



## **Follow-up to the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination – Report of the open-ended meeting of Member States**

The Director-General has the honour to transmit to the Sixty-ninth World Health Assembly the report of the Open-ended meeting of Member States to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development (see Annex).

## ANNEX

### **REPORT OF THE OPEN-ENDED MEETING OF MEMBER STATES TO ASSESS PROGRESS AND CONTINUE DISCUSSIONS ON THE REMAINING ISSUES IN RELATION TO MONITORING, COORDINATION AND FINANCING FOR HEALTH RESEARCH AND DEVELOPMENT**

The Open-ended meeting of Member States to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development was held from 2 to 4 May 2016 at WHO headquarters in Geneva as requested by resolution WHA66.22. The meeting was chaired by Mr Bhanu Pratap Sharma from India. Ms T. Dussey-Cavassini from Switzerland was elected as Vice-Chair. Representatives from Member States, intergovernmental organizations, nongovernmental organizations in official relations with WHO and special invitees attended the first two days of the meeting. The third day was a closed meeting for Member States only.

The meeting adopted its agenda and proceeded as outlined in the Proposed programme of work (see Appendix 1). The presentations that were made are available on the WHO website<sup>1</sup> after seeking permissions from the presenters. A progress report was submitted to the open-ended meeting (see Appendix 2). The meeting also discussed the draft decision/resolution, set out in Appendix 3 of the present document, which is forwarded to the Sixty-ninth World Health Assembly for its consideration. The meeting recommended that the Health Assembly set up a drafting group to finalize discussions on the draft decision/resolution.

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<sup>1</sup> <http://www.who.int/phi/cewg-presentations/en/> (accessed 9 May 2016).

## Appendix 1



**Open-ended meeting of Member States to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development  
Geneva, 2–4 May 2016**

**A/RDMCF/1 Add.1  
22 April 2016**

## **Proposed programme of work**

**Day 1  
Morning session**

**Monday, 2 May 2016 (open meeting)  
09:30–12:30**

### **Agenda items**

- 1. Opening of the meeting**
- 2. Election of Officers**
- 3. Adoption of the agenda**
- 4. Method of work**
- 5. Assessment of progress and continuation of 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**
  - (a) Progress in implementing resolution WHA66.22 (2013)

*Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation*
  - (b) Presentations of WHO initiatives related to research and development relevant to the Consultative Expert Working Group on Research and Development: Financing and Coordination:
    - The research and development blueprint for emerging pathogens likely to cause severe outbreaks in the near future, and for which few or no medical countermeasures exist

*WHO Secretariat*

- Research and development in the context of the global action plan for antimicrobial resistance

*WHO Secretariat*

- (c) Presentation by the previous Chair of the Commission on Intellectual Property Rights, Innovation and Public Health, and co-Chair of the United Nations Secretary-General's High-level Panel on Access to Medicines

*Ms Ruth Dreifuss*

- (d) Discussion

## Afternoon session

**14:00–17:00**

### Agenda item 5 (continued)

- (e) Policy coherence in health research and development

*WHO Secretariat*

- (f) Discussion

- (g) Presentations on progress in implementation of the various elements of the strategic workplan agreed in resolution WHA66.22 (2013) on follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination:

- Global health research and development observatory, coordination of health research and development, and demonstration projects

*WHO Secretariat*

- Global health research and development fund: a proposal for financing and operation

*UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases*

- (h) Discussion

**Day 2**  
**Morning session**

**Tuesday, 3 May 2016 (open meeting)**  
**09:30–12:30**

**Agenda item 5 (continued)**

- (i) Discussion (continued)

**Afternoon session**

**14:00–17:00**

**Agenda item 5 (continued)**

- (j) Overview of current funding situation for research and development related to the priority diseases of the Consultative Expert Working Group on Research and Development: Financing and Coordination

*Policy Cures*

- (k) Discussion on future financing of health research and development:
  - Establishing a voluntary pooled fund for health research and development
  - Financing of the strategic workplan in follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
- (l) Discussion “on the remaining issues in relation to monitoring, coordination and financing for health research and development”

**Day 3**

**Wednesday, 4 May 2016 (closed meeting – Member States only)**

**Morning session**  
**Afternoon session**

**09:30–12:30**  
**14:00–17:00**

**Agenda item**

- 6. Report of the Open-ended Meeting of Member States to the Sixty-ninth World Health Assembly**

## Appendix 2



**Open-ended meeting of Member States to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development**  
**Provisional agenda item 5**

**A/RDMCF/2**  
**22 April 2016**

## **Progress report**

### **Report by the Secretariat**

1. In May 2013, the Sixty-sixth World 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, through which 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, safe and quality health products for which existing market mechanisms fail to provide incentives for health research and development ... 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 investments in health research and development for diseases disproportionately affecting developing countries”.

2. In the resolution the Health Assembly 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, it requested the Director-General, among other things:

- (a) “to establish a global health research and development observatory within the 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 health research and development demonstration 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”.

