70th World Health Assembly – May 2017
MSF Briefing on Medical Research and Development

Overview

Médecins Sans Frontières (MSF) welcomes the increased attention by WHO and Member States to find ways to ensure that medical R&D effectively prioritizes people's health needs globally, and delivers health tools that are affordable, available, and adapted to the health systems in which they are to be deployed. As a medical humanitarian organization that often is hindered in providing health care by the lack of access to appropriate medicines, vaccines and diagnostics because they don't exist, are too expensive, or are difficult to use in the contexts where we work, MSF believes a comprehensive reform of the way we prioritize, finance and conduct medical R&D is long overdue. Building on a growing momentum that recognizes that affordable access to medical innovation is a global issue affecting people wherever they live, at this WHA, WHO and Member States have a unique opportunity to advance this urgently needed public health-focused reform.

At the 68th World Health Assembly, MSF asked WHO and Member States to consider the lack of urgently needed medical tools in the Ebola crisis in West Africa as a wake-up call on the need for R&D reforms. MSF's 2016 report, Lives on the Edge: Time to align medical research and development with people's health needs[1], outlines the challenges and inefficiencies of the way we currently conduct R&D and sets out proposals for reform, including: setting priorities based on patients' needs; coordinating efforts and ensuring sustainable financing; promoting transparency in R&D costs, pricing and research results; and changing the incentives for R&D, including ending the reliance on the expectation of high prices and monopolies to pay for innovation.

Governments need not only to increase their investments in medical R&D, but to ensure public return on that investment in terms of affordability and availability of the resulting products, open sharing of data and knowledge, and ensuring that people's health needs are effectively prioritized. We encourage governments to work towards aligning R&D incentives with these needs, ideally through global frameworks to ensure that research and funding efforts will be effectively coordinated.

This briefing covers the research and development (R&D) elements of the following five agenda items of the 70th World Health Assembly and offers MSF's recommendations on key considerations for these items:

12.1: Research and development for potentially epidemic diseases: A blueprint for research and development preparedness and rapid research response (including CEPI)

12.2: Antimicrobial resistance (AMR)

13.3: Addressing the global shortage of, and access to, medicines and vaccines (including the report of the UN Secretary General's High Level Panel on Access to Medicines (UNHLP))

13.4: Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property (GSPOA)

13.5: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG report)

[1] MSF Report: Lives on the Edge - Time to align medical research and development with people's health needs, May 2016. Available here: https://www.msfaccess.org/content/report-lives-edge-time-align-medical-research-and-development-people%E2%80%99s-health-needs

Increasing policy coherence & coordination on R&D activities within and outside WHO

MSF welcomed resolution WHA69.23, and notes in particular operative paragraph 2(11), which requests the Director-General "to promote policy coherence within WHO on its research and development-related activities, such as those in relation to the Research and Development Blueprint for Emerging Pathogens and the Global Action Plan on Antimicrobial Resistance in terms of application of the core principles of affordability, effectiveness, efficiency and equity and the objective of de-linkage identified in resolution WHA66.22".

Given that WHO is also involved as an Observer in discussions and initiatives to promote R&D outside the organization, such as through the Coalition for Epidemic Preparedness Innovations (CEPI) and through discussions on AMR convened by the World Economic Forum (WEF), this focus on policy coherence must extend to these initiatives. Where WHO participates in such initiatives it should promote the innovation for access principles, as agreed by Members States and formulated in the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) report. This will provide a sound foundation on which to base all health R&D to develop essential health technologies to address public health needs and ensure a full public return on investment.

Research and development for potentially epidemic diseases: a blueprint for R&D preparedness and rapid research response (the R&D Blueprint)

MSF supports WHO having a leading role in efforts to improve R&D for potentially epidemic diseases, including through the implementation of the WHO R&D Blueprint. WHO should also have a stronger role in helping governments and other R&D funders set patient-driven priorities, monitor and coordinate R&D and ensure the affordability and availability of resulting new medical tools.

