

## **Report of the regional committee discussions by the Director-General**

1. The Health Assembly in resolution WHA65.22 requested regional committees to discuss at their 2012 meetings the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination<sup>1</sup> in the context of the implementation of the global strategy and plan of action on public health, innovation and intellectual property in order to contribute to concrete proposals and actions.

2. The Director-General has the honour to present summarized reports of the discussions by each of the regional committees and other relevant regional processes (see Annex).<sup>2</sup>

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<sup>1</sup> Document A65/24, Annex.

<sup>2</sup> The report of the Regional Committee for Africa will be issued separately as document A/CEWG/2 Add.1, following the meeting to be held 19–23 November 2012.

## ANNEX

### SUMMARY RESULTS OF DISCUSSION BY THE REGIONAL COMMITTEES

#### WHO Regional Committee for the Americas (Washington, 17–21 September 2012)

##### Consultations before the Regional Committee Meeting

The Pan American Sanitary Bureau in its capacity as secretariat, called on the Member States to participate in the regional consultation on the CEWG report and opened a parallel consultative process with interested sectors of civil society. It opted to organize the regional consultation through the Regional Platform on Access and Innovation for Health Technologies (PRAIS). This platform provides tools to link virtual communities of practice, enabling people and institutions to work together. A document providing background information on the consultation, the methodology used to carry it out, and a summary of the official contributions was presented to the 28th Pan American Sanitary Conference.<sup>1</sup>

Twenty-four health authorities designated focal points for the consultation and 12 Member States uploaded contributions to PRAIS. Several Member States informed the Pan American Sanitary Bureau that the regional consultation had promoted discussion at the national level. In some cases, the inability to hold national consultations prevented Member States from providing input to the regional consultation process. A community of practice was organized for civil society and seven contributions were received on behalf of different organizations.

##### Summary of the discussion during the Regional Committee

With active participation from delegates, the debate underlined the importance of this item in the agenda for countries of the Americas. Interventions from Member States emphasized that further action is required to address in particular the needs of developing countries. Some of the salient points of the discussion are listed below:

- (a) While many global, regional, and national initiatives have contributed to the advancement of research, development, and innovation (RDI) to address the needs of developing countries, all Member States agreed that current efforts are not sufficient and that increased funding and innovative approaches can accelerate the development of the products required to meet public health needs.
- (b) Some Member States and nongovernmental organizations manifested their support for a global convention proposed in the CEWG report, in accordance with the principles stated in *The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, as a means to improve RDI financing and coordination. Other Member States expressed their lack of support for a binding global treaty that would commit a percentage of each nation's gross domestic product for RDI including the requirement to set a portion of such funds into a pooled funding mechanism.

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<sup>1</sup> Document CSP28/18, Rev. 2 is available at: [http://new.paho.org/hq/index.php?option=com\\_docman&task=doc\\_download&gid=18745&Itemid=270&lang=en](http://new.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=18745&Itemid=270&lang=en).

(c) Voluntary mechanisms were proposed as a feasible alternative to a binding financial agreement. Emphasizing the need for quick and concrete actions, some Member States considered favourably the development of coordinating mechanisms such as a global observatory and proposed to move forward in building consensus around the other proposals that received considerable support during the consultation.

(d) Many Member States stressed that any path forward should address not only the development of appropriate health technologies but also mechanisms to ensure access to these essential health products. Some of the elements mentioned as critical for a comprehensive approach to strengthening health services that would deliver essential health products were: (a) the use of pooled procurement mechanisms such as PAHO's revolving funds, (b) investment in operational research, and (c) other means.

### **Recommendations and/or outcomes of the discussion**

Member States agreed on the utmost relevance of this issue and urged PASB to continue supporting an ongoing dialogue among stakeholders at the regional level and in global discussions so as to move forward with the development of concrete actions.

Member States considered that there was considerable merit to many of the proposals and recommendations within the CEWG, some of which could be taken forward for implementation at the global, regional, and/or national level, while at the same time there was a lack of consensus on the proposal for a global treaty.

