

Summary of 2nd CEWG meeting by Chair and Vice-Chair

Open Session

CEWG on R&D Financing and Coordination

July 8, 2011

Administrative

- Two members were unable to attend the meeting for personal reasons (Ms Hilda Harb from Lebanon and Prof Steve Morgan from Canada)
- Dr Christy Hanson from the USA has withdrawn from the group due to time constraints
- No new disclosures or material changes in conflict of interest

Prior to the meeting

- 21 new submissions were received from the call for submission of proposals
- The Secretariat documented the 22 grouped proposals (from 109 individual proposals/mechanisms) mentioned in EWG report using the CEWG proposal template
 - Including a description for each of the CEWG criteria and the evidence base
- Group members assessed their assigned proposals (both grouped EWG and new submissions) using the CEWG criteria (Inception Report, at:
http://www.who.int/phi/PHI_cewg_inception_report_2011_en.pdf)

CEWG criteria

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.

At the meeting

- Each proposal was appraised by one group member in accordance with the CEWG criteria
- A second group member performed a secondary appraisal
- The proposal was then discussed by the group as a whole and next steps determined

Proposals assessed

- Biomedical research and development treaty (including submissions from Health Action International, Initiative for Health & Equity in Society, KEI, MSF, TWN)
- Direct grants to small companies and for trials in developing countries (including submissions from CILFA and GFHR)
- Equitable Licensing (submitted by Pharma-Kampagne)
- Green intellectual property (including the submission from International Bank for Innovation)
- Health impact fund (including the submission from Incentive for Global Health)
- Neglected disease tax breaks for companies
- New donor funds for health research and development
- New indirect taxes
- Open source
- Orphan drug legislation
- Patent pools (UNITAID model)
- Precompetitive research and development platforms (including submission from UAEM)
- Priority review voucher
- Prizes, milestone and end (including submissions from Bioventures for global health and KEI)
- Pooled funds-related proposals (including submissions from Novartis, DNDi and India Drug Action Network, Centad, Berne Declaration, Initiative for Health & Equity in Society, TWN)
- Reduction of patents' duration to prevent collusion at industry level (submitted by Euromed Management School, Northwestern University)
- Regulatory harmonization
- Removal of data exclusivity
- Taxation of repatriated pharmaceutical industry profits
- Transferable intellectual property rights
- Voluntary contributions from businesses and consumers)

The 22 EWG grouped proposals plus 15 new submissions

6 submissions out of scope

- Employees' food safety knowledge and practices in foodservice operations serving high risk populations (Paez & Ortiz)
- Limbal Stem Cell Bioengineering (Raj & Anandan)
- Maternal Mortality Reduction (Christopher)
- Neglected Tropical Diseases Management Portal (Health Insight LTD.)
- Optimal hedging against the premature obsolescence of available treatments (Leoni & Luchini)
- Software for improving Maternal, Neonatal and Child Health Services in Pakistan (WHO Pakistan)

Preliminary summary of assessments

- Proposals meeting most criteria
 - Patent/IP pools
 - Open source, open/non-exclusive/equitable licenses, precompetitive R&D platforms
 - Direct grants to SMEs
 - Prizes (in particular milestones)

Preliminary summary of assessments

- Proposals meeting fewer criteria
 - Tax breaks, orphan drug like legislation (for countries to consider)
 - Removal of data exclusivity
 - Green IP (a new indirect tax)
 - Priority review voucher, transferable IPR
 - Health Impact Fund – need pilot to examine value based rewards (health impact)
 - Advance procurement agreements (AMC)
 - Regulatory harmonization
 - Reduction of patents' duration

Preliminary summary of assessments

- Proposals meeting most criteria, but where CEWG need to do more work
 - R&D treaty/A global framework for R&D
 - Pooling of funds (for PDPs, other etc)
 - Sources of funding (taxes, voluntary contributions etc)
 - Coordination (regional networks e.g. ANDI, etc)

Some preliminary recommendations on global mechanisms

- CEWG intends to recommend strengthening global financing and coordination mechanisms for R&D for health needs of developing countries under the auspices of WHO
- CEWG intends to recommend that formal intergovernmental negotiations begin for a binding global instrument for R&D and innovation for health

Next steps

- Regional consultations (Aug and Sept)
- 3rd CEWG meeting (Nov 17-18)

Questions?