Paper A70/10 includes a welcome acknowledgment of the complementarity between the R&D Blueprint and WHO's work on the GSPOA and the CEWG. Yet while WHO has committed to ensuring policy coherence, more steps must be taken to realize this alignment. In particular, WHO should provide greater insight and transparency on how existing plans to develop new medical tools for MERS and Zika will ensure they are affordable and accessible. This should include a description of how the management of intellectual property will align with the GSPOA and CEWG and build on the lessons learned from the Pandemic Influenza Preparedness (PIP) Framework.

Additionally, MSF supports efforts to establish a 'Global Coordination Mechanism' (GCM) to better coordinate R&D activities during epidemics, and the recent efforts to formulate principles and practices in collaboration with other entities, including MSF. However, these efforts must derive from a transparent and inclusive intergovernmental process, and be fully aligned with the principles and commitments made at WHO, including those introduced under the CEWG. It is important that decisions and governance of such a GCM are led by WHO and Member States, and not by non-State actors, foundations or think-tanks.

WHO should consider what steps can be taken to improve approaches to R&D that are underway through new financing initiatives, especially where WHO is acting as an Observer. As the Report notes, WHO has signed a Memorandum of Understanding as an Observer to the Coalition for Epidemic Preparedness Innovations (CEPI). CEPI has a goal to ensure access for all, but does not have policies and practices in place that will guarantee access for those in need. MSF has been concerned with four problems with CEPI:

1. ability of companies to charge tiered prices for new vaccines that emerge from CEPI-funded projects
2. inadequate management of intellectual property by CEPI which only provides CEPI with step-in rights that may not safeguard affordability, supply and timely development of new vaccines
3. insufficient commitment to transparency wherein CEPI will not fully publish terms and conditions signed between CEPI and Awardees, including access commitments of Awardees.

4. untoward influence and engagement of the pharmaceutical industry in the governance of this public health initiative, including in the development of policies and practices related to pricing and access

WHO should continue to insist that CEPI take steps to improve its policies and practices, in particular since WHO has lent its prestige and imprimatur to CEPI as an Observer.

Research and development to respond to antimicrobial resistance (AMR): implementing the commitments of the UN High-Level Meeting on AMR

It is now widely recognized that we lack the medical tools combat the growing problem of AMR globally, including for MDR-TB, and that the current market-driven R&D model is ill-suited to deliver the needed diagnostics and treatments in an efficient and affordable way.

MSF welcomes the commitment of Member States to create of new financing and incentive mechanisms, as well as the political and financial support to new initiatives like the MSF-supported Global Antibiotic Research and Development Partnership (GARDP)[2] and 3P TB Project (Push, Pull, Pool)[3]. However, the on-going development of a new initiative at the World Economic Forum (WEF) that may define new incentive mechanisms without appropriate representation of Member States and civil society and with undue pharmaceutical industry influence is concerning.

It is essential that in all new initiatives under development, including the one convened by the World Economic Forum, Member States, WHO and other stakeholders respect and implement the global consensus reached at the High-Level Meeting on AMR at the UN General Assembly in September 2016 in their investments in AMR R&D. This consensus was articulated in the resulting Political Declaration, noting that *"all research and development efforts should be needs-driven, evidence-based and guided by the principles of affordability, effectiveness and efficiency and equity, and should be considered as a shared responsibility: in this regard, we acknowledge the importance of delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales so as to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results to be gained through research and development"*[4].

Addressing the global shortage of, and access to, medicines and vaccines: implementing the recommendations of the UN High-Level Panel on Access to Medicines

Under agenda item 13.3, Member States are invited to discuss the findings and recommendations of the report of the UN Secretary-General's High-Level Panel on Access to Medicines (UNHLP), and to consider next steps. Launched in November 2015, the UNHLP convened leaders and experts across government, the pharmaceutical industry, civil society and academia to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."

The Panel's final report of September 2016 was welcomed by the UNSG and provides a range of recommendations to address challenges related to innovation and access to medicines for all countries and diseases. It includes recommendations that reaffirm and expand upon the commitments already made under the CEWG and GSPOA related to R&D for priority health needs. The UNHLP recognizes that the current system is not working for any country and that patients are suffering, no matter where they live.

