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Médecins Sans Frontières (MSF) briefing on agenda item 11.5:
Addressing the global shortage of, and access to, medicines and vaccines,
Document A71/12

Background

As an international medical humanitarian organisation providing medical assistance to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in more than 60 countries, Médecins sans Frontières (MSF) witnesses the devastating impact that widespread lack of access to affordable and able medicines, vaccines and diagnostics has on people's lives.

Whether people living with hepatitis C virus (HCV) or with drug-resistant infections such as drug-resistant tuberculosis (DR-TB), or children who have not received lifesaving vaccines such as the pneumococcal conjugate vaccine (PCV), we see the suffering, disability and death that result when medicines and vaccines are unsuitable, unsafe, ineffective or priced out of reach. Our teams see lives cut short because the medicines and vaccines our patients need simply do not exist at all.

Most of these challenges are due in large part to the fact that medical innovation is motivated predominantly by commercial interests and designed to maximise financial return on private investment. Despite being heavily publicly financed, biomedical R&D largely fails to ensure *public* return on public investment by delivering affordable and accessible health technologies that address people's health needs. Most new medical products offer little added therapeutic benefit, and the few that do are priced too high for most people and health systems to afford.

Meanwhile, deadlocks in innovation and access leave healthcare providers like MSF without the tools they need to treat millions suffering from the world's deadliest diseases. For example, over the past 50 years only two new medicines have been developed for TB, and they remain largely underused. Patients with multidrug-resistant TB (MDR-TB) are still being treated with complex treatment regimens that can last for two years and include eight months of painful daily injections and nearly 15,000 pills. Cure rates for such arduous regimens in real-life settings are abysmal: just 52% for patients with MDR-TB and just 28% for patients with extensively drug-resistant TB (XDR-TB).

MSF welcomes agenda item 11.5 of the 71st World Health Assembly (WHA), entitled Addressing the Global Shortage of, and Access to, Medicines and Vaccines. Executive Board decision EB142(3) requests the Director-General to elaborate, in consultation with Member States, a roadmap report outlining WHO's work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023.[1]

Document A71/12[2] provides an important opportunity for Member States to shape the concrete priority interventions that the WHO Secretariat should lead in its work on the roadmap. MSF welcomes that the document bases its analysis on, among other sources, WHO resolutions related to access to medicines and the Report of the United Nations High-level Panel on Access to Medicines (UNHLP). Together with commitments in the Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPOA)[3], these documents should inform a clear and bold roadmap that reflects strong leadership, policy coherence and ambition of the WHO, and the political will of Member States to ensure that medical innovation and access is driven by patients' needs and deliver quality-assured medicines that are adapted and affordable.

Ensuring the availability and affordability of health technologies for all people is fundamental to achieving the "triple billion" goals of WHO's Programme of Work[4], including universal health coverage.

MSF recommendations

Based on MSF's experiences providing healthcare to vulnerable people, we urge the WHO Secretariat and Member States to prioritise action in five areas to ensure patient-centred innovation and access to medicines, vaccines and diagnostics.

1. Promote alternative R&D approaches that meet people's health needs

There is a desperate lack of medical tools needed to prevent, diagnose and treat neglected diseases, including deadly infections such as DR-TB. The state of the innovation pipeline for DR-TB is particularly dire – showing little promise of delivering the tools we need, including accurate and easy-to-use diagnostics and new medicines that can be combined into shorter, more effective and less toxic treatment regimens. Recent experience shows that even when safer, more effective medicines are developed, they often do not reach those in need. Bedaquiline, an effective novel medicine for use in combination DR-TB treatment, has not been registered in 11 high DR-TB burden countries.

Too often, pharmaceutical corporations develop health technologies that have benefited from public R&D funding without commitments or conditions to ensure access for people in need. Sofosbuvir, one such example, is a novel and groundbreaking drug for HCV developed by a small company, Pharmasset, with support from the US government. Gilead acquired Pharmasset and priced sofosbuvir beyond reach of anyone but the wealthiest when they launched the drug at a staggering US$84,000 per 12-week treatment course. The public investment from the US government did not translate into public return for people in need – i.e. affordable access to lifesaving treatment.