### **Conclusion**

PAHO Member States remained committed to the principles of *The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, and support innovative solutions to increase funding and coordination for RDI to address the needs of developing countries. The countries of the Americas support a continuous and in-depth dialogue that involves Member States and other relevant stakeholders to find common ground to solve this pressing public health issue. Member States have taken divergent positions on the implementation of the binding mechanism for funding and coordination proposed by the CEWG. Notwithstanding, Member States considered that many proposals of the CEWG constitute the foundation for concrete actions in the short to mid-term.

### **WHO Regional Committee for South-East Asia (Yogyakarta, Indonesia, 4–7 September 2012)**

#### **Consultations before the Regional Committee Meeting**

The CEWG Report consultations for WHA65.22 in the South-East Asia Region took place:

- at national levels in the Member States and
- a Regional Technical Consultation was organized in Bangkok, Thailand, from 15 to 17 August 2012.

National level consultations took place in a number of Member States in the South-East Asia Region. The national level consultations were outlined by India and Thailand. The general consensus emerging from the national consultations on CEWG report is that there is a need to delink the cost of Research and Development and the price of the drugs in order to enhance the innovative capacity in developing

countries and technology transfer to these countries. There was also agreement that there is a need to improve priority-setting based on the public health needs of the countries. Decision-making on the CEWG recommendations must be based on governance structures which are transparent and give developing countries a strong voice.

The general objective of the Regional Technical Consultation was to take forward the recommendations of the CEWG report as outlined in resolution WHA65.22 and the specific objectives were: (i) to enhance understanding and discuss the report of the CEWG in the context of the South-East Asia Region and (ii) to develop regional perspectives on the different proposals including a Research and Development treaty proposed by the CEWG.

This Regional consultation was held at the request of our Member States who have been actively involved since the beginning of the discussions leading to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI). This reflects the importance of the issue to this Region as well as the desire to contribute to global health. This consultative process was necessary to demystify the CEWG report and enable our Region to move forward in a concerted manner in further deliberations for ensuring sustainable financing mechanisms for research and development to meet our specific needs.

Thirty-one participants from all Member States with the exception of DPR Korea participated in the Consultation. We were joined through video conference by WHO Assistant Director-General, Dr Marie-Paule Kieny and Dr Zafar Mirza, Coordinator from WHO headquarters.

This Consultation provided an opportunity to receive feedback on the national consultations and develop a regional perspective for the CEWG report for consideration by the Regional Committee. This enabled Member States to take an informed decision on the CEWG report as envisaged by resolution WHA65.22 at the Regional Committee in Yogyakarta in September 2012 prior to the open-ended meeting of all Member States proposed in November 2012.

### **Summary of discussion during the Regional Committee Meeting**

During the deliberations in the Regional Committee, the Member States noted that this is the third consultation in the Region related to these issues. To develop a regional and national position on the Global Strategy (GSPA-PHI) SEARO had earlier convened a Regional Consultation on 5–6 April 2011 for Development of a Regional Framework on Public Health, Innovation and Property. It was observed that to provide input to the CEWG process, consultations were held in the South-East Asia Region on 7 October 2011 in New Delhi. The proposals under consideration of the CEWG were grouped into three sets: those that felt short of meeting the criteria; those that did not principally contribute to improved financing or coordination of research and development (R&D); and those that the CEWG felt best met the criteria summarized under the headings of public health impact, technical, financial and implementation feasibility.

It was observed that the outcomes in the CEWG report reflect the aspirations of the South-East Asia Region. The Regional Committee noted that CEWG had considered a number of innovative sources of financing for increased commitment for meeting the needs of developing countries. The Regional Committee supported the commencement of negotiations for a proposed R&D convention, in principle, as suggested by CEWG. The Regional Committee emphasized the importance of capacity building and technology transfer to developing countries. The Regional Committee also suggested further improving commitment to improve R&D to better address the public health needs of

developing countries. The need to include traditional medicine in the R&D agenda was also emphasized.

