RESEARCH AND DEVELOPMENT

6. While there is currently no existing mechanism that coordinates health research and development at the global level, there are numerous mechanisms that seek to coordinate research and development within a specific disease area. The Secretariat has reviewed these disease-specific mechanisms in order to generate options for global coordination, and has identified three models for consideration by Member States:

(a) passive coordination achieved through better sharing of information;

(b) active coordination through networks of researchers agreeing on priorities and collaboration; and

(c) managed coordination through formal structures to manage the research undertaken and the allocation of resources to support them.

Passive coordination: better sharing of information

7. Coordination can be improved when all stakeholders have access to the same, standardized information and analysis to guide their decision-making. However, a significant weakness in current global health research and development efforts is the absence of quality information that provides a comprehensive overview of what health research is being supported, who is supporting it, and how and where it is being supported.

[1] See A global health R&D observatory – developing a case for its development. Geneva: World Health Organization; 2013 (draft working paper 1, http://www.who.int/entity/phi/documents/dwp1_global_health_rd_observatory_16May13.pdf).

[2] See REPORT: WHO Informal workshop – monitoring financial flows in support of health research & development. Geneva: World Health Organization; 2013 (http://www.who.int/entity/phi/1-REPORT_WHO_RandD_mapping_workshop_2013.pdf).

Active coordination: research networks, joint planning and collaboration

8. Providing better information may lead to better coordination, but real improvement will require more active interventions to bring the various stakeholders together, identify priorities and agree on separate or collaborative research to address them. The Consultative Expert Working Group has recommended the establishment of a new global advisory body. Such a body would be able to take the data and analysis provided by the Global Observatory and make recommendations on research priorities.

9. Meetings or conferences attended by members of research networks, professional associations of researchers and research funders are well established in a majority of disease-focused groups, and donor agencies often bring these types of groups together. However relatively few forums focus on the health issues identified in the Global strategy and plan of action on public health, innovation and intellectual property. One new proposal would be to establish an annual global health research and development stakeholder conference, in order to maintain focus and momentum on these issues. Ideally, it would take place in a different region each year and be hosted by a major research institute active in this area. The agenda would be informed in part by the analysis provided by the Global Observatory and shaped by a new global advisory body.

10. Within WHO, the Advisory Committee on Health Research could be reconstituted to fulfil this advisory role. Membership would be drawn from the existing independent experts who currently advise the WHO technical programmes, thereby ensuring coordination within WHO; they would be supplemented by other stakeholders. In addition, such a body within WHO could provide a focus for interaction with existing groups in the development and donor community that fund research (the ESSENCE group, for example, which has its secretariat within the Special Programme for Research and Training in Tropical Diseases) and other research funders (Heads of International Research Organizations, for instance).

11. The impact of such a global advisory body would be measured by the degree to which it oriented existing actions, networks and the funding behaviour of research bodies towards the agreed global priorities. The Global Health Research and Development Observatory would provide a mechanism for monitoring this impact.

Managed coordination

12. Managed coordination, the third model identified above, requires formal structures to manage the research undertaken and the allocation of resources to support them. While no single fund could meet all health research and development needs, the creation of any new funding mechanism would necessarily introduce strong, managed coordination of the research that the new fund would support. The priorities supported under such a financing mechanism would be those identified through the Global Advisory Body and discussed and agreed at the annual research and development stakeholder conference. There would be a strong interconnection between the Global Observatory, the priorities it identified, and the research supported under any new financing mechanism. Improved coordination and an increase in the product pipeline for neglected diseases would be outcomes that would be monitored by the Global Observatory.

In summary

13. The Global Health Research and Development Observatory has as its primary objective the collection and sharing of information which should, in time, improve access to comparable

information on health research and development pipelines and on who is funding what research and where. The Global Observatory would also act as the monitoring mechanism to track the change in funding flows and improvements in the product pipeline. The Global Observatory, when operational, would therefore meet the requirements for the first coordination model indicated above.

14. Possible measures for bringing about the second model of coordination include the establishment of a global research and development advisory body (through adaptation of the WHO Advisory Committee on Health Research, for instance) and the institutionalization of an annual research and development stakeholder conference. The Global Observatory would, in time, provide data that could be used to provide an analysis of the gaps and priorities in health research and development. A global advisory body would provide a high-level focus for advocacy around these priorities, while a stakeholder conference could be one arena where researchers, developers and funders could discuss and agree on separate or collaborative research agendas.

