



REGIONAL COMMITTEE

Provisional Agenda item 9.7

*Sixty-seventh Session
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SEA/RC67/20

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Progress reports on selected Regional Committee resolutions:

**Consultative Expert Working Group on Research and Development:
Financing and Coordination (SEA/RC65/R3)**

The Sixty-fifth Session of the WHO Regional Committee for South-East Asia held in Yogyakarta, Indonesia, adopted resolution SEA/RC65/R3 that outlined detailed recommendations and action points for Member States and WHO on the follow-up of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). The Regional Committee resolution provided the basis for the draft resolution during the open-ended meeting of all WHO Member States, held from 26 to 28 November 2012 in Geneva, leading to WHA66.22 in 2013. As a result, the objectives and actions outlined in SEA/RC65/R3 are included in WHA66.22. Therefore, actions taken for WHA66.22 cover both the Regional Committee and World Health Assembly resolutions.

Resolution WHA66.22 calls for:

- (1) specific actions* through a strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health research and development (R&D) (in line with WHA61.21, Global Strategy and Plan of Action); and
- (2) identification of a few health R&D demonstration projects as a step towards achieving the goal of development and the delivery of affordable, effective, safe and high-quality health products.

To take resolutions SEA/RC65/R3 and WHA66.22 forward, the Regional Office organized the following meetings:

- (1) Regional consultation to develop a strategic workplan as a follow-up of the meeting of the Consultative Expert Working Group on Research and Development: Financing and Coordination, 25–26 July 2013, in Bangkok, Thailand. This meeting has suggested an important grid for classification of norms and standards for health R&D in the proposed observatory and also identified the priority areas for demonstration projects. The recommendations of this regional consultation are at Annex 1.

- (2) Meeting of Experts on Demonstration Projects, New Delhi, India, 24–25 October 2013, facilitated the submission of projects at the global level by Member States of the South-East Asia Region. Of the four projects submitted by the WHO Regional Office, the “Multiplexed point-of-care test for acute febrile illness” scored 45.50 points and was placed second and “Dengue vaccine development” – which did not meet the 60% bar, but was the eighth highest-scoring project – was selected and is the “7+1” project.

The meeting to examine the additional information in relation to the “7+1” demonstration projects held on 10 March 2014 at WHO headquarters did not take up the projects submitted by the WHO Regional Office. However, by decision WHA67(15), Member States have requested the Director-General to expedite the processing of the remaining projects in addition to the four already agreed.

The High-Level Preparatory (HLP) Meeting held in the Regional Office in New Delhi, India, from 14 to 17 July 2014 reviewed the attached working paper and made the following recommendations:

Actions by Member States

- (1) To take forward the strategic workplan for the Region as a follow-up of the CEWG on Research and Development: Financing and Coordination.
- (2) To engage in promoting and strengthening health R&D, including coordination, monitoring and capacity-building through assessment of the Global Strategy and Plan of Action.
- (3) To further engage in developing health R&D demonstration projects for the addition of innovative components and financing.

Actions by the WHO Regional Office

- (1) To provide technical assistance to countries on the CEWG on Research and Development: Financing and Coordination process, including the assessment of the Global Strategy and Plan of Action
- (2) To promote information-sharing mechanisms in respect of health R&D, including employing the Global Health R&D Observatory for this purpose
- (3) To support the further development of health R&D demonstration projects for the addition of innovative components and financing.

The working paper and the HLP recommendations are submitted to the Sixty-seventh Session of the Regional Committee for its consideration.

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

Introduction

1. The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) set up by the Sixty-fifth World Health Assembly submitted its report in May 2012. This report made a number of proposals for new and innovative sources of financing to stimulate research and development (R&D) related to Type II and Type III diseases, and the specific R&D needs of developing countries in relation to Type I diseases¹.

2. In resolution WHA66.22 and decision WHA67(15), Member States resolved to hold consultations at the national level among all relevant stakeholders, as well as in each of the six WHO regional committee meetings scheduled for 2012. They also decided to hold an open-ended meeting of Member States at WHO headquarters, Geneva, to develop consensus. Pursuant to this, Member States of the WHO South-East Asia Region held national consultations and participated in a regional technical consultation organized by the WHO Regional Office for South-East Asia, on 15–17 August 2012, in Bangkok, Thailand, to develop regional perspectives on the CEWG report.

3. Member States of the WHO South-East Asia Region adopted resolution SEA/RC65/R3 at the Sixty-fifth Session of the Regional Committee for South-East Asia in 2012. This resolution also provided the basis for the draft resolution during the open-ended meeting of all WHO Member States in November 2012 at Geneva leading to WHA66.22. This resolution was also discussed at the regional committees of the other regions of WHO. Resolutions SEA/RC65/R3 and WHA66.22, *inter alia*, urge Member States and WHO to strengthen health R&D capacities for and investment in diseases that disproportionately affect developing countries. The resolutions also request WHO to establish a global health R&D Observatory to monitor and analyse relevant information on health R&D as well as to promote advisory mechanisms.