[2] Global Antibiotic Research & Development Partnership (GARDP), https://www.dndi.org/diseases-projects/gardp/
[3] Tuberculosis and antimicrobial resistance – new models of research and development needed, WHO Bulletin. http://www.who.int/bulletin/volumes/95/5/17-194837.pdf
[4] Paragraph 10 (c), Political Declaration of the high-level meeting of the General Assembly on antimicrobial resistance, http://www.un.org/pga/71/wp-content/uploads/sites/40/2016/09/DGACM_GAEAD_ESCAB-AMR-Draft-Political-Declaration-1616108E.pdf

The recommendations of the Panel are relevant to a variety of agenda items included in this briefing, in addition to other priorities that will be discussed at this WHA on the lack of access to and innovation for medical technologies. For that reason, MSF has supported the efforts of some Member States to have a stand-alone discussion at the Assembly with concrete recommendations for next steps.

It is disappointing that WHO has not sufficiently recognised the global impact of the UNHLP report in its own report back to Member States on agenda item 13.3 'Addressing the global shortage of, and access to, medicines and vaccines'. WHO is already addressing issues of innovation and access to medicines elsewhere on a global basis, whether addressing shortages of medicines, affordability of new medicines to treat cancer and hepatitis C, or developing new R&D incentive models to address AMR or emerging infectious diseases. Not framing the UNHLP report from a global perspective ignores the original mandate of the Panel and downplays the access to medicines challenges faced by all Member States, not just lower income countries.

MSF urges Member States to take on board the key recommendations of the UNHLP that build on the findings of the CEWG and GSPOA, and to determine which recommendations WHO should take forward to build greater policy coherence in Member State and WHO activities to address priority unmet health needs.

The disappointing evaluation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)

Almost nine years after the adoption of the historic GSPOA, the recent evaluation merely restates the problem statement identified clearly in the Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), that "current market mechanisms and publicly-funded research result in far too little investment in R&D for diseases that mainly affect lower-middle-income and low-income countries." Member States, under the leadership of WHO, should waste no more time in taking coordinated efforts to meet the aims of the GSPOA, which were, 'to promote new thinking on innovation and access to medicines and… ***to provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development*** relevant to diseases that disproportionately affect developing countries…'

Regrettably, the evaluation is of limited use, neglecting key elements of the Strategy and containing concerning statements such as, "Innovation is primarily demonstrated by the private sector in market-driven conditions and largely outside the scope of GSPOA," despite the GSPOA's mandate to consider the challenges of market-driven innovation.

Omission of key elements of the GSPOA:

- There is no mention of element 2.3(c) where WHO and other stakeholders were mandated to undertake "further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including, inter alia, an essential health and biomedical research and development treaty."
- There is no mention of the extent to which WHO and governments have delivered on their commitment in 5.3(a), "to explore and, where appropriate, promote a range of incentive schemes for research and development, including addressing, where appropriate, the delinking of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases that disproportionately affect developing countries."

Given the evaluation's conclusion on the role of market mechanisms and publicly-funded R&D, the recommendation that Member States simply 'ensure that their health R&D at national and sub-national level is prioritized', is at best vague and at worst deliberately obscure. Due to these important omissions and limitations, the evaluation does not provide a sound basis for informing the overall programme review planned for 2017.

Next steps on CEWG Global R&D Observatory

The launch of the CEWG WHO Global Observatory on Health Research and Development is a positive step. Yet in its current state of development, it falls far short of being able to provide the comprehensive data needed to prioritize and better coordinate decisions on R&D.

The Observatory currently only monitors funding flows for neglected tropical diseases (NTDs). Indicators selected to monitor health R&D do not include measures of any of the core CEWG principles: affordability, effectiveness, efficiency, equity and the principle of delinkage. The indicators for funding and R&D capacity by country, health gross domestic expenditure on R&D (health GERD) as a percentage of total gross domestic expenditure on R&D (GERD) and the proportion of health researchers among all researchers, are useful, but fall far short of providing sufficient information to allow for R&D priority setting.

WHO should outline clearly how the observatory will provide sufficient information to inform the priority setting and investment decisions of government and other R&D funders. The Observatory should also provide a monitoring function for key indicators of transparency, including transparency on the costs of clinical trials, on product prices, and on the access strategies for products in development.