15. Managed coordination, the third model of coordination, requires formal structures to manage the research undertaken and the allocation of resources to support them. The creation of any new funding mechanism would introduce strong, managed coordination of the research that the new fund would support. The priorities supported under such a financing mechanism would be those identified through the global advisory committee and could be endorsed at the annual stakeholder conference.

EXPLORATION AND EVALUATION OF EXISTING MECHANISMS FOR CONTRIBUTIONS TO HEALTH RESEARCH AND DEVELOPMENT

16. The Secretariat has explored the option of adapting and using an existing mechanism to increase the funding of research and development for diseases that disproportionately affect developing countries. It has identified a number of mechanisms that could be suitable starting points (see Table below) and assessed them against a set of criteria in order to explore their suitability. For each of the mechanisms, the Secretariat has developed a factsheet that can be found on the WHO website.[1] The factsheets and assessments were shared with the respective organizations, and feedback received was taken into consideration.

Identification of existing mechanisms

17. Any mechanism to pool funding for research and development at global level would have to be able to:

- receive voluntary funding from a variety of sources, including WHO Member States, and
- manage and disburse funds to private and/or public entities for the financing of research in various areas of diseases that disproportionately affect developing countries.

18. The mechanism would also have to put in place an appropriate access policy to ensure that any product developed using its funds is made available at an affordable price in countries in need.

19. The purpose of the mechanism would be to finance health needs-driven research and development based on evidence. The analysis therefore starts from the assumption that suitability for

[1] http://www.who.int/phi/en/.

such a task – financing of research and development in the area of health – would require that the mechanism selected already operates in the health sphere. The financing mechanism would not be tasked with identifying research gaps and priorities. The data gathered by the Global Health Research and Development Observatory would allow for the identification of research gaps. Based on this and other sources of information, an appropriate process would take on a coordinating role and identify research priorities to be funded by the financing mechanism.

20. Given the goal of establishing an international mechanism, the assessment presented in this report is limited to existing international or regional mechanisms that could in principle pool funding for health research and development. It does not therefore include national organizations or mechanisms that depend on, or were created by, an individual or a company, such as the Bill & Melinda Gates Foundation or the Wellcome Trust. Likewise, it does not include national or regional research programmes such as Horizon 2020 – the European Union's Framework Programme for Research and Innovation (2014–2020).

21. A number of product development partnerships are active in the area of research and development for diseases that disproportionately affect developing countries (see Annex 1). Some of the major international partnerships (the Drugs for Neglected Diseases initiative (DNDi), the Medicines for Malaria Venture (MMV) and the Program for Appropriate Technology in Health (PATH)) were selected as examples to assess the potential of product development partnerships to host a new funding mechanism. The three partnerships were chosen because they are among the largest product development partnerships in terms of funding. Furthermore, PATH and DNDi have an unusually broad scope, because they do not focus on specific diseases or technologies.

22. It should be noted that a product development partnership hosting a pooled fund might have a conflict of interest in that it would find itself in competition with other such partnerships and organizations as a potential beneficiary of the funding mechanism. Elevating one product development partnership to become an overarching funding mechanism that would finance research and development projects managed by other entities is also likely to change the character of the partnership concerned. The International Vaccine Institute (IVI), the European Molecular Biology Laboratory (EMBL) and the European and Developing Countries Clinical Trials Partnership (EDCTP) were analysed because they have many attributes of a product development partnership in the way they engage in health research and development, but they possess a different legal status: IVI is an intergovernmental organization and EMBL is an intergovernmental institution with legal personality, both established through treaties, while EDCTP is a European Economic Interest Grouping. The International Agency for Research on Cancer (IARC) was included as a WHO agency and owing to its long-standing experience in managing research projects.

23. The African Network for Drug and Vaccine Innovation (ANDI), the Roll Back Malaria Partnership (RBM), and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) were included because of their involvement in financing and/or coordinating of research and other activities with respect to neglected diseases.

24. The Global Alliance for Chronic Diseases (GACD) was selected as an example of the coordination of research programmes financed by different entities of both developed and developing countries while the Human Frontier Science Programme (HFSP) is an international programme financing research on the complex mechanisms of living organisms.

25. Assessments were also made of the suitability of the major international mechanisms responsible for the procurement of health products for the benefit of developing countries, namely: the

Global Fund to Fight AIDS, Tuberculosis and Malaria; the GAVI Alliance; and the International Drug Purchase Facility, UNITAID.

