

Consultative expert working group on research and development: financing and coordination

The Director-General has the honour to transmit to the Executive Board the workplan and inception report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (see Annex).

ANNEX

**REPORT OF THE FIRST MEETING OF THE CONSULTATIVE EXPERT
WORKING GROUP ON RESEARCH AND DEVELOPMENT:
FINANCING AND COORDINATION**

1. The Consultative Expert Working Group on Research and Development: Financing and Coordination held its first meeting from 5 to 7 April 2011 in Geneva, attended by 19 of its 21 members. The Consultative Expert Working Group elected Professor John-Arne Røttingen (Norway) as Chair and Professor Claudia Inês Chamas (Brazil) as Vice-Chair. In addition, it elected rapporteurs from each of the other four WHO regions:

- Professor Bongani Mawethu Mayosi (South Africa)
- Dr Leizel Lagrada (Philippines)
- Mr L C Goyal (India)
- Ms Hilda Harb (Lebanon)

2. The meeting was open to observers on the first two days, except for the final sessions on each day. On 6 April, the Consultative Expert Working Group held an open forum at which 14 presentations were made by a variety of stakeholders. The audiovisual records of these open sessions, and presentations made, are available on the WHO web site.¹ The final day's work essentially took place in a closed session. It was followed by a briefing on the outcomes given by the Chair in an open session.¹

SUMMARY OF OUTCOMES**Conflict of interest**

3. The Consultative Expert Working Group was fully mindful of issues raised with regard to the work of its predecessor, the Expert Working Group on Research and Development: Coordination and Financing, the request in resolution WHA63.28 that the Consultative Expert Working Group should "observe scientific integrity and be free from conflict of interest in its work", and the views of Member States expressed at the 128th session of the Executive Board.² The Consultative Expert Working Group discussed the issue of conflict of interest in the light of the determination by WHO that four members had relevant conflicts of interest.³ The Secretariat noted that it was WHO's policy to be transparent about conflicts of interest, and to seek to manage such conflicts bearing in mind the contributions that individuals could make to public health in spite of a declared conflict of interest.

¹ See http://www.who.int/phi/news/cewg_2011/en/index.html (accessed 28 April 2011).

² See document EB128/2011/REC/2, summary records of the second meeting, section 2 and the ninth meeting, section 1.

³ See presentation at http://www.who.int/phi/news/cewg_2011/en/index.html.

4. After due consideration, it was agreed that any member of the Consultative Expert Working Group would be free to raise the issue of the potential conflict of interest of any other member at any time during their discussions if they considered it relevant, and that the Consultative Expert Working Group would then agree how to address any perceived conflict in relation to the topic being discussed. It was also agreed that, in the particular case of Professor Herrling, he should excuse himself from participating in the discussion of the proposal he had sponsored.

Mandate/scope of work

5. The Consultative Expert Working Group considered how to interpret its mandate as set out in resolution WHA63.28, including taking forward the work of the former Expert Working Group on Research and Development: Coordination and Financing, deepening its analysis, considering additional submissions and proposals, and examining the feasibility of regional approaches to implementation. The Consultative Expert Working Group noted also that its core mandate remained the one set out for the establishment of the former Expert Working Group in resolution WHA61.21 and in the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property as adopted by that resolution.

6. In light of the above, the Consultative Expert Working Group decided that its focus should be on the financing and coordination of research and development for health products and technologies (including, for example, medicines, vaccines, diagnostics, devices and delivery technologies) related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases. However, it acknowledged the importance of other relevant areas of research and development which may require additional financing and/or improved coordination such as:

- better policies for research and development and innovation
- improved public health, clinical and preventive interventions including, for example, diagnostic algorithms
- health policy and health systems, to improve delivery and access to new and existing products.

7. The Consultative Expert Working Group also emphasized the links between its specific mandate and the other elements of the global strategy and plan of action on public health, innovation and intellectual property. Its core mandate was centred on Element 2 (Promoting research and development) and Element 7 (Promoting sustainable financing mechanisms). However, it was important also to take account of research and development needs and priorities (Element 1), improving innovative capacity (Element 3), technology transfer (Element 4) and intellectual property management (Element 5). Moreover, the Consultative Expert Working Group recognized the central importance of ensuring that research and development policies took account of the need to improve availability, acceptability and affordability to contribute to improved delivery and access (Element 6).

8. The Consultative Expert Working Group recognized that resolution WHA63.28 had requested it to examine, in particular, the practical details of four innovative sources of financing,¹ to review five

¹ See *Research and development coordination and financing: report of the expert working group*. Geneva, World Health Organization, 2010, Chapter 5.3.

promising proposals,¹ and to further explore the six proposals that did not meet the criteria applied by the Expert Working Group on Research and Development: Coordination and Financing.² However, the Consultative Expert Working Group decided to analyse all 22 proposals referred to in the former Expert Working Group's report (including those in Chapters 5.4 and 5.5) together with any new or improved proposals submitted by Member States or other stakeholders. Furthermore, the Consultative Expert Working Group considered that Member States and other stakeholders should, if they wished, resubmit any proposals from among the 109 that had originally been compiled by the former Expert Working Group,³ or any other proposals that they felt had not received proper consideration by that Expert Working Group.