Member States must ensure the WHO Secretariat takes specific steps to:

a. Build upon the principles and strategies reflected in the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG)[5] and GSPOA resolution WHA69.23 requesting the Director-General to promote policy coherence within WHO on its R&D-related activities – including those related to (i) the Research and Development Blueprint for Emerging Pathogens, (ii) the Coalition for Epidemic Preparedness Innovations (CEPI), and (iii) the Global Action Plan on Antimicrobial Resistance (in terms of application of the core principles of affordability,

effectiveness, efficiency and equity), and (iv) resolution WHA66.22[6] endorsing the strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health research and development;

b. Build upon the GSPOA and CEWG resolutions as well as on the UN declaration on AMR to lead the development and implementation of biomedical R&D normative frameworks that ensure that publicly supported R&D efforts are (i) needs-driven, (ii) evidence-based, (iii) guided by principles of affordability, effectiveness, efficiency and equity, and (iv) treated as a shared responsibility. Paying for innovation should be de-linked from the expectation of high prices, monopolies and volume sales; and

c. Outline which information the Global Observatory on Health R&D will collect to inform the priority-setting and investment decisions of government and other R&D funders. Observatory activities currently are not inclusive of all diseases and the indicators selected to monitor health R&D (i) do not include measures of any of the core CEWG principles and (ii) do not provide sufficient information to allow for R&D priority setting.

MSF urges WHO to actively pursue a health needs-driven R&D agenda that fosters sustainable innovation and access to medicines, including promoting R&D approaches that will end the reliance on high prices and monopolies to finance R&D and that address innovation and access concerns for all diseases (types I, II and III) and health technologies for all countries. Ensuring the availability and affordability of health technologies for all people is fundamental to achieving the "triple billion" goals of WHO's Programme of Work[4], including universal health coverage.

2. Address intellectual property (IP) barriers to access to medicines and vaccines

Patents and other forms of IP create monopolies, result in non-competitive markets and contribute to high prices. The availability of PCV – a lifesaving vaccine that protects children from pneumonia – is constraint by the monopolies of two corporations that price the vaccine far out of reach of people in need. Indeed, their high prices deprive one-third of the world's countries from being able to include PCV as part of standard vaccination packages. If multiple manufacturers could produce PCV, including in developing countries, prices would lower and more countries and treatment providers like MSF would be able to buy affordable vaccines.

MSF welcomes an active role for WHO in addressing IP barriers to access to medicines and vaccines, including fostering collaboration to safeguard public health needs over IP and trade interests as highlighted in its mandate. This includes supporting Member States to overcome IP barriers through the use of flexibilities embedded the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The WHO Secretariat should take specific steps to:

a. Operationalise an effective collaboration with other UN agencies and international organisations on the issues of IP, trade policy, pricing and governance in alignment with the recommendations of the UNHLP report – expanding beyond the current trilateral collaboration with WIPO and WTO to include other UN agencies such as UNDP and UNCTAD.

b. Work closely with Member States and partners at regional and national levels to expand technical assistance provided to build Member States' capacity to effectively adopt and utilise TRIPS flexibilities to safeguard public health;

c. Develop methodologies and implement studies that can be consistently and reliably used to assess the public health impact of trade agreements, especially concerning TRIPS-plus provisions such as data exclusivity, patent term extension and patent linkage; and

d. Provide support to the Medicines Patent Pool (MPP) based on a thorough feasibility review, and establish criteria and principles as conditions for this support. The conditions of transparency, maximum geographic coverage, improved terms for facilitating generic entry, and the complementarity of voluntary licenses with other TRIPS flexibilities needs to be clearly articulated.

MSF urges the WHO Secretariat, with the support of Member States, to strengthen the leadership of the organisation to address IP barriers to access to medicines, diagnostics and vaccines, including through technical support and capacity-building, and to ensure Member States effectively adopt and use public health safeguards in IP laws and policies. WHO must provide explicit political support and encouragement to Member States to prioritise access to medicines and public health over commercial interests, and counterbalance pressure from the private sector towards Members States that promote access to health technologies.

3. Improve data, cost and price transparency to improve access to affordable medicines, vaccines and diagnostics

The widespread secrecy related to various aspects of the R&D, manufacturing and marketing processes provide fertile ground for unchecked high medicine prices. Member States must strengthen the WHO's mandate to promote transparency throughout the value chain, including the public disclosure of clinical trial data, research and development costs, production costs, procurement prices and procedures, and supply chain mark-ups. Additionally, WHO should be requested to expand two key programmes: (i) the Vaccine Product, Price, Procurement (V3P) Project[7], which promotes transparency on vaccines prices worldwide, and (ii) the recently launched International Clinical Trials Registry Platform (ICTRP)[8], which aims to improve transparency in clinical trials – a critical component of R&D.

Efforts to improve transparency should focus on all components of the price and clinical benefit of medicines and vaccines – including the cost of R&D, the cost of production and the cost of marketing (and its link to the price of end products). Improvements in transparency are also needed with regard to efficacy and safety data, data on where medicines are registered, the registration plans of pharmaceutical corporations, the patent landscape and prices paid for medicines. Member States should also ensure that all public funding allocated to the development of new medical technologies – including tax credits, subsidies and grants – are disclosed by corporations.

