

May 2011 Occasional Information General Distribution Dear **ECONMED** participants

On this occasion we are glad to share a brief summary of the first working session held in WHO Geneva between April 5th and 7th of the Consultative Expert Group on Research and Development: Financing and Coordination (CEWG) and an outline of its next steps. This communication shall be also perceived as part of longer series of analytical and informative materials on a wide range of topics as virus exchange, efforts on combat and eradication of counterfeiting of health technologies and others which were just addressed at the 64th World Health Assembly (May 16th-24th) and might be worthy of ECONMED participants interest; ECONMED will be addressing some of specific aspects of such topics, to be found in daily work of public health professionals and/or currently faced by national policy-makers. As usual, contributions from participants are encouraged and welcomed.

This first working session of the group comprising <u>a set of experts</u> nominated by Member States and selected by the Director General of <u>WHO</u>, in compliance with the mandate conferred at the 63th WHA regarding the *Establishment of a consultative expert working group on research and development: financing and coordination* (<u>WHA63.28</u>) focused on analyzing the mandate conferred by the Assembly, linking it to the ongoing implementation of the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (GSPA as set out in Resolution <u>WHA61.21</u>), currently being implemented in the Americas through the *Regional perspective* embodied in Resolution <u>CD.48R15</u>, <u>most specially to those actions and commitments referred to the promotion of the Research and Development (Element 2) and the existing need to work <u>towards sustainable financing mechanisms for health research</u> (<u>Element 7</u>), the <u>interdependent nature of the components of the GSPA</u> was explicitly acknowledged, stressing the necessity of taking into <u>account other subjects such as the priority-setting of R&D, enhancement transfer of technology or setting up a framework for a management and application of intellectual property rights that effectively serves public health interests.</u></u>

In its first meeting the CEWG chose a <u>shared co-chairmanship</u> between Norwegian <u>John Arne Rottingen</u> (<u>Institute for Health Metrics and Evaluation</u>, <u>School of Medicine Oslo University</u>) and Dr. Claudia Chamas (coordinator of the area of innovation and Intellectual Property at <u>FIOCRUZ</u> and <u>ECONMED</u> participant) consensus was reached to continue with the analysis of those proposals previously selected by the Expert Working Group on Research and Development Financing and Development (<u>EWG</u>) as innovative financing sources (Section 5.3 of the report of the EWG):

- 1. A new indirect tax.
- 2. Voluntary contributions from businesses and consumers
- 3. Taxation of repatriated pharmaceutical industry profits
- **4.** New donor funds for health research and development

It was also agreed to proceed with the examination of five proposals considered as promising by the EWG (Section 5.6 of the Report):

- 1. Open source
- 2. Patent pools (UNITAID- Patent Pool)
- 3. Health impact fund
- 4. Priority review youcher
- 5. Orphan drug legislation.

It was also decided to extend consideration during the <u>CEWG</u> works to six proposals that were not considered in-depth by the <u>EWG</u> (Annex of the <u>report)</u>

1. Transferable intellectual property rights

- 2. green intellectual property
- 3. Removal of data exclusivity
- 4. Biomedical research and development treaty
- **5.** Large end-stage prizes (impact-based rewards)
- 6. Neglected disease tax breaks for companies.

In addition it was considered that any of the <u>22 proposals already accepted and examined</u> by the <u>EWG</u> shall not be submitted again except in case of substantial amendment or transformation, ensuring that the <u>109 proposals already presented</u> (and not recognized explicitly as innovative or promising) opening the door to the possibility of new proposals.

Finally, as a closure of this first session an open and public forum was held to allow for all interested parties to deliver presentations proposals submitted beforehand. The works of examination and discussion of proposals on the part of the members of the CEWG will follow a different methodology of evaluation from the set of indicators and acceptability thresholds of used in the EWG and seeking synergy between submitted contributions..

It should be pointed out explicit acknowledgement expressed in this first session of the importance of the regional applicability of the submitted proposals. Parallel consultations on the proposals are schedule to be held in parallel o the meetings of the regional committees of the Organization (in the case of the Americas it will be held the 51st Session of PAHO Directive Council between September 26 and 30th), organized/facilitated and coordinated by the Secretariat.

At the beginning of this month the <u>CEWG</u> opened the term in order to receive new proposals. All received proposals will be made public through the Web page of the group from 19 June. As it is indicated in the expression of interest, the proposals should fulfill the following criteria:

- 1. Potential public health impact in developing countries
- 2. Rational and equitable use of resources/efficiency considerations
- Cost-effectiveness
- **4.** Technical feasibility, scaling-up potential, replicability, speed of
- 1.implementation
- 5. Financial feasibility and sustainability
- 6. Additionality
- 7.IP management issues
- 8. Potential for de-linking R&D costs and price of products
- 9. Equity/distributive effect including on availability and affordability of products
- 2. and impact on access and delivery
- 10. Accountability/participation in governance and decision making
- 11. Impact on capacity building in, and transfer of technology to, developing countries
- **12.** Potential synergy with other mechanisms/potential for combining with others.

It is established that the proposals should not exceed the 3000 words. And they should be submitted to the direction cewg@who.int (which has been added to ECONMED). We leave to participants discretion to share them with ECONMED participants.

The <u>CEWG</u> will meet again between 7 and 8 July and will have a third working session 17 and 18 November. According to resolution <u>WHA63.28</u> having submitted to the 129 Session of the Executive Committeea <u>progress report</u> its final report in the 64 WHA in May 2012.

ECONMED counts on the contribution (through requests of information, sharing of best practices, dissemination of interesting materials...)of its participants to keep building up collaborative spaces of work between public health professionals in the Americas. You can submit your communications on any topic related to the legal and economic regulation of pharmaceutical products for approval to econmed@listserv.paho.org