¹ **Type I diseases** are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Examples of communicable diseases include measles, hepatitis B, and *Haemophilus influenzae* Type b, and examples of noncommunicable diseases abound (e.g. diabetes, cardiovascular diseases and tobacco-related illnesses). Many vaccines for Type I diseases have been developed in the past 20 years, but have not been widely introduced into the poor countries because of cost. **Type II diseases** are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90% of cases are in the poor countries. **Type III diseases** are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially-based R&D in the rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans. Type II diseases are often termed *neglected diseases* and Type III diseases *very neglected diseases* (CIPIH p. 13).

Action on SEA/RC65/R3 and WHA66.22

4. Resolution WHA66.22 calls for:
 - a. specific actions² through a strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health R&D (in line with WHA61.21, Global Strategy and Plan of Action); and
 - b. identification of a few health R&D demonstration projects as a step towards achieving the goal of development and the delivery of affordable, effective, safe and high-quality health products.
5. For the above, the following work has been performed by the WHO Secretariat:
 - a. Establishment of a global health R&D observatory:
 - i. An informal workshop on the global health R&D observatory to share details on major initiatives to map international R&D resource flows with a focus on health was held in February 2013, followed by an exercise to map stakeholders.³
 - ii. A review of published health R&D priorities that have been identified through WHO's technical programmes is being synthesized into a searchable database as one means of providing a systematic overview.
 - iii. The Secretariat held a public briefing at WHO headquarters on 6 December 2013 on the actions taken to date.
 - b. Three models are explored for review of existing mechanisms to assess their suitability to perform the coordination function of health R&D:
 - i. Passive coordination is achieved through better sharing of information, i.e. 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 R&D efforts is the absence of quality information that provides a comprehensive overview of what health research is being supported.
 - ii. Active coordination happens through networks of researchers agreeing on priorities and collaboration. The Consultative Expert Working Group has recommended the establishment of a new global advisory body.
 - iii. Managed coordination is achieved through formal structures to manage the research undertaken and allocation of resources to support them.
 - c. Financial contributions to health R&D:

² The Director-General was requested, *inter alia* to: (1) establish a global health R&D 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 R&D; and (3) explore and evaluate existing mechanisms for financial contributions to health R&D and, if there is no suitable mechanism, to develop a proposal for effective mechanisms, and a plan to monitor their effectiveness independently.

³ 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).

6. The following existing mechanisms are explored and evaluated (details on WHO website⁴):
 - i. African Network for Drug and Vaccine Innovation (ANDI), Drugs for Neglected Diseases Initiative (DNDi), European Molecular Biology Laboratory (EMBL), European and Developing Countries Clinical Trials Partnership (EDCTP), GAVI Alliance, Global Alliance for Chronic Diseases (GACD), The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), Human Frontier Science Programme (HFSP), International Agency for Research on Cancer (IARC), International Vaccines Institute (IVI), Medicines for Malaria Venture (MMV), Programme for Appropriate Technology in Health (PATH), Roll-Back Malaria Partnership (RBM), UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), and UNITAID.
 - ii. For the assessment, the following criteria were used: adaptability, scope of research, geographical scope, inclusive governance structure, experience in funding and managing R&D, and transparency. The analysis brought out that all the selected existing mechanisms meet a number of the criteria; however, no existing mechanism currently met all criteria. Thus, if any existing mechanism were to be selected to host a new funding mechanism, some adaptation would be required. It would also be necessary to ascertain if they would be willing to take over such a task.
 - iii. In line with resolution WHA66.22, a proposal for new mechanisms has not been developed.
7. For identification of demonstration projects, the WHO Secretariat convened the Global Technical Consultative Meeting of Member States on the identification of health R&D demonstration projects on 5 December 2013 in Geneva.
8. The Global Technical Consultative Meeting of experts on the identification of health R&D demonstration projects was convened on 3–4 December 2013 in Geneva.
9. In addition to the shortlisted projects, the group intensively discussed project no. 9 submitted by Thailand, entitled “Dengue vaccine development”, which did not meet the 60% bar and was the eighth highest-scoring project. The experts felt strongly that this project fulfils most of the criteria for a demonstration project. Thus the shortlisted projects were as follows:
 - i. Visceral Leishmaniasis (VL) Global R&D and Access Initiative;
 - ii. multiplexed point-of-care test for acute febrile illness;
 - iii. demonstration of the potential of a single-dose malaria cure of artemether-lumefantrine through reformulation in a nano-based drug delivery system;
 - iv. exploiting the pathogen box: an international open source collaboration to accelerate drug development in addressing diseases of poverty;
 - v. development of a vaccine against schistosomiasis based on the recombinant sm14, a member of the fatty acid-binding protein: controlling transmission of a disease of poverty;

⁴ <http://www.who.int/phi/en/>

- vi. development of Class D Cpg Odn (D35) as an adjunct to chemotherapy for cutaneous leishmaniasis and post kala-azar dermal leishmaniasis (Pkdl);
- vii. development of easy-to-use and affordable biomarkers as diagnostics for type II and type III diseases; and
- viii. (7+1) dengue vaccine development.

