



## **MSF Access Campaign Comments on the WHO Roadmap for access 2019 – 2023: Comprehensive support for access to medicines and vaccines ‘Zero Draft’**

In May 2018, the World Health Assembly adopted decision 71(8) requesting you ‘to elaborate a roadmap report, in consultation with Member States, outlining the programming of WHO’s work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023.’<sup>1</sup> We are writing to provide our initial feedback on the Secretariat’s zero draft document of the Roadmap on Access to Medicines and Vaccines 2019-2023, created for consultation with Member State in response to this decision.

Médecins sans Frontières (MSF) is 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. We bear witness to the devastating impact that widespread lack of access to affordable and suitable medicines, vaccines and diagnostics has on peoples’ lives. With this experience in mind, we raise the following key points we believe will help strengthen the Roadmap.

### **1. Building Local Capacity for Research and Development**

WHO has been requested to build and strengthen local capacity for research and development (R&D), including through the provision of technical assistance, in a number of WHA resolutions.<sup>i</sup> Element 2 of the GSPOA, ‘Promoting research and development’ also strongly highlights the importance of building local capacity for research. However in its current form, the draft Roadmap does not cover this mandate in sufficient detail. It includes a ‘mid-term’ commitment to support policy options for designing R&D models that promote innovation and access in line with the CEWG principles, and a ‘long-term’ commitment to developing sustainable financing mechanisms models for R&D where the market does not attract sufficient investments. Both these deliverables are important, but they are insufficient. WHO should also provide technical assistance and build local capacity for the implementation of health needs-driven R&D in line with the CEWG principles.

MSF urges WHO to actively pursue a comprehensive 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.

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<sup>1</sup> WHA71(8). 25 May 2018. [http://apps.who.int/gb/ebwha/pdf\\_files/WHA71/A71\(8\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(8)-en.pdf).

- In line with commitments in the GSPOA and previous resolutions: include a deliverable on the provision of technical assistance and capacity building to implement health needs-driven R&D in line with the CEWG principles. This falls under the first activity pillar: ‘Research and development for medicines and vaccines that meet public health needs’.

## 2. Fair Pricing and Financing Policies

The Roadmap sets out important work in the area of fair pricing and financing policies, particularly in relation to supporting processes for selection and health technology assessment and implementation in countries; and the work to reduce out of pocket payments including the adoption of generics and biosimilar selection, procurement and use. However the definition of a ‘fair price’ provided in the document is problematic and should imperatively be revised and there is an insufficient focus on measures to increase transparency.

‘Fair pricing’ should be considered a dynamic concept applying to the negotiations taking place with the pharmaceutical industry with the objective of reaching a balanced and acceptable outcome for society – that is affordable and reasonable prices. It is only possible to reach a ‘fair price’ if fair negotiating conditions are established. This includes prioritizing efforts to increase transparency on all aspects of the research, development, production and marketing processes of medicines as well as preventing undue or abusive monopolies that put the public authorities in a weak negotiating position, delay price lowering-competition and keep prices high – through unwarranted patents, evergreening, data exclusivity and trade secrets. The limitation of all unnecessary monopoly situations should be a guiding principle of public policies in order to achieve fair pricing.

The widespread secrecy related to various aspects of the R&D, manufacturing and marketing processes provide fertile ground for unchecked high medicine prices. Transparency is needed throughout the biomedical R&D chain; from the initial step of basic research to the delivery of medicines to patients. This is necessary so that public authorities negotiating with pharmaceutical companies have the data they need to negotiate with the private sector, and an informed vision about the real investments made by public and private sectors.

In its current form, the Roadmap only contains one deliverable on transparency in the activity area of ‘fair pricing and financing policies’, and that is to promote global and regional collaboration to increase price transparency and to facilitate dialogue between public payers, government decision makers and industry. While such measures are welcome, promoting fair pricing will require a more proactive role for WHO in promoting transparency and will need to be far more comprehensive than simply focusing on end product prices.