3. The Director-General was also requested to convene another open-ended meeting of Member States before the Sixty-ninth World Health Assembly 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 analyses included in the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination.<sup>1</sup> This report responds to that request.

## GLOBAL OBSERVATORY ON HEALTH RESEARCH AND DEVELOPMENT

4. A demonstration version of the Global Observatory on Health Research and Development was launched at the beginning of 2016. In its first phase, the Observatory integrates available information on funding for health research and development, health products in the pipeline, clinical trials and research publications.<sup>2</sup> In subsequent phases, the Observatory’s functions and remit will be broadened as it receives additional resources, data and analyses. In addition to an online portal,<sup>3</sup> a key output of the Observatory will be the development of standard and on-demand analyses of gaps in health research and development, highlighting the main findings of a review of the data collected by the Observatory and contributing to priority-setting mechanisms as part of the coordination function for health research and development. In doing so, it will also support capacity strengthening at regional and national levels in the governance of health research and development and innovation for improved access.

5. Additional activities towards the Observatory’s goals and objectives include supporting the publication of a peer-reviewed series on “Informing the establishment of the WHO Global Observatory on Health Research and Development”<sup>4</sup> and, resources permitting, investing in finding efficient solutions to common problems in the sharing of research and development data, such as inconsistencies in what is reported and in terminologies and methods of data collection, in collaboration with key partners in this field. These activities will also contribute to capacity-building by sharing knowledge and tools and facilitating the development of norms and guidelines for future data collection and sharing.

6. The goals and objectives of the Observatory make it the most suitable option for hosting a broad range of data on health research and development and for meeting the associated information-sharing and capacity-building needs. Using the existing Observatory platform to strengthen and facilitate sharing of information on antimicrobial resistance, emerging diseases likely to cause major epidemics, and other diseases will facilitate global data analysis and comparisons and pave the way for more coordinated approaches to priority setting for health research and development.

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<sup>1</sup> Document A66/23 ([http://apps.who.int/gb/ebwha/pdf\\_files/WHA66/A66\\_23-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_23-en.pdf), accessed 4 April 2016).

<sup>2</sup> Kieny MP, Viergever RF, Adam T, Boerma T, Røttingen JA. Global platform to inform investments for health R&D. *Lancet*, 2016, 387:1157 (<http://who.int/research-observatory/en/>, accessed 4 April 2016).

<sup>3</sup> <http://www.who.int/research-observatory/portal/en/> (accessed 8 April 2016).

<sup>4</sup> <http://www.health-policy-systems.com/series/GlobalObs> (accessed 8 April 2016).

## HEALTH RESEARCH AND DEVELOPMENT DEMONSTRATION PROJECTS

7. Regional calls for proposals with consultations and broad engagement of relevant stakeholders identified 22 health research and development projects. Pursuant to decision WHA66(12) (2013), the Director-General convened a global technical consultative meeting of experts in Geneva, 3–5 December 2013<sup>1</sup> to discuss further the projects in line with the guidance provided by the Health Assembly's decision. The experts reached consensus on eight potential demonstration projects, and recommended the top four for implementation. In light of the recommendations of the meeting, two out of the four projects, both related to leishmaniasis, were merged. In May 2014, the Sixty-seventh World Health Assembly requested the Director-General in decision WHA67(15) to expedite the process of the remaining four projects, in addition to the four already agreed. In August 2014, Brazil hosted a workshop to assist proponents of the remaining four projects in further development of their proposals. The proponents of one decided not to pursue their application but the other three proposals have since been assessed as fulfilling the requirements set for demonstration projects through an evaluation process involving the former Chair and Vice-Chair of the Consultative Expert Working Group and observers from six Member States.

8. The following six demonstration projects were thus 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, 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 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).

9. These projects are at different levels of implementation. An Ad-hoc Technical Committee for the Demonstration Projects/Global Observatory on Health Research and Development<sup>2</sup> was established to which demonstration projects' proponents submit their project plans and financial requirements. The Committee met in Geneva (19 June 2015), reviewed the technical workplans and

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<sup>1</sup> [http://www.who.int/phi/implementation/phi\\_cewg\\_meeting/en/index1.html](http://www.who.int/phi/implementation/phi_cewg_meeting/en/index1.html) (accessed 8 April 2016).

<sup>2</sup> [http://www.who.int/phi/news/adhoc\\_committee/en/](http://www.who.int/phi/news/adhoc_committee/en/) (accessed 4 April 2016).



budgets proposed for the first year of implementation, and recommended allocation of funding to three projects. Letters of agreement were signed and funds were disbursed. The funding requirements from two more selected projects were reviewed, and financial contributions are awaited from Member States before disbursements can be made.

