

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

Introduction

1. The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) held its third meeting on 16-19 November 2011 in Geneva, attended by 18 of its 20 members. Two members, Hossein Malekafzali from Iran and Shozo Uemura from Japan, sent their apologies for personal reasons.
2. On 18 November 2011 the Chair, Professor John-Arne Røttingen, provided a briefing on the main outcomes of the meeting to Geneva-based missions and other interested stakeholders. This briefing is available on the CEWG website as a powerpoint presentation.¹
3. There were no changes in the conflicts of interest statements of any member of the group.
4. The Agenda of the third meeting is in the Annex of this report.

Regional Consultations

5. The Group considered the results of regional consultations held to date. These were attended by regional CEWG members in each case and were held as follows:
 - AFRO – 27 August
 - EURO – 5 October²
 - SEARO – 7 October
 - WPRO – 13 October
 - PAHO – 7 November

Reports of these meetings are available on the CEWG pages on the WHO website.³

Small Group Meeting

6. An intermediary meeting of the CEWG bureau took place in Oslo on 18-20 September to advance work on the analysis of proposals and on the preparation of the report, with a focus on areas identified at the second CEWG meeting where further work was required.⁴ Prior to this meeting, an outline of the report and revised assessments were prepared by the secretariat and distributed to all CEWG members. Members of the CEWG bureau attending were

- The Chair (EUR, Norway)

¹ http://www.who.int/phi/news/cewg_meetings_2011/en/index.html

² No dedicated regional consultation meeting was convened in the European Region, but the Group's work was presented and discussed on 5 October at the 7th European Congress on Tropical Medicine & International Health (Barcelona, Spain, 3–6 October 2011).

³ http://www.who.int/phi/news/cewg_regional_consultations/en/index.html

⁴ See report of second meeting, paras 12 and 13 http://www.who.int/phi/news/cewg_rd_2nd_meeting_report.pdf

- The Vice Chair (AMR, Brazil)
- EMR rapporteur (Lebanon)
- SEAR rapporteur (India)
- WPR rapporteur (Philippines)

The AFR representative was unfortunately unable to attend.

Summary of Outcomes

7. During the 3rd CEWG meeting, a representative of WHO Legal Counsel presented the different normative instruments under the WHO Constitution: Articles 19 (conventions), 21 (regulations) and 23 (recommendations). The CEWG also received a presentation on the Framework Convention for Tobacco Control, the only Convention negotiated under the auspices of the WHO to date.

8. The CEWG reviewed in detail first drafts of the report chapters and revised assessments of grouped proposals. It agreed on minor revisions to the way criteria are used in the assessment of proposals, and to address the proposal of equitable licensing in a separate assessment based on earlier submissions. The CEWG confirmed that the following proposals met best its criteria for proposal evaluation:

- A binding global instrument
- Direct grants to companies in developing countries
- Equitable licensing
- Patent pools
- Pooled funds, administered by WHO
- Precompetitive R&D platforms/open source/open access
- Prizes, in particular milestone prizes.

9. It also confirmed that the following proposals met its criteria less well:

- Green intellectual property
- Health Impact Fund
- Orphan drug legislation
- Priority review voucher
- Purchase or procurement agreements
- Tax breaks for companies
- Transferable IP rights.

10. It considered that the following two proposals, while meeting some of the CEWG criteria, were not principally directed at enhancing R&D for diseases relevant to its mandate:

- Regulatory harmonization
- Removal of data exclusivity.

11. In summary, the CEWG proposes to make recommendations on the following lines:

- Supporting an Open Knowledge Innovation approach including the use of:
 - Equitable licensing
 - Patent pools
 - Precompetitive R&D platforms/open source and access
 - Prizes, in particular milestone prizes.
- Direct grants to small and medium companies in developing countries.
- Pooled funding mechanism.
- A binding global instrument for health R&D covering both financing and coordination.
- The need for strengthening global coordination of efforts to address R&D for developing countries and the importance of WHO's role in such coordination.
- The importance of building R&D capacity in, and technology transfer to, developing countries.

12. With regards to the recommendation under 11 above of a binding global instrument, the CEWG discussed the different options under the WHO constitution. Article 19 and 23 were considered the two relevant ones. CEWG concluded that a binding instrument should be established under article 19 of the WHO constitution for R&D related to Type II and III diseases and the specific R&D needs of developing countries in relation to Type I diseases. The CEWG considered that such a convention might incorporate the following principles:

- Open knowledge innovation, de-linkage, competition, enhanced access and strengthening of innovative capacity in developing countries
- A global coordination mechanism
- Increased and committed public investment
- A mechanism for redistributing resources
- Pooling of funds to meet these aims.

The CEWG saw the convention not as a replacement for the existing IPR system, but as a supplementary instrument where the current system does not function.

13. In order to make progress it will be necessary to conduct further analytical work and to build a platform for negotiation. The exact nature of these preliminary arrangements would depend upon discussions at the World Health Assembly and on a resolution charting a way forward.

