8.5 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

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In focus

The Secretariat report (<u>EB140/21</u>), prepared in response to requests made by the Health Assembly in resolution <u>WHA69.23</u> (2016), proposes:

- terms of reference and a costed workplan of the <u>Global Observatory on Health</u> <u>Research and Development</u> (Annex 1 in <u>EB140/21</u>); and
- goals and an operational plan for a voluntary pooled fund to support research and development (Annex 2 in <u>EB140/21</u>; see also <u>TDR report</u>).

Responding to further requests in A69.23, EB140/21 also

- reviews the six demonstration projects and their funding status (in paras 9-10);
- sketches out the roles and inter-relationships of the Global Observatory, the Expert Committee and the Scientific Working Group (in paras 11-14);
- reviews the funding so far secured for the demonstration projects and the global observatory (facing a \$US73m shortfall); and
- (in para 19) acknowledges the need for policy coherence across the principles agreed to regarding R&D under the follow up of the CEWG; the Research and Development Blueprint to foster research and development preparedness for infectious diseases with epidemic potential, and the Global Antibiotic Research and Development Partnership, a joint venture by WHO and the Drugs for Neglected Diseases initiative.

The second report produced in fulfillment of <u>A69.23</u> is <u>EB140/22</u> which proposes terms of reference for a WHO Expert Committee on Health Research and Development.

The elephant in the room during this debate will be the June 2016 report of the UNSG's High Level Panel on Access to Medicines (here). There were requests for the report to be included on the agenda for EB140 but the officers of the Board determined otherwise.

In several important respects the HLP has reopened a number of contentious issues which had been closed off in the WHA's deliberations to this point. These include:

- the need for a binding agreement to delink the costs of R&D from prices;
- the need for governments to be free to use to the full the flexibilities available under the TRIPS agreement (including sanctions against countries which pressure other countries to forego the use of such flexibilities);
- the need for transparency regarding the costs of R&D (including the degree to which R&D underpinning privately owned IP has been publicly funded); and
- for WHO to establish and maintain an open database of the prices of patented, generic and biosimilars in the public and private sectors of all countries where they are registered.

Background

The prehistory of the CEWG discussion is described here.. The critical documents are the report of the Commission on PHIIP (Jan 2006), the finally agreed GSPOA (May 2009), the final report of the CEWG (May 2012), and WHA66.22 and WHA66(12) (both May 2013) which adopted the CEWG report and authorised a number of parallel but interlocking initiatives including the observatory, the pooled fund to support R&D and the demonstration projects.

The <u>High Level Panel on Access to Medicines</u> was established by the UN SG in November 2015 as an outcome of the <u>Global Commission on HIV and the Law</u> which was convened by UNDP on behalf of UNAIDS in 2010. See the coverage by <u>IP-Watch</u> for comments on the HLP report.

PHM comment

The proposals advanced in <u>EB140/21</u> and <u>EB140/22</u> are reasonable in the light of the decisions which have preceded them in the Assembly and the Board.

The big shadow looming over all of them is the funding (see paras 15-18 of EB140/21):

- a minimum of \$100m is required for the voluntary pooled fund;
- a funding gap of \$2-3m per year for the global observatory;
- insufficient funds for the 5th and 6th demonstration projects.

Para 18 of EB140/21 advises that the Secretariat will be holding a 'high level event' in the first half of 2017 to promote increased investment into R&D in areas where the current investment levels are insufficient to meet global public health needs.

However, the report of the HLP reopens important issues regarding delinking R&D costs from monopoly pricing and places new issues on this agenda.

It seems likely that the report of the HLP will be considered further within the UN system, outside the WHO. While the structures currently being developed under the CEWG process

could probably be adapted to whatever comes out of the HLP process, undoubtedly the HLP report will have ramifications within WHO's governing bodies.

PHM urges public interest NGOs, social movements and progressive governments to promote the recommendations of the HLP (see above) and to advance their implementation.

Notes of discussion at EB140