MSF urges Member States to strengthen WHO's mandate to improve transparency concerning all aspects of medicines, vaccines and diagnostics R&D, manufacturing and marketing, including costs, pricing, and data – building upon the success of the current WHO projects and programmes that effectively improve transparency.

4. Promote and strengthen quality assurance mechanisms for medicines and vaccines

Ensuring access to safe, effective medicines and vaccines for all also requires well-resourced quality assurance mechanisms. MSF welcomes the emphasis that the Director-General's report places on the value of the WHO Prequalification of Medicines Programme (PQP) and its important role in helping to ensure access to quality-assured products for global procurement. The WHO Regulatory Systems Strengthening Department requires additional resources to perform its core quality-assurance and capacity-building functions and to expand its mandate to include additional essential health products. For example, the timely validation of additional generic direct-acting antivirals (DAAs) for HCV or of follow-on vaccines for pneumonia could dramatically improve access for people in need.

Additional, sustained investment from Member States is needed to allow the PQP to (i) assess more essential health products, (ii) improve the efficiency of product registration through regulatory reliance initiatives (including the expansion of the WHO PQ and stringent regulatory authority Collaborative Registration Procedure for medicines and vaccines) and regional regulatory convergence initiatives, (iii) support its efforts to strengthen pharmacovigilance and post-market surveillance systems, and (iv) provide technical assistance to strengthen national medicines regulatory agencies.

MSF urges Member States to provide the additional, sustained resources required for WHO to promote and strengthen the quality assurance of safe, effective medicines and vaccines that meet public health needs, specifically through additional, sustained investment in the WHO PQP.

5. Ensure effective policy coherence between the roadmap and WHO and UN health programmes and interventions

Ensuring access to safe, effective, affordable medicines and vaccines requires intervention across multiple diseases, medical technologies and global health programmes to address a wide variety of challenges faced by Member States and the people whose health they are obliged to protect. It is critical that the WHO roadmap is effectively integrated and reflected across the mandate of the organisation, including in disease-specific action plans and strategies across departments so that coherent strategies, guidance and policy direction can be realised.

As the lead UN agency on health, the WHO should also work to increase policy coherence across the UN system by encouraging and facilitating a comprehensive, coherent UN response to health technology access and innovation, including by promoting the discussion and consideration of the recommendations of the UNHLP on Access to Medicines among other UN agencies, the UN General Assembly and the UN Secretary General.

MSF urges the WHO Secretariat to ensure policy coherence in the process of developing the roadmap on access to medicines and vaccines, and to promote leadership and accountability among UN agencies to safeguard public health. MSF calls on Member States to support and fund the development of the WHO roadmap, building on existing resolutions and mandates on access to medicines and on the recommendations of the UNHLP on Access to Medicines.

Summary of MSF recommendations

1. MSF urges WHO to actively pursue a health needs-driven R&D agenda that fosters sustainable innovation and access to medicines, including promoting R&D approaches that will end the reliance on high prices and monopolies to finance R&D and that address innovation and access concerns for all diseases (types I, II and III) and health technologies for all countries. Ensuring the availability and affordability of health technologies for all people is fundamental to achieving the "triple billion" goals of WHO's Programme of Work[4], including universal health coverage.

2. MSF urges the WHO Secretariat, with the support of Member States, to strengthen the leadership of the organisation to address IP barriers to access to medicines, diagnostics and vaccines, including through technical support and capacity-building, and to ensure Member States effectively adopt and use public health safeguards in IP laws and policies. WHO must provide explicit political support and encouragement to Member States to prioritise access to medicines and public health over commercial interests, and counterbalance pressure from the private sector towards Members States that promote access to health technologies.

3. MSF urges Member States to strengthen WHO's mandate to improve transparency concerning all aspects of medicines, vaccines and diagnostics R&D, manufacturing and marketing, including costs, pricing, and data – building upon the success of the current WHO projects and programmes that effectively improve transparency.

4. MSF urges Member States to provide the additional, sustained resources required for WHO to promote and strengthen the quality assurance of safe, effective medicines and vaccines that meet public health needs, specifically through additional, sustained investment in the WHO PQP.

5. MSF urges the WHO Secretariat to ensure policy coherence in the process of developing the roadmap on access to medicines and vaccines, and to promote leadership and accountability among UN agencies to safeguard public health. MSF calls on Member States to support and fund the development of the WHO roadmap, building on existing resolutions and mandates on access to medicines and on the recommendations of the UNHLP on Access to Medicines.

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