14. In relation to financing of R&D for diseases under its mandate, the CEWG emphasized the importance of government commitment and considered a number of options for quantifying that commitment:

- Total public funding of health R&D
 - (2% of health budget)*
 - To be defined as proportion of GDP

- Public funding of R&D on technologies in the CEWG mandate
 - To be defined as proportion of GDP
- Public funding to global pool
 - To be defined as proportion of GDP
- Proportion of health development aid (ODA) to health R&D
 - (5%)*

*As proposed by the Commission on Health Research for Development in 1990

15. The CEWG also considered options and principles for raising additional funding for R&D:

- Governments may consider different forms of revenue generation to meet the proposed funding commitments
- Taxes on activities harmful to health (e.g. tobacco, alcohol) may be appropriate and earmarked, inter alia, for health R&D
- If member states introduce international indirect taxation to finance global public goods e.g. a tax on financial transactions, a portion of the revenues generated may be dedicated to global health R&D
- Voluntary private funding to a global pooled funding mechanism may be encouraged.

16. The CEWG finally also discussed options and principles for an improved coordination of health R&D:

- WHO should play a central role in the global coordination and management of health R&D, in particular with regard to the following functions:
 - Advisory function: WHO should use its existing structures and bodies, such as the Advisory Committee on Health Research (ACHR) and similar regional committees, to advise governments
 - Sharing/learning: WHO should use its convening power to assemble research organizations and large R&D funders, such as for example the Heads of International Research Organizations (HIROS), in multi-stakeholder forums with a view to enable knowledge-sharing and better coordination among these stakeholders.
 - Monitoring & evaluation: A «Global Health R&D Observatory» with regional functions should be established to monitor and evaluate global health R&D investments, needs and gaps.
- Regional and national coordination should be further strengthened and extended
- All coordination mechanisms should, where appropriate, build on existing structures and institutions.

Next Steps

17. In its final session on 19 November the CEWG reviewed its progress, and continued discussions on revising assessments, elaborating possible recommendations, and the process and timetable for the remainder of its work. It considered and agreed on the steps necessary to complete the report by the first quarter of 2012.

**CONSULTATIVE EXPERT WORKING GROUP
ON R&D: FINANCING AND COORDINATION
Geneva, 16-19 November 2011
- TENTATIVE AGENDA -**

All sessions are closed sessions unless specifically marked otherwise

Wednesday, 16 November 2011

- 13.00 - 13.15** **Opening Session**
Welcome by the Chair - Dr John-Arne Rottingen
Welcome by the Vice-Chair - Prof Claudia Chamas
Welcome by the Secretariat - Dr Marie-Paule Kieny, WHO
Update on Conflict of Interest
Adoption of Agenda
- 13.15-14.15** **Update on Regional Consultation Meetings**
Presentations of outcomes of regional consultation meetings
AFRO: Prof Bongani, Dr. Loua
SEARO: LC Goyal, Prof Trisnantoro
WPRO: Dr. Lagrada
EURO: Prof. Jahn Dr. Koivusalu
PAHO: Prof. Chamas
EMRO: Dr. Zafar Mirza
Conclusions on input of regional consultation meetings
- 14.15 - 14.45** **Briefing on Small Group Meeting**
- 14.45 - 15.00* *Break*
- 15.00 - 15.45** **Finalization of Assessments of R&D financing proposals**
Update on the process since the 2nd CEWG meeting
Identifying any remaining issues in any of the assessments which needs more discussion (the next day)
- 15.45 - 18.00** **Discussion of Structure of Report**
Brief Presentation of Chapters and Annexes
Discussion

Thursday, 17 November 2011

- 09.00 - 10.30** **Sources of Financing of R&D
Coordination of Health R&D**
Scope of coordination

	Role for WHO in coordination
	Chapter 5 of the Report
10.30 - 11.00	<i>Coffee Break</i>
11.00 - 12.00	Finalization of Assessments of R&D financing proposals
12.00-13.30	<i>Lunch</i>
13.30 - 15.30	Discussion on the CEWG recommendations
15.30 - 16.00	<i>Coffee</i>
16.00 - 16.40	Presentation on the concept of a Treaty
	<i>Legal</i>
	Presentation on Tobacco Convention as an example of a public health treaty
	<i>FCTC</i>
16.45 - 18.00	Discussion on recommendation regarding global binding instrument for R&D

Friday, 18 November 2011

09.00 - 10.30	Discussion of Report and Finalization of Recommendations in the Report
	Discussion of individual chapters
10.30 - 11.00	<i>Coffee Break</i>
11.00 - 12.30	Discussion of Report and Finalization of Recommendations in the Report
	Discussion of individual chapters
12.30 - 14.00	<i>Farewell Lunch in the WHO Crystal Restaurant</i>
14.00 - 16.30	Discussion of Report and Finalization of Recommendations in the Report
	Discussion of individual chapters
16.30 - 17.00	<i>Coffee Break</i>
17.00 - 18.00	OPEN BRIEFING SESSION

Saturday, 19 November 2011

09.00 - 10.30	Discussion of Report and Finalization of Recommendations in the Report
10.30 - 11.00	<i>Coffee Break</i>
11.00 - 12.30	Conclusions and next steps