10. Based on the discussions held by Member States, the following additional information was sought for consideration by the 134th session of the WHO Executive Board on 20–25 January 2014, i.e. how the project:

- i. intends to delink the price of the final product from the cost of the R&D;
- ii. utilizes collaborative approaches, including open knowledge innovation approaches;
- iii. utilizes licensing approaches that secure access to the research outputs and final products;
- iv. proposes and fosters financing mechanisms including innovative, sustainable and pooled funding;
- v. fosters effective and efficient coordination mechanisms among existing organizations/initiatives; and
- vi. strengthens capacity for research, development and production, including through technology transfer, in developing countries.

11. On 10 March 2014, the former Chair and Vice-Chair of the Consultative Expert Working Group, facilitated by the Secretariat and observed by representatives of Member States, identified four of the “7+1” projects shortlisted through the Global Technical Consultative Meeting of Experts held on 3–4 December 2013 as having met the criteria set for demonstration projects. It may be noted that the WHO Regional Office for South-East Asia had employed the Agreement for Performance of Work (APW) mechanism to design an ‘ideal’ project proposal for visceral leishmaniasis (VL). Subsequently, since there was priority identification through a Member State-driven mechanism, we agreed to a request by the Drugs for Neglected Diseases Initiative (DNDi) for sponsorship by the WHO Regional Office for Africa. This project has been selected to move forward after the deliberations on 10 March 2014.

12. Based on this assessment, it was determined that the Secretariat will move forward with convening stakeholder meetings for the following four proposals:

- i. *The Visceral Leishmaniasis (VL) Global R&D and Access Initiative*: Drugs for Neglected Diseases initiative (DNDi), submitted through the regional offices for Africa and the Eastern Mediterranean.
- ii. *Exploiting the pathogen box*: An international open source collaboration to accelerate drug development in addressing diseases of poverty – Medicines for Malaria Venture (MMV) – submitted through the WHO Regional Office for Europe.
- iii. *Development of Class D Cpg Odn (D35) as an Adjunct to Chemotherapy for Cutaneous Leishmaniasis and Post Kala-Azar Dermal Leishmaniasis (Pkdl)* – United States Food and Drug Administration (USFDA), et al., submitted through the WHO Regional Office for the Americas.

- iv. *Development of easy-to-use and affordable biomarkers as diagnostics for types II and III diseases: African Network for Drugs and Diagnostics Innovation (ANDI), et al., submitted through the WHO Regional Office for Africa.*

13. Noting the significant public health impact and scientific and technical merit of the remaining four projects, it was agreed that although these projects are not ready enough to move forward to the implementation stage, the Secretariat will assist their proponents to improve the innovative aspects of their projects if they so desire. However, by decision WHA66(15), Member States have requested the Director-General to expedite the processing of these remaining projects, in addition to the four already agreed. For this, WHO headquarters is proposing a workshop to be organized by the Fiocruz Foundation in Brazil on 26–27 August 2014.

Conclusions and recommendations

14. In view of the current developments in CEWG, the following are the recommendations for the Region:

- The classification for norms and standards developed by Member States of the South-East Asia Region at the regional consultation for developing a strategic workplan as a follow-up of the Consultative Expert Working Group on Research and Development: Financing and Coordination, Bangkok, 25–26 July 2013, needs to be deliberated on a global platform for which the Member States of the Region may take a lead position. This could place a foundation for the global health R&D observatory and would lead to capacity-building for our Region.

15. As mandated by decision WHA66(15) (A67/B/CONF./2 Rev.1 Agenda item 15.2) on 24 May 2014, Member States have requested the Director-General to expedite the processing of the remaining identified demonstration projects in addition to the four already agreed. WHO headquarters is proposing that a workshop be organized by the Fiocruz Foundation in Brazil on 26–27 August 2014, for which it is necessary to further engage in these projects.

- CEWG is part of the WHA61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA). The assessment of this parent resolution is due at the Sixty-ninth World Health Assembly in May 2016. The Regional Office for South-East Asia is working towards this assessment to identify progress and focus areas on which to move ahead, for which it is important to assess the work done/progress made for all eight elements.