16.2 Follow-up to the report of the CEWG on R&D: Financing and Coordination – Report of the open-ended meeting of Member States

Contents

In focus

In resolution WHA66.22 (2013), as part of the follow up of the report of the Consultative Expert Working Group (see pre-history below), the Director-General was requested, inter alia, to convene an open-ended meeting of Member States prior to the Sixty-ninth World Health Assembly in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development.

A69/40 reports on the outcomes of the open ended meeting in Geneva from 2-4 May. A69/40 includes:

- a report from the secretariat summarising progress in relation to the various elements of the CEWG workstream (Appendix 2); and
- a richly conflicted draft [decision / resolution] on the follow up to the report of the CEWG.

The Secretariat's Progress Report (A/RDMCF/2) reviews the elements of the CEWG workstream and summarises progress with respect to:

- the global health research and development observatory;
- the health research and development demonstration projects;
- the budget line for demonstration projects and the global health R&D observatory;
- exploration of financing mechanisms for contributions to health R&D;
- coordination of health research and development; and
- two new emerging areas of R&D requiring funding and coordination:
    - research and development blueprint for action to prevent epidemics; and
    - research and development for new antibiotics as part of WHO's global action plan on antimicrobial resistance.

During the EB138 discussion of this item (at PSR11(4)) there were expressions of support for the various elements of the program but regret at how far behind the financial commitments were against the estimated needs. .

See WHO preparatory page for the OE Meeting including reports, background documents and presentations.

Appendix 3 to A69/40 constitutes a draft [decision / resolution] which remains highly contested. From the pattern of brackets it seems that the main areas of disagreement include:

- Strong or weak in relation to member states support for R&D for diseases that primarily affect developing countries;
- Strong or weak in reaffirming the right to use TRIPS flexibilities;
- Whether or not to agree that IP protection is important for the development of new medicines (which would be problematic recognising that the focus of this whole project is on diseases that primarily affect developing countries and where market failure has been significant);
- Emphasis on poverty as a barrier to access to medicines;
- Welcoming or noting the establishment of the HLP on A2M;
- Whether the responsibility of member states is 'shared' or 'common';
- Level of support for the Global Observatory and specificity of funding obligations;
- Importance of funding the Global Observatory through assessed contributions and un-earmarked voluntary contributions;
- Conflict over advisory structures in relation to the coordination and funding of R&D for Types I, II and III diseases; and/or where market failure exists;
- Funding sources
- Delinkage
- Policy coherence between WHO decision making and the outcomes of the HLP on A2M.

See also Lancet assessment (7 May) that delinkage models are gaining ground while 'countries mull over incentives for developing antibiotics'.

It seems likely that there will be a drafting group appointed on Day 1 and it may come up with a consensus resolution by the end of the Assembly.

Background

While the focus of the Assembly will be on the conflicted draft resolution it is worth reviewing the background to the whole engagement and the more specific components.

CEWG Pre-history

See CEWG pre-history up to and including EB136 in Jan 2015.

WHA68 (May 2015) reviewed two reports: A68/34 dealing with the proposed funding mechanism; and A68/34 Add.1 which reported on progress made in implementing the selected health research and development demonstration projects.

Document A68/34 proposed the Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development. The report described how such a fund might be established and managed, as well as its relationship with the R&D Observatory and the future coordination mechanism.

The Secretariat's report was noted (Fifth meeting).

The observatory

In resolution WHA66.22 the Assembly requested the Director-General to establish a global R&D observatory and to review existing mechanisms which could be used to coordinate R&D under the CEWG process.

The Assembly (May 2014) considered the report A67/27 which *inter alia* reported on the work done to date in relation to the Observatory. It reported that the Secretariat has started the process of establishing the Global Health Research and Development Observatory. It proposed the establishment of a global research and development advisory body and the institutionalization of an annual research and development stakeholder conference.

The objectives of the Global Observatory are described in document A67/27. Further information is available at http://www.who.int/phi/implementation/phi_rd_observatory/en/.

Document A68/34 discusses how the the relations between the Funding Mechanism, the Observatory, the Coordination Group and TDR are seen by the Secretariat.

At the end of the debate at WHA68 the Secretariat noted that the Observatory was expected to be launched in Jan 2016. See call for publications.

See presentation on progress on the global observatory presented at OE MSM in May 2016

The demo projects

The emergence of the demonstration projects is documented here, from the original adoption of the Global Strategy and Plan of Action to the discussions at EB136.

A68/34 Add.1 refers to this history but focuses on the more recent re-evaluation of one merged project and three resubmitted projects.

See presentation on demo projects prepared for OE MSM.

More in A/RDMCF/2.

Funding mobilisation, hosting and coordination

Resolution A66.22 commissioned further exploration of pooled funding and funding coordination.