## **FUNDING FOR DEMONSTRATION PROJECTS AND THE GLOBAL OBSERVATORY ON HEALTH RESEARCH AND DEVELOPMENT**

10. As reported by the Director-General to the Sixty-eighth World Health Assembly,<sup>1</sup> a budget line was established outside the WHO's Programme budget in order to finance the strategic workplan agreed by Member States as a result of their analysis of the Consultative Expert Working Group's report. This budget line is 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 demonstration projects and establishment of the Observatory for four years (2014–2017) is US\$ 85 million, to which Member States have been asked to make a contribution. As at 6 April 2016, a total of US\$ 0.82 million has been contributed by France, Switzerland and the United States of America to the Observatory, and a total of US\$ 7.45 million has been contributed or pledged by Brazil, India, Norway, South Africa and Switzerland to the voluntary fund designated for demonstration projects and the Observatory. Another US\$ 1.02 million was contributed by Switzerland and Norway as matching grants for contributions from developing countries on the basis of half a dollar for each dollar contributed, and US\$ 1.56 million more matching fund was pledged, pending developing country contributions. Funds received have been fully implemented, leaving a financial gap until the end of 2017 of about US\$ 74 million.

## **EXPLORATION OF FINANCING MECHANISM FOR CONTRIBUTIONS TO HEALTH RESEARCH AND DEVELOPMENT**

11. The Sixty-seventh World Health Assembly in 2014 inter alia 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 II diseases and the specific research and development needs of developing countries in relation to Type I diseases, recognizing the following:

- the scope of the diseases should not be limited to Type III diseases but should be in line with the mandate of the global strategy and plan of action on public health, innovation and intellectual property;
- the need for a sustainable financing mechanism for health research and development;
- the role of Member States in the governance of the coordination mechanism.<sup>2</sup>

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<sup>1</sup> Document A68/34, noted by Committee B of the Sixty-eighth World Health Assembly, fifth meeting ([http://apps.who.int/gb/ebwha/pdf\\_files/WHA68-REC3/A68\\_2015\\_REC3-en.pdf#page=1](http://apps.who.int/gb/ebwha/pdf_files/WHA68-REC3/A68_2015_REC3-en.pdf#page=1), pp 310-315, accessed 4 April 2016).

<sup>2</sup> Decision WHA67(15) (2014).

12. The above option was further considered and noted by the Sixty-eighth World Health Assembly in 2015.<sup>1</sup> Subsequently, the Special Programme consulted extensively with a wide range of stakeholders from the public and private sectors, including funding agencies, ministries, academe, product development partnerships, industry and civil society.<sup>1</sup> Using these inputs, the Special Programme subsequently developed a new tool, Portfolio-to-Impact (P2I),<sup>2</sup> to model the timeline and minimum funding required to develop new medicines, diagnostics and vaccines for populations with limited resources that do not provide a strong incentive for commercial research and development.

13. Using the P2I tool, the Special Programme set out seven implementation scenarios for a new financing mechanism and estimated how many products, either new or re-purposed, might be developed under such a mechanism. The scenarios range from WHO acting primarily as a convener to set priorities to the management by the Special Programme of a pooled fund of various sizes (from US\$ 15 million to US\$ 500 million per annum) to finance product development of needed health products, diagnostics, vaccines and treatments, from promising leads through to the launch of a new product. The P2I is not disease-specific, but has the flexibility to accept the product development needs of developing countries.

14. Finally, the Special Programme explored options for a scientific working group to be responsible for managing the financing mechanism's portfolio, including selection of projects to be funded in line with the identified priorities, monitoring and evaluation of projects as well as financing of selected projects. The expertise required in the members of the scientific working group should include: experience in leading clinical development projects and in making portfolio decisions; field experience in developing country health systems; financing or business development experience; knowledge of infectious diseases; and regulatory agency experience. These core members could be supplemented by experts specific to individual priority disease areas or health interventions. Additional tools to assist the operation of the scientific working group have also to be presented in the report. The scientific working group would use an array of incentive mechanisms from grant-funded push mechanisms and prizes to purchase-commitment-type pull mechanisms in order to provide the best incentives for product developers.

15. Subject to a decision about the creation of a voluntary pooled funding mechanism and the availability of new funding, the Special Programme could adapt its processes and governance mechanisms currently in place to accommodate a new financial mechanism. A WHO-led coordinating mechanism would identify priorities using data from the newly established Global Observatory on Health Research and Development. These priorities would be operationalized by the scientific working group managed by the Special Programme.

## COORDINATION OF HEALTH RESEARCH AND DEVELOPMENT

16. In 2010, the Sixty-third World Health Assembly adopted resolution WHA63.21 on WHO's roles and responsibilities in health research, endorsing the WHO strategy on research for health

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<sup>1</sup> A full report is available outside the meeting and electronically at: [http://www.who.int/tdr/news/2016/funding\\_managing\\_health\\_product\\_R\\_D/en/](http://www.who.int/tdr/news/2016/funding_managing_health_product_R_D/en/) (accessed 4 April 2016). This work was supported by a designated award of SwFr 2 million from the Swiss Agency for Development and Cooperation.

