Sixty-ninth World Health Assembly, 2016
Agenda item 16.2: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Summary

MSF continues to wait for the full implementation of the 2012 Consultative Expert Working Group (CEWG) recommendations. Following on from the Open Ended Meeting of the CEWG on Research and Development: Financing and Coordination, MSF is hopeful that Member States will agree upon a resolution at this World Health Assembly (WHA) that commits and supports governments and the World Health Organisation (WHO) in their efforts to start overcoming the deficiencies with the current system of Research and Development (R&D). The strategy should involve the reaffirmation of the core principles and norms of the CEWG, as enumerated under WHA66.22, as well as implementation plans at national, regional and the global level. This should involve supporting the creation of new institutions and functions at WHO, and also seeking to align, integrate and influence the multiple processes underway that attempt to address the shortcomings of the current system of medical R&D.

Specific Recommendations

1. Comprehensive scope of diseases: Suggestions were made during the Open Ended Meeting that the true scope of the CEWG should be Type II and Type III diseases, implying that market failure does not exist for Type I diseases. MSF rejects any such limitations of the scope of the CEWG, and recommends Member States continue to uphold the agreed scope of the CEWG process, namely that it shall address Type II and Type III diseases and the particular health needs of developing countries related to Type I diseases.[1]

   Market failure is not only demonstrated by a lack of innovation. Financing biomedical R&D using high prices has a negative impact on availability and affordability for all medical tools, whether addressing Type I, II or III diseases. Lack of access to medicines due to high prices is a market failure regardless of disease type and must be included in the scope of the WHO work program.

   This proposed scope of diseases should apply to all activities under the CEWG, including the Observatory, Pooled Fund and Advisory Committee on Health Research. It should also ensure integration and alignment with other R&D processes, including discussions related to AMR and emerging infectious diseases.

2. Affirmation and progressive implementation of core principles and norms concerning innovation and access to medicines: Member States should ensure the resolution reaffirms and supports the progressive implementation of the principles and norms enumerated in WHA66.22, namely that R&D must be de-linked, needs-driven, evidence-based and ensure affordability, efficacy, equity – and be considered a global shared responsibility.

   Member States should ensure that the resolution acknowledges and builds upon a range of other legal and political commitments which all Member States have made over the last two decades, including; the 2001 Doha Declaration on TRIPS and Public Health[2], Target 3.3 and specifically target 3.b of the 2030 Agenda for Sustainable Development, as well as numerous other WHA resolutions since the inception of the Commission on Intellectual Property, Innovation and Public Health (in particular WHA 61.21, or the

[1] WHO defines Type I, II and III diseases such that: Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries.
[2] See: Paragraph 4 of the Doha Declaration which states: We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Global Strategy and Plan of Action on public health, innovation and intellectual property). Such an effort to reaffirm and integrate prior and on-going commitments is important given that certain Member States have sought to minimize or even ignore crucial political and legal commitments made in the past, and are in fact implementing trade and diplomatic policies which ignore and undermine such commitments.

3. Alignment with UN High Level Panel on Access to Medicines and UN High Level Meeting on Antibiotic Resistance: In late 2015, the UN Secretary General launched a 'High Level Panel on Access to Medicines' (UNHLP), which seeks to address the policy incoherence between the rights of inventors, human rights, trade rules and public health. One critical difference between the UNHLP and the CEWG is that the remit of the UNHLP is broader – covering all diseases and technologies of public health importance and covering all countries and populations. The UNHLP recommendations that will be released this summer could provide a unique opportunity for Member States to facilitate the implementation of the CEWG recommendations, norms and principles.

   The UN is also convening a 'Special Session on Antimicrobial Resistance (AMR)' which in part seeks to consider new approaches to R&D that can address the lack of medical tools to combat rising levels of AMR worldwide, and the need for new models for innovation that ensure both stewardship and sustainable and affordable access to such tools. The contours and scope of such a meeting are under discussion during the 69th WHA.

   MSF strongly recommends that Member States at WHO seek to align the CEWG with on-going and future discussions at the UN under the auspices of the UNHLP and the Special Session on AMR. One approach is to convene a second Open Ended Meeting, at some point after the conclusion of the UN General Assembly. This would enable Member States to agree upon a way forward giving consideration to these inter-related processes. Another approach is to ensure that the CEWG principles, as well as the recommendations of the UNHLP, guide the discussions on new models for innovation for AMR by providing Member States with a framework for discussions.

4. Engagement with R&D discussions on AMR and other areas of public health importance: New medical tools (drugs, vaccines and diagnostics) to address rising levels of AMR are urgently needed, and have been identified as a priority under the WHO Global Action Plan to address AMR. While the UN Special Session on AMR is one example of such a discussion, other dialogues on R&D related to AMR are now extending far beyond WHO and the UN to other venues, including discussions at the G7 and G20. In May 2016, the UK government is releasing a major new report – 'The AMR Review' – which will focus in particular on addressing the R&D gaps which have emerged after decades of private and public disinvestment in this area. Member States should ensure WHO is seeking to appropriately engage with these and future relevant processes that attempt to establish norms, financing mechanisms or rules to improve innovation for new medical tools to address AMR.