### **Recommendations and/or outcomes of the discussion**

The CEWG report was taken up as Agenda item 5.5.3 (Document SEA/RC65/1). As a result of detailed deliberations in the technical consultation held in Bangkok and since a number of participants from the Bangkok meeting were present in the Regional Committee meeting in Jakarta, the Member States' representatives in the Regional Committee were well prepared to take a view on the CEWG report. Thus, the CEWG report and resolution WHA65.22 were discussed in the 65th session of the WHO South-East Asia Regional Committee held in Yogyakarta, Indonesia during 5–7 September 2012 and resulted in the adoption of resolution SEA/RC65/R3 with detailed recommendations and action points for Member States and WHO.

### **Conclusion**

Since we had had detailed discussions at the technical consultation meeting organized by SEARO-WHO in Bangkok on 15–17 August 2012, there was a great deal of clarity among participants from Member States on resolution WHA65.22 and the CEWG report. Also, we were fortunate that many of the participants in the 65th session of the Regional Committee had participated in the technical consultation meeting in Bangkok. This facilitated greater understanding of the issues involved in CEWG and the resolution and agenda item deliberations at the Regional Committee meeting went smoothly.

For our next steps, there are two parts: one set of actions that is dependent upon the outcomes of the open-ended meeting of all Member States, the results of which would be presented to the Executive Board next year, and a second set of actions which is based on eight deliverables identified for Member States in the South-East Asia Region and six for SEARO in Resolution SEA/RC65/R3 (see Appendix) ([http://www.searo.who.int/en/Section1243/Section2599\\_16269.htm](http://www.searo.who.int/en/Section1243/Section2599_16269.htm)).

It may be recalled that further to these regional consultations, resolution WHA65.22 mandated that the Director-General hold an open-ended meeting of the Member States to thoroughly analyse the report and the feasibility of the recommendations proposed by CEWG. This meeting is proposed to be held from 26 to 28 November 2012. The Member States have also requested the Regional Director in SEA/RC65/R3 “to convey to the Director-General the wish of the Member States for consideration that the Chair of the Open-ended Meeting of Member States is from the South-East Asia Region”, which has since been conveyed to the Director-General.

## **WHO Regional Committee for Europe (Valleta, 10–13 September 2012)**

### **Consultations before the Regional Committee Meeting**

Reportedly some Member States in the European Region held national consultations employing different formats and involving different stake holders.

The Regional Office for Europe (EURO) organized a web-based regional consultation prior to the Regional Committee meeting and feedback was sought from the Member States on the CEWG report. Five Member States responded. It was felt that there was scope for reviewing elements of the current rules on intellectual property rights and the current R&D model. They expressed the view that all options should be explored before any tangible spending commitment was made or a binding

coordination mechanism could be agreed, and that many recommendations and options could be pursued – potentially in reworked formats – outside a binding framework. With respect to financing, some countries agreed in principle to commitment of a fixed proportion of the GDP but considered that any action would be premature; others were doubtful that such a commitment could be made, while one expressed the view that an obligatory commitment would be “unacceptable”. There had been no consensus on the use of pooled funds, though the option was not ruled out in specific cases. With regard to coordination, the countries had voiced support for WHO’s lead role in global coordination and management of health R&D but had recommended greater use of existing initiatives and structures rather than building a new body. Others had stated that better coordination was needed, with a new or revised structure. With respect to the proposed convention and legally binding framework, the countries had commented that its scope would first have to be agreed, with one country specifying that it should in fact be broadened to have a wider public health element as well. Doubt was expressed about its practical feasibility. There was thus no immediate support for the proposal.

### **Summary of discussion during the 62nd Session of the Regional Committee for Europe**

The Assistant Director-General, Innovation, Information, Evidence and Research and the Director, Division of Information, Evidence, Research and Innovation (EURO) introduced the subject and the requirements of resolution WHA65.22. This was followed by a discussion in which a number of Member States took part.