<sup>2</sup> UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (2016) Health product research and development fund: a proposal for financing and operation. [http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295_eng.pdf?ua=1) (accessed 8 April 2016).

requested in resolution WHA60.15 (2007) and highlighting the need for better coordination of health research globally. The report of the Consultative Expert Working Group also comments that there is no “global” coordination of research and development for major diseases, and that “global health research and innovation system is highly fragmented.”<sup>1</sup> The report concludes that it would be “difficult to create a single, overarching governance structure to coordinate global research and development, owing to the nature of research and development and differences in the structure of the world’s economies.” However, it emphasized the role of WHO’s “constitutional mandate for coordination, which might include research and development at global, regional and national levels.” On this basis, the Consultative Expert Working Group recommended the establishment of a new global advisory body. Such a body would be able to build on the data and analyses provided by the Global Observatory and to make recommendations on research priorities.

17. Pursuant to the request in resolution WHA66.22 (2013) on follow up of the report of Consultative Expert Working Group to the Director-General “to review existing mechanisms in order to assess their suitability to perform the coordination function of health research and development;” and “to report on the review of existing coordination mechanisms ... to the Sixty-seventh World Health Assembly, through the Executive Board at its 134th session,”<sup>2</sup> the Director-General submitted document A67/27 to the Health Assembly. In that report, three types of coordination mechanisms were described:

- (a) passive coordination achieved through 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.

The report further suggested that option (b) would be the most appropriate, and that the Advisory Committee on Health Research could be reconstituted to fulfil this advisory role. Another proposal made in the report was to establish an annual conference of global health research and development stakeholders in order to maintain focus and momentum on these issues. Ideally, this conference would take place in a different region each year and be hosted by a major research institute active in this area.

18. The Advisory Committee on Health Research is a formal expert group with a consultative mandate to support WHO in carrying out its constitutional role of promoting and conducting health research, acting in close cooperation with external institutions pursuing common goals and with the scientific community at large. The committee was established in 1959 as the Advisory Committee on Medical Research and was given the role of advising the Director-General on research issues and formulating “global priorities for health research” in light of policies set by WHO’s governing bodies. All WHO’s regional offices established their own advisory committees on health research. In 2010, a report was published by WHO covering 40 years of work of Advisory Committee on Health

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<sup>1</sup> [http://www.who.int/phi/CEWG\\_Report\\_5\\_April\\_2012.pdf](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf) (accessed 8 April 2016).

<sup>2</sup> Resolution WHA66.22 (2013), subparagraphs 4(5) and 4(8), respectively.

Research.<sup>1</sup> One of the major contributions of the Advisory Committee on Medical Research had been to recommend, in 1974, the establishment of the Special Programme for Research and Training in Tropical Diseases.

19. In its new role as the Global Research and Development Coordination Mechanism, the Advisory Committee on Health Research could review the analyses provided by the Global Observatory on Health Research and Development and the conclusions of the proposed annual conference of global health research and development stakeholders in order to articulate global priorities for research and development. These priorities would be presented to Member States through the statutory annual report of the Advisory Committee on Health Research to WHO's governing bodies. They would be reviewed annually and would form the basis for the work of the scientific working group managed by the Special Programme for Research and Training in Tropical Diseases.

## OTHER RELEVANT RESEARCH AND DEVELOPMENT-RELATED ACTIVITIES

20. Two new areas of research and development have emerged more prominently in the work of the Secretariat in the past few years. These are briefly described below.

21. The **research and development blueprint for action to prevent epidemics**. The recent Ebola virus disease epidemic, preceded by the outbreaks of severe acute respiratory syndrome and the Middle East respiratory syndrome and followed by the continuing Zika virus epidemic, has highlighted the need for a robust research and development preparedness for emerging diseases likely to cause severe outbreaks in the near future and for which few or no countermeasures exist. Currently, there is insufficient investment into the development of treatments, vaccines and diagnostics for these severe, emerging epidemic-prone diseases. These diseases are unpredictable, tend to occur in low-resource settings and affect either a limited number of people or populations with low purchasing power. The research and development blueprint addresses the primary issue for which the global strategy and plan of action on public health, innovation and intellectual property was created: ensuring access to affordable, safe and effective health products for which existing market mechanisms fail to provide incentives for health research and development.

22. The blueprint is a global strategy and preparedness plan to ensure that targeted research and development can strengthen the emergency response by bringing medical technologies to populations in need during outbreaks and epidemics. In particular, the blueprint aims to reduce the time between the declaration of a public health emergency of international concern and the availability of effective tests, vaccines and medicines that can be used to save lives and avert crises.

