

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 NEW TEXT: and taking into account discussions during regional committee meetings and regional and national consultations;

PP3 Further recalling NEW TEXT: the Global strategy and plan of action on public health, innovation and intellectual property and its aims to promote innovation, build capacity, improve access and mobilize resources³ as well as resolutions WHA59.24, NEW TEXT: WHA63.21 and WHA63.28;

PP4 Recognizing urgency to address the health needs of developing countries and the related inequities in the current research landscape NEW TEXT: due to recognized market failures in relation to diseases where the potential paying market is small or uncertain;

PP5 Recognizing the need for enhancing investments in health R&D⁴; [footnote added from WHA65.22 and related text removed from relevant paragraphs]

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;

NEW TEXT:

PP8 Recalling the Global strategy and plan of action which refers to a range of incentive schemes for R&D, including the de-linkage of the costs of R&D and the price of medical products [see action 5.3 of the GSPA]

PP9 Recognizing the interdependence of monitoring, coordination and financing of health R&D as well as the importance of sustainability and predictability of resources required to enhance health R&D

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

² And, where applicable, regional economic integration organizations.

³ WHA61.21 and WHA62.16

⁴ In the context of this resolution R&D shall refer to health research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.

PP10 Recognizing that improved availability and access to medical products such as medicines, vaccines and diagnostics in relation to Type II and Type III diseases and specific diseases of Type I in developing countries are the paramount goals; [based on PP on access from SEARO Resolution]

PP11 Recognizing that health R&D should be needs-driven and evidence based, and be guided by the following core principles: affordability, effectiveness, efficiency, equity, and it should be considered as a shared public responsibility

PP12 Recognizing the need to develop a framework for action to improve monitoring, coordination and ensure sustainable financing for health R&D

NEW TEXT proposed by the US:

PP13 Recognizing the need for greater information on gaps in health R&D financing that is directed at product development,

PP14 Recognizing that the provision of additional information on disease burden, research opportunities, the potential health impact, and estimations of the resources needed to develop new health products and make them accessible to the poor in developing countries can provide an important basis for advocacy for additional financing;

PP15 Noting that much work has been done to monitor health R&D, by the WHO, World Bank, and that R&D surveys have been conducted by UNESCO and the OECD, but that there is no funding to collect health R&D data or to house such data in a single online repository.

PP16 Recognizing that the World Intellectual Property Organization hosts a match-making database for research on neglected tropical disease, WIPO Re:Search, and that this database is a valuable resource for those able to further develop this research.

PP17 Recognizing the important role of the private sector in promoting innovation in product development and of the need for global coordination mechanisms to not crowd out existing areas of promising R&D investment for product development;]

NEW TEXT 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 States⁵, the private sector, academic institutions and nongovernmental organizations (NGOs) to strengthen health R&D capacities and to increase investments in health R&D; [based on WHA65.22]

⁵ And, where applicable, regional economic integration organizations.

OP1.2 Member States⁶, 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 States⁷:

OP2.1 to [consider] strengthen[ing] health R&D capacities through [increased [financial] 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];

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;

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, [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, 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]

⁶ And, where applicable, regional economic integration organizations.

⁷ 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 68th 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 sixty-seventh 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, 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]

NEW TEXT proposed by the US:

OP3.7 bis to similarly develop a proposal to independently monitor the effectiveness of any proposed vehicle for collecting voluntary contributions for these health R&D purposes, which focuses on the impact of these contributions in achieving access of new products to the poor, and improving health impact.

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