A67/27 discussed 'Managed coordination' of R&D activities and their funding. It argued that the creation of any new funding mechanism would introduce strong, managed coordination of the research that a new fund would support. The priorities supported under such a financing mechanism would be those identified through the global advisory committee and could be endorsed at the annual stakeholder conference.

In Decision A67(15) the Assembly asked the Secretariat to explore this proposal in more detail and to report, through EB136 to WHA68 in May 2015 on the outcomes of this exploration.

A range of possible hosts for the pooled funding had been considered in EB134/26 (Jan 2014) and the EB was advised that TDR had rated highly on most criteria. In early May 2014 WHO hosted a meeting of the proponents of the four projects selected in the initial round of demonstration projects (A67/28 Add.1). At this meeting TDR tabled a proposal (9 May 2014) outlining how it might take on the role of manager of the pooled funds (see also TDR news release 9 May). While the TDR proposal was not included in the papers published by the Secretariat for WHA67 it was clearly under consideration with several speakers referring to it in debate and its endorsement in A67(15) above.

The Joint Coordination Board (JCB), the top governing body of the Special Programme for Research and Training in Tropical Diseases (TDR) held its annual meeting in Geneva from 23 June 2014 to 25 June 2014. In its media note (26 June, 2014), TDR recorded the support of the JCB for taking on this role.

The TDR option was further discussed at EB136 (report of debate) and there was general support plus some specific suggestions which were incorporated into A68/34 which was noted.

More in A/RDMCF/2.

See presentations prepared for the OEMSM in May 2016 on: financing and coordination.

UN High Level Panel on Access to Medicines

Secretary-General Appoints Two Former Presidents, 14 Others as Members of High-Level Panel on Access to Medicines (19 Nov 2015)

See UNAIDS comment on the appointment of the HLP

> *The recently appointed United Nations High-Level Panel on Access to Medicines is meeting for the first time on 11 and 12 December in New York, United States of America, to explore innovative approaches of ensuring access to medicines for*

people most in need. The panel was set up as part of efforts to achieve Sustainable Development Goal 3: ensuring healthy lives and promoting the well-being of people of all ages.

The UN Secretary-General established the panel based on the findings and recommendations of the Global Commission on HIV and the Law convened by UNDP on behalf of UNAIDS. Its aim is to ensure that everyone can access quality, affordable treatment while incentivizing innovations and new health technologies. The newly established High-Level Panel will review and assess proposals and recommend solutions to policy incoherencies between the rights of inventors, international human rights law, trade rules and public health in the context of access to health technologies.

See report of discussion at EB138 at PSR11(4).

PHM comment

Overview

The scope of the proposed fund would be to finance R&D projects to address priority research gaps as identified by the Global Observatory and the future coordination mechanism (currently being explored by WHO).

The fund will be managed by the Special Programme, while the Global Observatory and the coordination mechanism will be managed by the WHO Secretariat.

The focus of the fund would be the development of effective and affordable health technologies related to type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases, taking into account the principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination, namely delinkage of the delivery price from research and development costs, the use of open knowledge innovation, and licensing for access.

The contractual arrangements for the funding of projects will ensure that any future health technologies financed through the fund will be accessible to those in need. Arrangements could include clauses on at-cost or preferential pricing, non-exclusive licensing agreements or licences to WHO or the Special Programme.

The priorities of the fund would be informed by the analysis of the research landscape provided by the Global Observatory.

The Health Assembly, on the recommendation of the Programme, Budget and Administration Committee of the Executive Board, would decide on the allocation of the research and development fund to be apportioned to support research and development projects and to support the Global Observatory and the coordination mechanism

A new scientific review group would be established within the Special Programme under the governance of its Joint Coordinating Board. The Joint Coordinating Board would approve the final selection of projects as submitted by the scientific review group.

There are weaknesses in the current proposals but they do represent a step towards public funding of R&D and delinking.

Funds mobilisation

PHM believes that voluntary funding of the system will prove to be unsustainable and that WHO will in due course need to return to a treaty with mandatory contributions.

Broader scope of R&D

In the KEI statement to the 2014 Assembly, HAI and KEI argued that the purposes to be addressed by this CEWG initiative should be widened to include the development of new antibiotic drugs, better low cost diagnostics, basic research in areas of particular interest to all member states, and the funding of independent clinical trials to evaluate the efficacy of pharmaceutical drugs.

Other items on the WHA69 agenda (see especially antimicrobial resistance and STIs) illustrate the need to broaden the range of medical products to be included under this mechanism.

Trade agreements

In the KEI statement to the 2014 Assembly, HAI and KEI argued for: need to confront more directly the barriers to access to treatment which arise from trade agreements. TRIP plus provisions are standard in contemporary plurilateral trade agreements.

Proceeding with the new system does not preclude WHO taking a more active stand in relation to the full use of TRIPS flexibilities and a moratorium on trade agreements which raise new barriers to affordability.

See note above about the new UN HLP on access.

Notes of discussion at WHA69