23. As part of the blueprint, an initial prioritized list of severe, emerging, epidemic-prone diseases for urgent research and development was agreed during a meeting of experts convened by WHO (Geneva, 8 and 9 December 2015). This list comprises: Crimean-Congo haemorrhagic fever, filovirus diseases (for instance Ebola virus disease and Marburg haemorrhagic fever), Lassa fever, highly pathogenic emerging coronavirus diseases (severe acute respiratory syndrome and the Middle East respiratory syndrome), Nipah virus disease and Rift Valley fever. Diseases that are considered serious and require action by WHO to promote research and development as soon as possible includes chikungunya, severe fever with thrombocytopenia syndrome, and Zika virus disease. The priority

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<sup>1</sup> World Health Organization. Research and the World Health Organization: A history of the Advisory Committee on Health Research 1959–1999. Geneva: World Health Organization, 2010 ([http://apps.who.int/iris/bitstream/10665/44484/1/9789241564113\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44484/1/9789241564113_eng.pdf), accessed 4 April 2016).

status of the Zika virus disease was raised after the declaration of a public health emergency of international concern by the Director-General on 1 February 2016 because of the ongoing outbreak of Zika virus infection associated with an increase in the number of cases of Guillain-Barré syndrome and microcephaly. Further work by the Secretariat includes defining the current status of basic and applied research for these prioritized epidemic-prone diseases, for incorporation into the work of the Global Observatory on Health Research and Development and to facilitate and coordinate the development of technology road maps to identify how to accelerate research and development for effective diagnostics, vaccines, therapeutics and other medical and information technology for the priority, epidemic-prone diseases. Other important developments concentrate on supporting improved regulatory preparedness for healthcare products epidemic control. The Secretariat is not engaged in research and development as such as part of the blueprint.

24. A research and development response during an epidemic relies on the existence of the right conditions – or an enabling environment – to facilitate timely and efficient action. This means that there must be, for example, a system in place for coordinated action, broad agreement on data and sample sharing, governance of research and development, and standards of care. This constitutes another area of work being covered in the research and development blueprint. Assessment of the effectiveness of the blueprint will rely on evaluating its ability to create such an enabling environment for research and development preparedness in developing countries, and on the impact that research and development plans on availability of medical technologies for the next outbreaks or epidemics.

25. Work is continuing to explore options for adequate and sustainable funding for priority research for severe, emerging, epidemic-prone diseases, for example through aligning and making more efficient use of existing funds and through linking this stream of work with related discussions of the Consultative Expert Working Group. A report on options for strengthening information-sharing on diagnostic, preventive and therapeutic products and for enhancing WHO's capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers, which contains further information on the research and development blueprint, is being submitted to the Sixty-ninth World Health Assembly for consideration.<sup>1</sup>

26. **Research and development for new antibiotics as part of WHO's global action plan on antimicrobial resistance.** In May 2015, the Sixty-eighth World Health Assembly adopted the global action plan on antimicrobial resistance in resolution WHA68.7. Because of inappropriate use of antibiotics in human and veterinary medicine and agriculture, pathogens quickly develop resistance. This occurrence is a significant disincentive for the industry to invest in research and development of new antibiotics as the resulting market is expected to be of short duration. As for neglected diseases, investment into the development of new antibiotics is insufficient, resulting in a meagre research and development pipeline. However, contrary to diseases of interest in the global strategy and plan of action on public health, innovation and intellectual property, the antibiotic market remains a commercial market and the diseases caused by resistant bacteria are not Type II and III diseases, but affect all countries. Therefore, the global action plan on antimicrobial resistance, under its Objective 5 on developing the economic case for sustainable development, requests the Director-General to explore options for the establishment of new partnerships to identify research and development priorities, to foster the development of new antibiotics, diagnostics, vaccines and other interventions, to improve the coordination of existing research and development related initiatives, to ensure access and to establish open collaborative research and development models.

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<sup>1</sup> Document A69/29.

27. To implement this part of the global action plan on antimicrobial resistance, the Secretariat and the Drugs for Neglected Diseases initiative have collaborated in the establishment of the Global Antibiotic Research and Development Facility, an independent product development partnership to develop new antibiotic treatments to counter antimicrobial resistance and to promote their responsible use for optimal conservation while ensuring equitable access for all. The Facility will work closely with all stakeholders in the field of antibiotic research and development from countries of all income levels. It will:

- (a) address global public health and specific needs of developing countries, targeting products that industry will not develop owing to lack of profitability;
- (b) pilot the use of alternative incentive models that support conservation of and access to new antibiotics based on the experience of the Drugs for Neglected Diseases initiative in implementing alternative research and development models for neglected diseases; and
- (c) ensure that new antibiotics are affordable to all.

The Board of the Drugs for Neglected Diseases initiative approved the role of the initiative as an incubator for the initial start-up phase of this new facility until it becomes an independent entity. The Secretariat will not be directly involved in product research and development activities related to this initiative.<sup>1</sup>

### **Policy coherence in activities related to research and development**

28. In the past few months, the Secretariat has set up, or participated in the establishment of, two initiatives to redress insufficient investment into research and development, namely in the areas of emerging infectious diseases with epidemic/pandemic potential (the research and development blueprint) and innovation in antibiotics (the Global Antibiotic Research and Development Facility). The paragraphs below summarize common and divergent features between the agendas driven by implementation of the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination, and those of the two initiatives just mentioned.