26. While this report focuses on identifying a mechanism that could take charge of the totality of the mandate proposed, it might also be possible to fulfil this mandate through a network of funding mechanisms active at regional level.

Possible organizational structure

27. Legally, a funding mechanism could be set up in different ways. In particular, a number of the existing mechanisms use a trust fund model, based on two distinct entities:

- a governance and decision-making organ, supported by (advisory) committees, and
- a trust fund hosted by a (development) bank or other organization, whose function is purely fiduciary (trustee).

28. In this model, the decision-making organ takes the substantial decisions on resource mobilization, replenishment strategies and what gets financed and monitors outputs, outcomes and impact. The trust fund manages the funds and releases funding following instructions from the decision-making body. The decision-making organs often include a board that exercises general oversight, takes strategic decisions and usually appoints subsidiary organs that provide scientific advice, such as scientific advisory committees, as well as financial committees. Should this model be used, the board of the health research and development financing mechanism would decide on research priorities based on the data gathered by the Global Observatory. A subsidiary scientific organ, constituted on the basis of agreed eligibility and selection criteria, would make recommendations on individual funding decisions. Examples of such a governance structure are the Global Fund's Technical Review Panel and UNITAID's Proposal Review Committee. To safeguard public health interests from undue influence, a mechanism must be put in place to manage any form of real, perceived or potential conflict of interest.

29. The trustee is responsible for day-to-day financial management and is financially accountable for the entrusted funds. It disburses funding on the instruction of the decision-making body, invests the funds according to the trustee's investment strategy and reports on financial management to the decision-making body.

30. Such an arrangement has been used in the past. For example, the World Bank has served as the trustee for the Global Fund since its creation in 2002. The World Bank is also the treasury manager for the International Finance Facility for Immunisation, an innovative financing institution whose aim is to provide funding for immunization programmes through the GAVI Alliance.

31. Another example of a trust fund managed separately from the decision-making organ can also be found within WHO. The Organization hosts the trust fund of the Codex Alimentarius with the objective of helping developing and transition economy countries enhance their level of effective participation in the Codex Alimentarius Commission.[1]

[1] http://www.who.int/foodsafety/codex/trustfundbackground/en/index.html.

32. To comply with the principles of good governance, only mechanisms with transparent governance structures and effective internal and external accountability would be considered suitable to pool funds for health research and development. Given the task of financing activities for the benefit of developing countries, such governance structures would require engagement of the relevant stakeholders: recipient and donor governments, researchers and nongovernmental organizations, including civil society and patient organizations, as well as the research and development "industry", with the latter represented through the relevant associations. Not all of these groups would have to have an equal number of seats in the decision-making body. There could be further differentiation in terms of voting and non-voting board members. Stakeholders could also have observer status, be represented in other governing bodies or be involved through specific mechanisms such as advisory bodies. Appropriate management of any form of real, perceived or potential conflict of interest would need to be ensured.

33. As outlined in the report by the WHO Secretariat to 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,[1] irrespective of the form chosen for a new funding mechanism, a number of factors are critical for its success. These include:

- political commitment to the establishment of the mechanism and its mission, or to the adaptation of an existing mechanism;
- inclusive governance, representing the interests of policy-makers, researchers and developers, funders and beneficiaries of research;
- a broad, stable, predictable and adequate financial basis and a financial structure that minimizes procedural obstacles for contributors; and
- a clearly defined, focused and realistic objective of the mechanism and a clear implementation model that can demonstrate outcomes; and an effective and efficient system for monitoring the disbursement of funds and evaluating performance, thereby guaranteeing value for money.[2]

Assessment of existing mechanisms

34. The Secretariat identified a set of criteria for assessing mechanisms and defined how the mechanisms were to be assessed against these criteria (for details of the method of rating, see Annex 2).

35. The following criteria were used.

- **Adaptability.** Can the mechanism be easily adapted to take up the global funding of health research and development? One consideration to be taken into account would be whether this would require a long process, such as ratification of an amendment to an international treaty.

[1] Document A/CEWG/3.

[2] See: WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Review of existing and potential sources and mechanisms of assistance (document A/FCTC/COP/1/4).

- **Scope of research.** Does the scope of the mechanism already encompass diseases that disproportionately affect developing countries? What technologies (medicines, vaccines, medical devices) are researched or procured to address these diseases?