   Member States should progressively take into account and introduce the principles, evidence and recommendations of the CEWG in national and global R&D initiatives. Thus the WHO should develop guidelines that can be applied through any such pluri-lateral or national level mechanisms to promote the core principles of the CEWG enumerated under WHA66.22.

5. Pooled Fund on Health R&D: MSF supports a Pooled Fund on Health R&D insofar that such a financing mechanism seeks ways to move towards sustainable forms of financing for health R&D, including mandatory funding covering Type I, II and III diseases and which only finances projects that strictly abide by the principles and approaches championed by the CEWG. This includes but is not limited to the management of intellectual property for such projects in a manner that promotes competition and access. Ensuring sustainable financing of the Pooled Fund could include aspirational targets for all Member States to progressively meet the recommendation of the CEWG to invest up to .01 percent of GDP towards health R&D, taking into account that reduced prices paid for medicines should facilitate such investments. MSF believes that efforts should be made to fully finance the demonstration projects, especially insofar as such projects are brought within the remit of the Pooled Fund and fully implement the CEWG recommendations and principles.

6. Global Observatory on Health R&D: In line with resolution WHA66.22, the Observatory should 'monitor and analyse relevant information on health research and development with a view to contributing to the identification of gaps and opportunities for health R&D and defining priorities'. To ensure the successful roll-out of the Global Observatory on Health R&D, it is critical that there is sufficient and sustainable funding for the Observatory which should cover all areas under the CEWG mandate, while also looking to broaden its approach as the Observatory reports results. Under no circumstance should the Observatory only be limited to Type II and Type III diseases, and it should be linked directly to WHO related activities on AMR and emerging infectious diseases. The Observatory can improve its reporting and analysis over time by Member States agreeing to report their R&D funding for the therapeutic areas within its scope, and by introducing measures to improve transparency by public, private and philanthropic funders of R&D. The Observatory could be an important tool to help Member States make better informed decisions if appropriately designed. However, under no circumstances should the only outcome of the CEWG be the establishment of an Observatory. Observation without action is meaningless.

7. WHO Coordination Mechanism should move ahead with establishing and hosting a mechanism that can convene a range of technical experts and R&D funders that should seek to help coordinate R&D amongst relevant stakeholders across all diseases of relevance to the CEWG, and which would also reconstitute the Advisory Committee on Health Research. Helping Member States with need-driven priority setting in particular could form a part of the coordination mechanism, or it could be a separate process and coordination could take place after priorities have been set. The Coordination Mechanism could be established based on a 'test and improve' strategy with evaluation and revision after two years.

8. Policy coherence at WHO on R&D activities ('joiningthe dots'): Proposals to address the interconnected innovation crises will be discussed at the WHA (namely Ebola and other emerging infectious diseases through the R&D Blueprint, AMR, and CEWG). There are also a variety of agenda items at the WHA that will discuss the affordability and supply challenges caused by the current R&D system.

   Progress has been made at the Open Ended Meeting to encourage maximal alignment and integration of these discussions, but ultimately MSF continues to recommend that these inter-related innovation and access crises must be dealt with under one framework, namely that of the CEWG. Otherwise there is a risk that the multiplication of proposed initiatives will further fragment, rather than reconcile efforts to accelerate innovation and ensure equitable access to desperately needed new health technologies for a wide range of diseases. Moreover, it sends the wrong signal to other R&D actors that fragmentation is somehow an acceptable by-product of the current R&D system.

   Policy coherence must at a minimum ensure: (a) application of CEWG principles across all R&D initiatives, frameworks, and proposals before Member States, (b) ensure inclusion of all such areas of R&D under the planned Global Observatory on Health R&D and (c) consider the integration of financing of such R&D activities. The CEWG principles represent a sound foundation on which to base health R&D work to develop essential health technologies to address public health needs.

9. 'Remaining issues' under the CEWG: Three years ago when resolution WHA66.22 was negotiated by Member States, the words 'remaining issues' were short-hand for the central recommendation of the CEWG report, namely that: 'the time had now come for considering a coherent and comprehensive international framework or convention under the auspices of WHO for supporting priority medical R&D aimed at diseases that are prevalent in developing countries…'. Many Member States pushed to start a political process to move towards agreeing the contours of this framework. No consensus was possible in 2012, but there was a consensus that this central recommendation must be dealt with 'prior to the 69th WHA in May 2016'. Perhaps the bland language of 'remaining issues' has distracted us from the importance of this point. It is the *overarching recommendation* without which the other recommendations will struggle to succeed. Member States must give 'remaining issues' the attention it deserves and to agree to a process that takes forward discussions on the scope of an overarching agreement that advances R&D to meet the needs of people around the world.