29. **Scope of the initiatives.** The Consultative Expert Working Group was tasked with framing its analysis around Type III diseases (those that are overwhelmingly or exclusively incident in developing countries), Type II diseases (those that are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries) and special needs of developing countries concerning Type I diseases (those that are incident in both rich and poor countries, with large numbers of vulnerable populations in each). In the absence of an epidemic, diseases targeted by the research and development blueprint all fall into the category of Type II or Type III diseases. During a large epidemic, these diseases have a potential to qualify as Type I. Many if not all new treatments needed to combat antimicrobial resistance target diseases that can be categorized as Type II and III diseases (for example, multidrug-resistant tuberculosis or neonatal sepsis), while others target Type I diseases.

30. As is the case for diseases of interest in the report of the Consultative Expert Working Group, both the research and development blueprint and the Global Antibiotic Research and Development

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<sup>1</sup> [http://www.who.int/phi/implementation/consultation\\_imnadb/en/](http://www.who.int/phi/implementation/consultation_imnadb/en/) (accessed 5 April 2016).

Facility pay attention to gaps that are not filled by the market-driven research and development system. It is important to note that the reasons for market failure are different for the three areas:

- in spite of a large unfulfilled demand for medical technologies, the market related to diseases targeted by the Consultative Expert Working Group is seen as unattractive because the population in need is poor;
- the demand for medical technologies for emerging epidemic/pandemic infectious diseases is low or inexistent in the absence of an epidemic – vaccines or therapies targeting them are therefore essentially destined to be stockpiled, in relatively limited volumes;
- similarly, new antibiotics are proposed to be used rationally and essentially reserved for cases where current treatment modalities fail, which means that the demand is likely to be low and therefore a disincentive for the market.

31. The research and development blueprint and the Global Antibiotic Research and Development Facility initiatives have capitalized on the experiences accumulated and mechanisms refined during implementation of the recommendations in the report of the Consultative Expert Working Group, especially in exploration of possible financing models to support biomedical research and development. De-linkage of the market price from research and development costs, use of open knowledge innovation, and use of licensing conditions to favour access, which are the core principles formulated by the Consultative Expert Working Group, are the basic principles of the two initiatives.

## Appendix 3

----Draft [Decision][Resolution]----

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

**The Sixty-ninth World Health Assembly,**

1. Recalling WHA resolution 66.22 and subsequent WHA decisions<sup>1</sup> on the Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination and noting progress made in the implementation of the Strategic Workplan agreed in WHA resolution 66.22
2. [Reaffirming UNGA Resolution 70/1 on the 2030 Agenda for Sustainable Development and recalling the Means of Implementation, in particular target 3.b by which Member States agree to support, [the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of IP Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all]
2. alt. [Acknowledging that the 2030 Agenda for Sustainable Development, includes the commitment to support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of IP Rights regarding flexibilities to protect public health, and in particular, provide access to medicines for all]
3. 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 resources to address diseases that disproportionately affect developing countries.

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<sup>1</sup> WHA decisions 66(12) and 67(15)



4. [Reaffirming the right to use, to the fullest extent, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health, the decision of the General Council of the World Trade Organization of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and, when formal acceptance procedures are completed, the amendment to article 31 of the TRIPS Agreement, as proposed by the General Council of the World Trade Organization in its decision of 6 December 2005, which provide flexibilities for the protection of public health, and in particular to promote access to medicines for all, and to encourage the provision of assistance to developing countries in this regard, and calling for broad and timely acceptance of the amendment to article 31 of the TRIPS Agreement.] (A/RES/70/183)
5. [Recognizing the continued importance of the Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property protection is important for the development of new medicines and also recognizes the concerns about its effects on prices.]
6. [Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote.] (A/67/81)
7. [[Welcoming] [Noting [with interest] the establishment of] the High-Level Panel on Access to Medicines convened by the UN Secretary-General.]
8. [Recognizing the shared [common] responsibility of all Member States<sup>1</sup> to invest in R&D for diseases in accordance with the scope of the CEWG Report and in line with the Global strategy and plan of action on public health, innovation and intellectual property]
8. alt. [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]
1. URGES Member States<sup>2</sup>:

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<sup>1</sup> And, where applicable, regional economic integration organizations

<sup>2</sup> And, where applicable, regional economic integration organizations

- (1) [to [step up and continue implementing] [prioritize the full implementation of] the Strategic Workplan agreed in WHA66.22]