9. Resolution WHA63.28 specified that the Consultative Expert Working Group should examine the appropriateness of different financing approaches and the feasibility of implementation in each of the six WHO regions. The Consultative Expert Working Group underscored that it would be very challenging to analyse the regional appropriateness of different proposals within its time limits, and stressed that a full assessment would need to take regional and national issues into account and should therefore be carried out by local policy-makers. Resolution WHA63.28 also requested the Director-General to provide upon request and within available resources, technical and financial support for regional consultations to inform the work of the Consultative Expert Working Group. In the time available to it, the Consultative Expert Working Group thought it most appropriate to explore the possibility of organizing side meetings during the sessions of the WHO regional committees which are being held from August to October 2011 – should such meetings be requested by the WHO regional offices. The side meetings would involve the members of the Consultative Expert Working Group belonging to a particular region, the Regional Office concerned and the Secretariat at headquarters; invitees would include Member States and regional stakeholders. These regional meetings, if held, would enable the Consultative Expert Working Group to incorporate regional perspectives into its deliberations.

Analytical framework

10. The Consultative Expert Working Group decided that it would provisionally categorize proposals under two headings:

- Financing mechanisms – including both financing and allocation proposals in the terminology of the former Expert Working Group
- Coordination mechanisms – including those to improve efficiency, networking arrangements, and mechanisms with overarching implications that include global governance issues.

11. The Consultative Expert Working Group also decided that in reviewing proposals before it (i.e. proposals from the former Expert Working Group, or new, improved or resubmitted ones), it would not seek to give them a ranking or score as its predecessor had done. No proposal would be rejected unless clearly agreed to be outside the Consultative Expert Working Group's mandate.

¹ See *Research and development coordination and financing: report of the expert working group*. Geneva, World Health Organization, 2010, Chapter 5.6.

² See *Research and development coordination and financing: report of the expert working group*. Geneva, World Health Organization, 2010, Annex 2.

³ See "Methodology Used by the EWG": www.who.int/phi/explanation_of_methodology_used_by_the_EWG.pdf (accessed 29 April 2011).

Rather, the Consultative Expert Working Group would provide a qualitative appraisal of each proposal, based on the evidence, where available, and its own judgment, according to its own criteria. On the basis of this analysis the Consultative Expert Working Group would aim to provide concrete recommendations on how Member States, the Secretariat and other stakeholders could take the agenda forward to improve financing and coordination in research and development.

12. The Consultative Expert Working Group considered a number of criteria that should inform its analysis, bearing in mind that their applicability would vary according to the type of proposal involved, and the diverse set of constraints in the research and development process that different proposals set out to address. These criteria included:

- potential public health impact in developing countries
- rational and equitable use of resources/efficiency considerations
- cost-effectiveness
- technical feasibility, scaling-up potential, replicability, speed of implementation
- financial feasibility and sustainability
- additionality
- intellectual property management issues
- potential for de-linking research and development costs and the price of products
- equity/distributive effect, including on availability and affordability of products and impact on access and delivery
- accountability/participation in governance and decision-making
- impact on capacity building in, and transfer of technology to, developing countries
- potential synergy with other mechanisms/potential for combining with others.

Invitation to submit proposals

13. The Consultative Expert Working Group decided to issue an invitation to submit proposals at the end of April which would solicit the following: any improved versions of the 22 proposals considered by the former Expert Working Group; any proposals from that Expert Working Group's wider list of 109 that Member States or other stakeholders felt should be reconsidered by the Consultative Expert Working Group; and any new proposals, or any other proposals that were felt not to have received proper consideration by the former Expert Working Group. The Consultative Expert Working Group asked the Secretariat to issue the call for proposals using a standardized template that required an assessment of each proposal according to agreed criteria, including the evidence base, where available, supporting the proposal.

Workplan

14. Following the timeline set out in resolution WHA63.28, the Consultative Expert Working Group decided on the intermediate steps required to enable it deliver its report to the Sixty-fifth World Health Assembly in May 2012. The workplan is attached at Appendix.

Appendix

**DRAFT WORK PLAN FOR THE CONSULTATIVE EXPERT WORKING
GROUP ON RESEARCH AND DEVELOPMENT: FINANCING
AND COORDINATION (2011–2012)**

Workplan and inception report finalized for consideration by the Executive Board at its 129th session	26 April 2011
Announcement for web-based public submissions (allowing six weeks for submission)	30 April 2011
Deadline for web-based public submissions	15 June 2011
Second meeting of the Consultative Expert Working Group	7 and 8 July 2011
Update to Member States on second meeting	8 July 2011
Regional consultations – side events during sessions of the WHO regional committees ¹	August to October 2011
Circulation of first draft of the report to members of the Consultative Expert Working Group (draft assessment of proposals and draft recommendations)	30 October 2011
Third meeting of the Consultative Expert Working Group	17 and 18 November 2011
Update to Member States on third meeting	18 November 2011
Second draft of report finalized	30 November 2011
Consultative Expert Working Group members' comments on second draft of report	December 2011
Progress report of the Consultative Expert Working Group submitted for consideration by the Executive Board at its 130th session	6 December 2011
Finalization of draft report	late December 2011 to early February 2012

¹ Consultations to be held upon request by regions. Dates of the regional committees in chronological order are as follows (some venues remain to be finalized): Regional Committee for Africa (Abidjan, 28 August – 2 September); Regional Committee for South-East Asia (India, 6–9 September 2011); Regional Committee for Europe (Baku, 12–15 September 2011); Regional Committee for the Western Pacific (Manila, 19–23 September 2011); Regional Committee for the Americas (Washington, DC, 26–30 September 2011); and Regional Committee for the Eastern Mediterranean (Syria, 2–5 October 2011).

Consultative Expert Working Group members' comments on draft report	February 2012
Report in six languages submitted (online) to Member States	2 April 2012
Submission of final report to the Sixty-fifth World Health Assembly	16 May 2012

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