- **Geographical scope.** Is the mechanism geographically limited regarding its activities and if so, to what extent (for example, focused on one region or a limited set of countries)?

- **Inclusive governance structure.** Does the main governing body include relevant stakeholders?

- **Experience in funding research and development.** Does the mechanism have proven experience in financing research projects, including the identification of areas of research and the allocation of funds and monitoring of funding with regard to external research projects?

- **Experience in managing research and development.** Does the mechanism have proven experience in managing research projects?

- **Transparency.** Are the criteria used to distribute funding and the minutes of governing body meetings publicly available?

36. The criteria were not weighted for their relative merits. The assessment (Table) is designed to give an indication regarding the suitability of the various existing mechanisms. It does not aim to be a scientific quantitative assessment, but rather to point towards those mechanisms that might be worth exploring further.

Table Product development partners

	Adaptability	Scope		Geographical coverage	Experience in funding research and development	Experience in managing research and development	Inclusive governance structure	Transparency	
		Disease areas covered	Technologies covered					Criteria to fund research and development publicly available	Minutes of governing body meetings publicly available
ANDI	***	***	***	**	***	***	**	***	*
EDCTP	**	**	***	**	***	*	**[1]	***	*
EMBL	*	***	**	*	*	***	*		*
GAVI Alliance	***	**	*	**	*	*	***		***
GACD	***	**	***	***	**	*	**		*
Global Fund	**	**	***	***	*	*	***		***
HFSP	***	***	***	***	***	*	*	***	*

[1] Membership will be open to non-members of the European Economic Area in the future.

	Adaptability	Scope		Geographical coverage	Experience in funding research and development	Experience in managing research and development	Inclusive governance structure	Transparency	
		Disease areas covered	Technologies covered					Criteria to fund research and development publicly available	Minutes of governing body meetings publicly available
IARC	**	*	**	***	*	***	*		***
IVI	*	**	*	**	*	***	**		*
RBM	***	*	***	**	*	*	***		***
UNITAID	***	**	***	***	**	*	**	***	***
TDR	***	**	***	***	***	***	***	**[1]	***
DNDi	**	**	**	***	***	***	**	***	*
MMV	**	**	*	***	***	***	**	***	*
PATH	**	***	***	***	***	***	*	*	*

37. The assessment shows that all the selected existing mechanisms meet a number of the criteria. While some meet more criteria than others, no existing mechanism currently meets all the criteria. Thus, if any existing mechanism were to be selected to host a new funding mechanism, some adaptation would be required. Some changes needed to address certain criteria (such as publishing the minutes of governing body meetings) may be relatively easy to implement, while other criteria (such as an inclusive governance structure) may be difficult to meet because they concern the functioning of the individual mechanisms, each of which has a governance structure tailored to its particular needs.

38. However, it may be concluded from this assessment that in principle a number of existing mechanisms are suitable to host a new funding mechanism.

39. In line with resolution WHA66.22, the Secretariat has not at this point developed a proposal for new mechanisms.

40. Should Member States decide to pursue the possibility of using an existing mechanism to hold a pooled fund for voluntary contributions towards research and development for diseases that disproportionately affect developing countries, the next step would be to explore whether any of the mechanisms, among those assessed as meeting most criteria, would be willing to take over such a task.

OTHER ACTIVITIES BY THE SECRETARIAT

41. The strategic work plan contained in resolution WHA66.22 has a number of additional elements.

[1] TDR's Joint Coordination Board in 2013 has requested that criteria are developed and made available publicly. They should be in place in the second half of 2014.

42. With respect to the facilitation of demonstration projects, the Director-General is convening a technical consultative meeting on 3–5 December 2013 in order to help identify such projects, as called for by decision WHA66(12). An accompanying report (document EB134/27) will summarize the outcome of the meeting.

43. Further work will be done to develop norms and standards for the classification of health research and development, building on existing sources, in consultation with Member States and relevant stakeholders, as well as to carry out the other elements of the strategic work plan.

ACTION BY THE EXECUTIVE BOARD

44. The Board is invited to note this report and to provide further guidance on future strategic directions and activities.