[Move to PP:] [Recognizing progress in the establishment] [Reaffirms the central role of] [Noting efforts to establish] the Global Observatory on Health Research and Development to consolidate, monitor [analyse relevant information on health R&D activities] and [identify gaps and opportunities on health research and development] [[to analyse relevant information on health research and development activities, [where market failures exist,]], including on [[related to]type II and III diseases and the specific R&D needs of developing countries in relation to type I diseases, [including]] antimicrobial resistance and emerging [infectious] diseases likely to cause major epidemics, [with a view to contributing to the identification of gaps and opportunities] for health research and development that informs prioritization and supports coordinated actions on health research and development; and urges[encourages]

- (2) [[to promote and support] [[ensure] [provide] sustained [sustainable] funding for] the Global Observatory on Health Research and Development]

- (2) bis. to provide support to the DG for the development of sustainable financing mechanisms for the full implementation of the CEWG strategic workplan agreed in WHA66.22

- (3) to create, [, strengthen, [empower] and] or sustain appropriate [sustainable] national or regional [observatory] [mechanisms] to facilitate [annual] [regular] [reporting] of relevant information on [all] [health R&D capacities, public and private] [publicly funded] [on] health research and development [either directly] to the Global Observatory on Health Research and Development [or to other international survey mechanisms which directly feed into the Global Observatory]

- (4) [to consider aspiring to meeting a benchmark for investments in R&D for diseases in accordance with the scope of CEWG at 0.01% of GDP in line with the CEWG recommendations]

- (5) To PP [[Expresses concern] at the [to take note of the] [significant] [substantial] gap in funding of the six selected demonstration projects [and urges Member States<sup>1</sup>] to [secure] the financial resources and the coordination required at all levels to support the demonstration projects]

## 2. REQUESTS the Director-General:

- (1) to expedite [within the [follow-up of the report of the CEWG] [context of CEWG] [and as part of the [priority activities] [core functions] of WHO]] the

establishment of a fully [functioning] [functional] Global Observatory on Health Research and Development and explicitly include its operational costs in the regular Programme Budget [and sustain its activities[, including by utilising [preferably] financial resources from assessed [contributions] and [also] core voluntary contributions to WHO]]

- (1) bis. to submit terms of reference and a costed workplan of the Global Observatory on Health Research and Development to the Seventieth World Health Assembly through the 140<sup>th</sup> session of the Executive Board under the CEWG related agenda item

[and a diagnosis on the status of research and development in health that includes a comparative study on the models of research and health priorities]

- (2) to expedite, as part of the development of the Global Observatory on Health R&D the development of norms and standards for classification of health research and development, including common reporting formats, building on existing sources, in consultation with Member States experts and relevant stakeholders, in order to collect and collate information systematically and facilitate sharing of data and interoperability of data sets
- (3) to promote the Global Observatory on Health R&D among all stakeholders, including through regular open-access publications and outreach activities and encourage all stakeholders to regularly share relevant information on health research and development with the Global Observatory on Health R&D
- (4) to decide to establish an [geographically representative] [independent] [WHO expert advisory committee] [footnote] on health research and development, with [balanced] [due geographical and gender] representation] as an [independent] [coordination] mechanism for [identifying priorities for] [priority setting of,] [global] research and development [due to recognized market failures] [related to] [needs], [especially] for Type [II] III and [III] II diseases and specific R&D needs of developing countries in relation to Type I diseases [where market failure exists,] based on the analyses provided by the Global Observatory on Health Research and Development and to submit its terms of reference including [profiles of the] [general] composition [footnote] to the Seventieth World Health Assembly through the 140<sup>th</sup> session of the Executive Board for its consideration and adoption]

[Decides to establish an WHO expert [advisory] committee on health research and development, with balanced geographical and gender representation as an [independent] coordination mechanism for priority setting of global research and development needs for Type II and III diseases and specific R&D needs of developing countries in relation to Type I diseases, [[and] [potential other areas] where market failure exists], based on the analyses provided by the Global Observatory on Health Research and Development.]

[OP 4.2. to submit the terms of reference including general composition [footnote] of the expert committee on health research and development [refer to operative paragraph] to the Seventieth World Health Assembly through the 140<sup>th</sup> session of the Executive Board for its consideration and adoption]]

alt. [OP 4.2. to establish an WHO expert committee to provide technical advice on prioritization of health research and development for Type II and III diseases and specific R&D needs of developing countries in relation to Type I diseases, [[and] [potential other areas] where market failure exists], based on the analyses provided by the Global Observatory on Health Research and Development.

alt. [OP 4.2. to [present] [submit] to the Seventieth World Health Assembly the terms of reference of a WHO Technical Advisory Group on health research and development as a coordination and prioritization mechanism of global research and development needs for Type II and III diseases and specific R&D needs of developing countries in relation to Type I diseases, [[and] [potential other areas] where market failure exists], based on the analyses provided by the Global Observatory on Health Research and Development.