A representative speaking on behalf of the European Union and its member countries said that current measures to ensure a global framework for R&D that addressed the priority health needs of developing countries were insufficient. The European Union considered that the solution lay in strengthening coordination. It acknowledged the CEWG’s consideration of the wise use of public resources in assessing proposals, and stressed that WHO needed a better role in prioritizing research areas. Long-term research coordination was necessary, to strengthen the role and capacity of WHO in identifying and addressing R&D priorities. Work should build on and complement existing initiatives to the largest extent possible. The scope of activities should be agreed, including how to prioritize coordination efforts with a view to strengthening and balancing the entire health research process of innovation, implementation, access, monitoring and evaluation. The European Union acknowledged the CEWG’s assessment and exploration of models delinking the costs of R&D from the price of medicines, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights. The European Union recommended the collection of sufficient, reliable data from Member States on R&D, voluntary public spending on health research, and transparency in the flow of resources to priority areas. Lastly, the representative also stressed the Council of Europe conclusions which they noted had been referred to in the consultation document itself and the CEWG report. They expressed the view that the November meeting should focus on substance and not on structure, and that an “options” paper prepared by the Secretariat would be helpful.

One representative commented that some of the recommendations in the CEWG report would require further discussion before they could be implemented. There was an obvious lack of R&D on diseases that affected developing countries disproportionately and therefore of the medicines to treat them. Although the existing intellectual property regime supported R&D, it failed when innovation was stifled by market failures. It was therefore essential to identify the diseases that fell into that category, as it was those diseases that were the focus of the CEWG recommendations. In her opinion, a binding convention would not be the best way to ensure financing for R&D; it would be difficult to persuade governments to ratify it, and the negotiations would be protracted, although the needs were immediate or short-term. Other mechanisms should be found to ensure the coordination and financing of R&D,

such as mobilization and pooling of voluntary funds, with subsequent transfer of the funds to a more appropriate structure.

Another representative expressed support for the establishment of a European branch of a WHO global health R&D observatory, for the proposed financing mechanisms for health and health R&D in developing countries, and for the proposed global coordination mechanisms. He agreed with the proposal to establish a network of research institutions and suggested that regional expert and consulting councils be founded for better coordination of national research initiatives. His country would hold national consultations on the CEWG report and participate in the regional consultation in order to make concrete proposals. This was essentially an endorsement of the CEWG report in totum.

*Médecins sans Frontières* and Stichting Health Action International also made statements. The former focused on: the need for R&D in neglected areas including antibiotics; that while progress has been made in the past decade it is fragile and not coordinated; and that more sustainable solutions need an R&D convention to tackle the problem. The latter welcomed the CEWG proposals; expressed support for a convention on R&D to fund needed R&D; and urged Member States to agree to start to negotiate such a convention.

There was no Regional Committee resolution on this topic.

## **Conclusion**

It was recognized that it would be premature for countries to support a convention or a treaty on R&D financing immediately. The Regional Committee agreed that the web-based consultation be extended so as to give Member States further opportunities to comment.

## **WHO Regional Committee for the Eastern Mediterranean (Cairo, 1–4 October 2012)**

### **Consultations before the Regional Committee Meeting**

In the Eastern Mediterranean Region (EMR) reportedly only Islamic Republic of Iran held a national consultation to discuss the report of the CEWG. This consultation was held on 26th September 2012 in Tehran under the auspices of International Relations Department of the Ministry of Health and Medical Education in close collaboration with the WHO country office. According to the report of this national consultation the participants favored the ideas of pooled funding; global health R&D observatory; priority setting for research and development for developing countries; and intersectoral collaboration especially between academia, industry and public sector. After reviewing the recommendations of the CEWG report the meeting concluded that an expert group involving all concerned stakeholders should be established at the national level to systematically review the proposals and recommendations of the report. Jordan also communicated to EMRO about the need for Members States engagement at regional and global level forums to support and strengthen health research systems at national and regional levels. Some Member States, for example Oman and Egypt are planning to hold national consultations after the Regional Committee meeting.

There were no regional or subregional consultations before the Regional Committee meeting.

### **Summary of discussion during the 59th Session of the Regional Committee for the Eastern Mediterranean**

A presentation was made in the beginning to introduce the subject and the requirements of resolution WHA65.22. This was followed by a discussion in which seven Member States took an active part.

