As of 27 November 2012 at 21:15

Draft proposal on elements of a draft resolution:

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

The Sixty-sixth World Health Assembly,

PP1 Having considered the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG);¹

PP2 Recalling resolution WHA65.22 which requested the Director-General, inter alia, to hold an open-ended meeting of Member States² to thoroughly analyse the report and the feasibility of the recommendations proposed by the CEWG;

PP3 Further recalling resolutions WHA59.24, WHA61.21 and WHA62.16; WHA63.28;

PP4 Recognizing urgency to address the health needs of developing countries and the related inequities in the current research landscape;

PP5 Recognizing the need for enhancing investments in health R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases;

PP6 Recognizing the need for improving monitoring of R&D resource flows, coordination of R&D and priority-setting based on the public health needs of developing countries;

PP7 Recognizing the importance of securing sustainable financing mechanisms for R&D to develop and deliver medical technologies to address the health needs of developing countries;

[OP1 proposed by Iran - Decides to establish a Global Health R&D Monitoring, Coordination and Financing Action Framework, as an initial step towards the development of effective, safe, quality, suitable and affordable health technologies that existing market mechanisms and public policies fail to deliver]

OP1 Calls upon

OP1.1 Member States³, the private sector, academic institutions and nongovernmental organizations (NGOs) to strengthen health R&D capacities and to increase investments in health R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases; [based on WHA65.22]

¹ Documents A65/24; Annex and A65/24 Corr.1.

² And, where applicable, regional economic integration organizations.

³ And, where applicable, regional economic integration organizations.

OP1.2 Member States¹, the private sector, academic institution and NGOs, to share the information with regard to health R&D with WHO in order to contribute to a Global Health R&D Observatory;

OP2 URGES Member States²:

OP2.1 to [consider] strengthen[ing] health R&D capacities on diseases of Type II, III and specific R&D needs of developing countries on diseases of Type I, through [increased [financia]] resources [from the [existing]] government budgets [and private sources through different incentive schemes, and [explore potential] new or innovative sources specifically for health R&D];[insert footnote 3 from WHA65.22]

OP2.2 to establish or strengthen national health R&D [observatories]/[capacities] [or equivalent functions] for tracking and monitoring [resource flows]/[the flow of information] on health R&D[, including data on financial and human resources and infrastructure as well as [R&D] product pipeline][and related IP data]/[and in line with the norms and standards to be developed according to OP3.3] and contribute to the work of a global health R&D observatory; [insert footnote 3 from WHA65.22]

OP2.3 to promote coordination of health R&D [among [public and private] partners] [at national, regional and global levels] [in the country, and support regional and global coordination for health R&D] in order to maximize synergies and avoid duplications;

[add paragraph from Iran on global solidarity]

[to work further with the objective of elaborating an international instrument on R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases that incorporates actions on monitoring, coordination and financing without prejudice of the legal nature of the resulting instrument]

OP3 REQUESTS the Director-General:

OP3.1 to support [Member States]/ [developing countries] in their endeavor to establish or strengthen health R&D capacities and monitor [resource flows] / [information] in support of health R&D related to Type II and III diseases and the special R&D needs of developing countries in relation to Type I diseases, [including [but not limited to] data on financial and human resources, infrastructure as well as product pipeline;][in line with the norms and standards to be developed according to OP3.3]

OP3.2 to establish a scientifically independent Global Health R&D Observatory within WHO['s Secretariat to monitor [resource flows]/[all the relevant information] from both public and private sources [in support of]/[related to] health R&D related to Type II and III diseases and the special R&D needs of developing countries in relation to Type I diseases, building, where possible on national [and regional] observatories or equivalent functions and existing data collection mechanisms] [in line with the norms and standards to be developed according to OP3.3] [with a view to identifying gaps]

OP3.3 to develop norms and standards for classification of health research in order to systematically collect and collate data from Member States and other relevant sources;[footnote on scope]

¹ And, where applicable, regional economic integration organizations.

² And, where applicable, regional economic integration organizations.

OP3.4 [to establish a [systematic independent] prioritization process, based on evidence generated from the observatories [with the involvement of Member States]];

OP3.5 [to reconstitute the WHO Advisory Committee on Health Research (ACHR) as an advisory mechanism at a global level to [coordinate]/[make recommendations on priority areas] health R&D, drawing membership from existing R&D advisory committees in the different research and disease areas, ensuring appropriate input from regional ACHR, other experts and relevant non-state actors];

OP3.6 to develop [, on a basis of broad consensus among key stakeholders,] strategic research roadmaps for funding, and to facilitate implementation of specific R&D projects for medical technologies [X, Y, Z, to be added following decision by WHA] [as well as those proposals from the CEWG Report that have the potential to be implemented earlier such as milestone prizes and open collaborative models] for selected diseases addressing gaps already identified, and selected by the sixty-sixth WHA following informal consultations of Member States; [proposal of the EU] [add text regarding regional consultations]

or

3.6[to facilitate, as a first step, the implementation of up to five specific R&D activities to address already identified gaps which predominately affect the poor and for which the first stage can be developed quickly]

3.6 bis[to organize a multisectoral platform for information sharing, harmonization and alignment of research challenges and financing in relation to the R&D specified in OP3.6]

3.6 ter[to evaluate the experiences gathered and to submit an evaluation report with associated recommendations to the 68^{th} World Health Assembly] [add text regarding phases] [add text regarding regional consultations]

OP3.7 to further develop [an assessment]/ [a proposal], to be submitted to the sixtyseventh WHA [on potential existing structures], [to set up [that considers the establishment of] a specific vehicle,] [or adaptation of existing structures] with [a corresponding][an] inclusive governance structure, [and adequate expert support to prioritize, coordinate and help the harmonization and alignment of R&D related][, within one of the WHO-related entities to collect and disburse funds to be devoted to health R&D related to Type II and III diseases and the special R&D needs of developing countries in relation to Type I diseases, in line with Member States' agreed priorities; this vehicle should be able to collect assessed contributions from Member States who have voluntarily adhered to this mechanism, as well as voluntary contributions from other sources; [move to OP1]

[To convene an intergovernmental working group open to all Member States to identify the objectives and components of an instrument without prejudice to its legal nature, on monitoring, coordination and financing of health R&D related to Type II and III diseases and the special R&D needs of developing countries in relation to Type I diseases]

OP3.8 To report to the sixty-[...] World Health Assembly, through the Executive Board at its [...] session.

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