(5) [to take into account [without prejudice to consider others in the future] the study conducted by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases<sup>1</sup>, [taking into account the study and in line with the report of the CEWG] in presenting a [roadmap [workplan] outlining] [business plan for] the development of a voluntary pooled fund [for health research in diseases for which market mechanisms fail to provide incentives.] [towards 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] The plan shall include, inter alia, options for sustainable funding as well as standard operating procedures [as well as an open-access IP policy] for its Scientific Working Group to operate in conjunction with the WHO Global Observatory on Health Research and Development and the [independent coordination] [coordinating] mechanism, and be submitted to the Seventieth World Health Assembly through the 140<sup>th</sup> session of the Executive Board]

5 bis. [to continue exploring other mechanisms of contribution to health research and development related to Type II and Type III diseases and the specific research needs of developing countries in relation to Type I diseases, including its introduction to the regular Programme Budget and utilization of

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<sup>1</sup> Health Product Research & Development Fund: A proposal for financing and operation - [http://www.who.int/tdr/publications/r\\_d\\_report/en/](http://www.who.int/tdr/publications/r_d_report/en/)

- preferably financial resources from assessed contributions and also core voluntary contributions to WHO]
- (6) to [promote [and advocate] sustainable and innovative] [advocate for sustained] financing [models] for all aspects of the [CEWG] [WHA66.22] Strategic Workplan and to include the Strategic Workplan in a special [session of the regular] financing dialogue for mobilizing sufficient resources to meet the objectives of [CEWG] [WHA66.22]
- (6) alt. [to promote and advocate sustainable and innovative financing for all aspects of the Strategic Workplan agreed in WHA66.22 and to include the Strategic Workplan in a [any] special session of the [regular] financing dialogue [in addition to the regular financing dialogue] for mobilizing sufficient resources to meet the objectives of WHA66.22]
- (7) [to [ensure] [promote] [that] policy coherence [guides] [within] WHO research and development activities [such as the [Research and Development Blueprint for Emerging Pathogens] [Emergency Research and Development Blueprint] and the [AMR Global Action Plan] [global development framework for innovation in antimicrobial medicines and diagnostics]] in terms of application of the core [CEWG] principles of affordability, effectiveness, efficiency and equity [and the objective of] [and] de-linkage identified in WHA resolution 66.22] [including where appropriate and in consultation with other stakeholders the Research and Development Blueprint for Emerging Pathogens and the AMR Global Action Plan]
- (8) [to develop [draft] guidelines [to inform Member States and other stakeholders on the use of principles of affordability, effectiveness, efficiency and equity [and the objective of] [and] de-linkage identified in WHA resolution 66.22] in relevant R&D efforts] [that promote the implementation of the [CEWG] [WHA66.22] principles in R&D efforts [[funded] [established] by Member States and other [funders of research] [stakeholders]] [for submission to the 140<sup>th</sup> Session of the Executive Board]]]
- (8) bis. [to convene an open-ended meeting after the publication of the report of the UN Secretary General High-Level Panel on Access to Medicines, and the UN High Level Meeting on Antimicrobial resistance in order to seek policy coherence on health innovation and access and inform further governmental discussions on the follow up to the Consultative Expert Working Group on Research and Development: Financing and Coordination;]
- (9) to report to the Seventieth World Health Assembly through the 140th session of the Executive Board with reference to this decision[. including milestones for the full operationalization of the Global Observatory and the prioritization setting mechanism.]

- (9) bis. [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]

**Alternative text for paras OP1 and OP2 (1) submitted by India & Switzerland at request of the Chair (to be integrated in appropriate location):**

PP: Noting with concern the significant gap in funding the Strategic Workplan including the six selected demonstration projects

PP: Acknowledging the central role of the Global Observatory on Health Research and Development to consolidate, monitor and analyze relevant information on health research and development activities related to type II and III diseases and the specific R&D needs of developing countries in relation to type I diseases including antimicrobial resistance and emerging infectious diseases likely to cause major epidemics, 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 research and development and defining priorities and supporting coordinated actions on health research and development

OP 1 alt: Urges Member States (with foot note):

1) to make concerted efforts for the full implementation of the Strategic Workplan agreed in WHA66.22

2) to provide sustainable funding for the Global Observatory on Health Research and Development

3) to create, operationalize and strengthen, as appropriate, national Health Research and Development observatories or equivalent functions to provide regular information on relevant Health Research and Development activities to the Global Observatory on Health Research and Development or to other existing data collection mechanisms which provide regular reports to the Global Observatory on Health Research and Development

4) to secure necessary financial resources and the coordination required at all levels to support the demonstration projects

5) [to consider aspiring to meeting a benchmark for investments in R&D for diseases in accordance with the scope of CEWG at 0.01% of GDP in line with the CEWG recommendations]

6) [to provide support to the DG for the development of sustainable financing mechanisms for the full implementation of the CEWG strategic workplan agreed in WHA66.22]

OP2. Request the Director-General:

1) alt to expedite within the follow-up of the report of the CEWG [and in accordance with core functions of WHO] the further development of a fully functional Global Observatory on Health Research and Development and to explicitly include its operational costs in the regular Programme Budget

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