There was a general support for the CEWG report and its recommendations and implementation of practical recommendations was emphasized. The importance of research and development with respect to developing countries was discussed and the need for national capacity building in health research was particularly pointed out. Some Member States highlighted the need for practical measures for R&D rather than just abstract discussions and they also emphasized the need for transfer of technology to research institutions and local pharmaceutical companies in developing countries. Others provided examples of what measures they have taken to strengthen health research policy, management and infrastructure in their countries. A point was also made about a more active and important role to be played by the regional office in promoting health research in the Member States. Some Member States proposed to link the health research with the accreditation process of the medical schools and hospitals. The Member States also recognized the importance of public–private partnerships in undertaking health research and development.

There was no Regional Committee resolution on this topic.

### **Outcome of the discussion**

While discussing the specific recommendations of the CEWG report the Member States showed their support to the idea of creating a global health R&D observatory and the need for a voluntary contributions based pooled funding mechanism at global level which can support the required R&D needs in developing countries.

### **Conclusion**

Member States generally welcomed the CEWG report and its recommendations. Some Member States still want to hold the national consultations. They want to see the strengthened role of the health research support from the regional office. They recognize the need for strengthening financing and coordination for R&D and WHO's central role in this area and they are supportive of the ideas of establishing global health R&D observatory for better monitoring and information and pooled funding mechanism.

### **WHO Regional Committee for the Western Pacific (Hanoi, 24–28 September 2012)**

The Regional Committee for the Western Pacific held consultations regarding the CEWG report both in its 2011 and 2012 sessions. The 2012 session had a much more active and wider participation by the Member States compared with the 2011 session showing the growing interest of Member States in the issue of financing and coordination of research and development and the CEWG work.

All background documents relating to the Member States meeting will be available at: <http://www.who.int/phi/en/>.



## Proceedings

A side meeting was organized during the Regional Committee meeting in Hanoi, Viet Nam on 26 September 2012, from 12:00 to 13:00 to consult Member States and discuss the recommendations of the CEWG report. Nine countries and areas (Australia, Cambodia, China, Hong Kong (China), Japan, Malaysia, the Philippines, Viet Nam and the United the States of America) participated in the meeting. Five made specific comments: Australia, Cambodia, China, Hong Kong (China) and Japan.

Dr Henk Bekedam (Director, Health Sector Development, WHO Regional Office for the Western Pacific) chaired the meeting and Mr Robert Terry of the Department of Public Health, Innovation, Intellectual Property and Trade (PHI), WHO headquarters, provided an overview of the CEWG report and summarized the current consultation held by WHO Americas, European, and South-East Asia Regions. The WHO Regional Office for the Western Pacific provided updates on the ongoing work to support low- and middle-income countries in developing systems for research governance and management.

In addition to the side meeting, the CEWG report was also discussed during the plenary session on Agenda item 17 “Coordination of the work of the World Health Assembly, the Executive Board, and the Regional Committee”. Three Member States (Australia, China and the United States of America) made interventions on the CEWG report during this session.

Summary of feedback from Member States:

- Member States acknowledged the importance of the CEWG report and the need for better coordination and financing of research and development to develop health products responding to the needs of developing countries.
- Members States supported the CEWG recommendation to improve global coordination of research to develop innovative health products meeting the needs of developing countries. They supported further work on how to efficiently monitor research and development data and financial flows.
- Some Member States requested technical support at the country level to assist in collecting, collating and analysing these data and developing national research capacity.
- The participants welcomed the idea of a Research and Development Observatory, with WHO being the most suitable host for such a function. However, this should be built up from the country level to the global platform.
- National consultations held in countries did not reach a consensus or were not supportive of a global binding convention and pooled funding mechanism.
- Some participants suggested that earmarking development aid contributions might identify new resources for research and development funding.