ANNEX 1

PRODUCT DEVELOPMENT PARTNERSHIPS AND RELATED ENTITIES

In 2011, funding for product development partnerships involved in research into neglected diseases totalled US$ 451.4 million. This represented 14.8% of global funding for research on neglected diseases. Four product development partnerships – Program for Appropriate Technology in Health, Medicines for Malaria Venture, the International AIDS Vaccine Initiative, and the Aeras Global TB Vaccine Foundation – accounted for over half of all funding for product development partnerships.[1]

HIV/AIDS

- International AIDS Vaccine Initiative
- International Partnership for Microbicides
- South African AIDS Vaccine Initiative

Malaria

- Malaria Vaccine Initiative
- Medicines for Malaria Venture

Tuberculosis

- Aeras Global TB Vaccine Foundation
- Foundation for Innovative New Diagnostics
- Global Alliance for TB Drug Development
- Tuberculosis Vaccine Initiative

Other partnerships include

- Drugs for Neglected Diseases Initiative
- Institute for OneWorld Health
- European and Developing Countries Clinical Trials Partnership
- European Vaccine Initiative
- Infectious Disease Research Institute
- Innovative Vector Control Consortium
- International Vaccine Institute
- Program for Appropriate Technology in Health
- Sabin Vaccine Institute

Source: Adapted from: Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization and World Trade Organization; 2012.

[1] Data compiled using G-Finder, a public search tool on global funding of innovation for neglected diseases (https://g-finder.policycures.org/gfinder_report/).

ANNEX 2

METHOD FOR ASSESSING EXISTING MECHANISMS FOR CONTRIBUTIONS TO HEALTH RESEARCH AND DEVELOPMENT

Adaptability: Organizations scored three stars if an adaptation would be relatively easy to achieve, e.g. through a board decision. It scored one star if a ratification process would be necessary, as for example in the case of the European Molecular Biology Laboratory and the International Vaccines Institute. The product development partnerships scored two stars, as it was considered challenging to elevate a product development partnership that is managing research and development projects into an overarching funding mechanism that would finance projects carried out by the various product development partnerships in other organizations. This would in fact change the character of the partnership concerned and transform it into a financing mechanism.

Scope of research:

- **Disease areas covered:** Mechanisms scored one star if they cover no disease or only one disease that disproportionately affects developing countries; they scored two stars if they cover more than one disease, and three stars if all disease areas are covered. This is independent of whether the organization funds research and development. Thus an organization such as the Global Fund, which does not fund research and development, could still score two stars.

- **Technologies covered:** This relates to the scope and spread of medical technologies researched or procured. Mechanisms scored one star if they cover only one relevant technology (vaccines, medicines, diagnostics and other medical devices). They scored two stars if they cover more than one technology, and three stars if there are no limitations regarding the scope of research in this regard.

Geographical scope: The scoring depends on whether and to what extent the mechanism is geographically limited regarding its activities the European Molecular Biology Laboratory, for instance, scored one star, as it focuses on one region and does not include developing countries. The African Network for Drug and Vaccine Innovation and the European and Developing Countries Clinical Trials Partnership scored two stars, as they focus on one region, Africa, and thus include developing countries. The GAVI Alliance scored two stars because 73 countries are eligible for funding, while the Global Fund scored three stars as more than 120 countries were eligible for grants in 2012.

Inclusive governance structure: Mechanisms scored one star if two or less of the following five groups are represented:

- high-income countries
- developing countries
- researchers/research organizations
- civil society/patient organizations
- private sector/industry.

They scored two stars if at least three groups are represented and three stars if four or more groups are represented. This does not mean that all these groups necessarily have to be represented in the

decision-making body of a new mechanism, be represented in the same proportions or have equal (voting) rights.

Experience in funding research and development: Experience in financing research projects includes identification of areas of research, as well as allocation and monitoring of funding for external research projects, but does not include the management of research projects. Most mechanisms scored either three stars or one star, depending on whether they have experience of this kind.

Experience in managing research and development: Experience in managing research projects. For example, PDPs typically identify particular projects, such as a diagnostic for tuberculosis or a paediatric version of an existing antiretroviral, and manage the research often by mandating competent external entities to do the required work. Most mechanisms scored either three stars or one star, depending on whether they have experience of this kind.

Transparency: The column headed "Criteria to fund research and development publicly available" refers to criteria on which to allocate funding for research and development. Mechanisms that do not fund research and development, such as the Global Fund, do not have such criteria and thus the relevant box has been left blank. Mechanisms scored either three stars or one star, depending on whether they publish such information. It should be noted that, although the assessment uses two indicators (public availability of criteria used to distribute funding and minutes of governing body meetings), transparency can also be achieved by different means, including allowing observers to attend governing body meetings.

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