# APPENDIX



## RESOLUTION OF THE WHO REGIONAL COMMITTEE FOR SOUTH-EAST ASIA

SEA/RC65/R3

### **CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION**

The Regional Committee,

Recalling resolutions WHA59.24 on Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action, and its subsequent resolutions WHA61.21 and WHA62.16 on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;

Further recalling resolution WHA63.28 on the establishment of a Consultative Expert Working Group (CEWG) on Research and Development: Financing and Coordination; requesting the Director-General, *inter alia*, to establish the CEWG to take forward the work of the Expert Working Group earlier established under resolution WHA61.21;

Noting the resolution WHA65.22 which requests Regional Committees to discuss at their 2012 meetings the report of the CEWG in the context of the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in order to contribute to concrete proposals and actions;

Recognising the need for enhancing investments in health 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 diseases;

Recognising that improved access to medical products such as medicines, vaccines and diagnostics in relation to Type II and Type III diseases and specific R&D needs of diseases of Type I in developing countries are the paramount goals;

Acknowledging the importance of innovation, technology transfer and access to medical products for essential health R&D relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, estimating funding needs in this area, and coordinating, facilitating and promoting health R&D;

Recognising the importance of securing sustainable financing mechanisms for R&D to develop and deliver health products to address the health needs of developing countries and develop mechanisms to monitor and evaluate the implementation of the Global Strategy and Plan of Action, including reporting systems;

Realizing the need for improving priority-setting and transparent decision-making processes based on the public health needs of developing countries;

Appreciating the Regional Director for convening a regional technical discussion on the report of the CEWG where Member States take an active role in the discussions; and

Welcoming the recommendations made by the CEWG and the need of Member States of the Region to implement the same in phases starting with coordination mechanisms, including the setting up of a global health R&D observatory, inter alia, to determine the existing capacities, requirements and the absorptive capacities of developing countries in essential health R&D relevant to diseases which disproportionately affect developing countries which would enable the individual countries to decide the level of commitment of resources;

URGES Member States:

- (1) To strengthen health R&D capacities on diseases of Type II, III and specific R&D needs of developing countries on diseases of Type I, through increased financial resources from the existing government budgets and private sources through different incentive schemes, and explore potential new or innovative sources specifically for health R&D;
- (2) To build, strengthen and sustain human resources and infrastructure for health research and development;
- (3) To promote coordination of health R&D among public and private partners in the country, and support regional and global coordination for health R&D in order to maximize synergies and avoid duplications;

- (4) To establish or strengthen national health R&D observatories for tracking and monitoring human and financial resources spent on health R&D and contribute to the work of a global health R&D observatory;
- (5) To promote the establishment of Advisory Mechanisms and the Global Health R&D Observatory as suggested by the CEWG to enable WHO to play a central and stronger role in improving coordination of R&D directed at the health needs of developing countries;
- (6) To support the formation of a working group with equal representation from each Region to undertake future preparatory work for the convention as suggested by the CEWG;
- (7) To explore the potential role of pooled funding at the global level, from different sources of finance, in supporting health R&D, and that the promising medical products, technologies and innovations generated from the pooled fund are global public goods and made available free of R&D cost; and
- (8) To engage actively in the negotiations in an open-ended meeting of Member States in November 2012, inter alia, by supporting the development of the Global Health R&D Observatory, effective global R&D coordination, adequate and sustainable funding for R&D on diseases of Type II and III and specific R&D needs of diseases of Type I in developing countries; and

REQUESTS the Regional Director:

- (1) To support Member States in their endeavour to establish or strengthen health R&D capacities and national health R&D observatories, which inter alia also contribute to the Regional and Global Health R&D observatory;
- (2) To facilitate the establishment of Regional and Global Health R&D Observatories and related Advisory Mechanisms as suggested by the CEWG through technical and financial support;
- (3) To strengthen the capacity of Member States to access and benefit from mechanisms as suggested by the CEWG, including the Global Health R&D Observatory and the pooled fund mechanism;
- (4) To promote partnerships and coordination at the country, regional and global levels in order to maximize synergies in health R&D;
- (5) To convey to the Director-General the wish of the Member States for consideration that the Chair of the open-ended meeting of Member States be from the SEA Region; and
- (6) To report to the Sixty-seventh Session of the WHO Regional Committee for South-East Asia in 2014 on the progress made in implementing this resolution.

Fifth meeting, 7 September 2012