- Under the second activity area of ‘Fair pricing and financing policies’, WHO should:
  - Remove the simplistic definition of ‘fair pricing’
  - Expand the work of WHO on transparency throughout the lifecycle of medicines from research, development to manufacturing and marketing.

### **3. Strengthening the Public Health Perspective in National Intellectual Property Systems Global Patent Databases**

Element 5.1.e of the GSPOA provides a clear mandate for WHO to, ‘strengthen education and training in the application and management of intellectual property from a public health perspective, taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights.’ However, the draft Roadmap introduces several caveats to this work which serve to unduly diminish this mandate. Rather than establishing this commitment as a clear deliverable, WHO waters this down claiming it will, ‘provide as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, to policy processes to countries that intend to make use of the provisions contained in the Agreement on TRIPS, including the flexibilities recognized by the Doha Declaration...’

It is well acknowledged that developing countries come under significant pressure when seeking to make use of the public health safeguards in the TRIPS agreement. Given this, and in light of the clear mandate WHO has through the GSPOA; MSF strongly urges WHO to remove all additional qualifications to this work. We urge WHO instead to proactively assess the needed resources to implement training and support for countries in order that they can apply and manage intellectual property from a public health perspective, and further to take up the recommendation in the UN HLP report for WHO to strengthen the capacity of patent examiners to apply public health sensitive standards<sup>ii</sup>.

Further, MSF urges WHO to include a clear deliverable in the Roadmap reflecting the GSPOA mandate to WHO to develop global databases containing public information on the administrative status of health-related patents.<sup>iii</sup> Currently the draft roadmap contains a commitment to ongoing work to facilitate the assessment of the patent status of essential medical products at national and regional level in collaboration with competent partners, but does not outline plans to develop global databases for health-related patents that permit both to establish a clear correlation between patents and health products and the level of constraint patents exert on generic production according to patent quality.

- Under the third activity area, ‘Application and management of intellectual property to contribute to innovation and promote public health’:
  - Change the deliverable on the provision of technical support and capacity building to reflect the commitment of the GSPOA, ‘Provide education and training in the application and management of intellectual property from a public health perspective, taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights.’
  - Include a clear deliverable reflecting the GSPOA mandate to WHO to develop global databases containing public information on the administrative status of health-related patents.

- Include a deliverable reflecting the UNHLP recommendation for WHO to strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs

#### **4. Procurement and Supply Chain Management**

MSF welcomes the acknowledgement in the Roadmap of the critical challenges facing countries transitioning from donor support for specific vertical programs. Countries' national procurement systems may not have the negotiating power, transparency, forecasting, or the legislative and regulatory policies in place which are necessary to ensure that quality, supply and price don't suffer as a result of the transition.

While MSF also welcomes the Roadmap's action on collaboration and support in procurement and supply chain management, such partnerships must be transparent, balanced and strategic. The pharmaceutical industry, for example, has recently driven discussions at WHO on the integration of national Supply Chains, while at the same time launching their own treatment-specific, vertical "access programmes" in various LMICs globally.

- MSF urges WHO to give technical assistance to transitioning countries for the procurement of quality-assured medicines for their national programmes.
- When "supporting collaborative approaches for strategic procurement", WHO should ensure its independence from industry.

#### **5. Regulatory systems to ensure quality, safety and efficacy of medicines and vaccines**

MSF welcomes the emphasis that the Roadmap places on quality and safety of medicines, support to global procurement through the WHO Prequalification Programme (PQP), and strengthening national medicines regulatory systems.

- Additional, sustained investment 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 Collaborative Registration Procedures) and regional regulatory convergence initiatives, and (iii) support its efforts to strengthen pharmacovigilance and postmarket surveillance.

#### **6. Strengthening Transparency Tools in Good Governance**

Under the eighth activity area on 'Good governance' WHO commits to 'develop and maintain tools and platforms for facilitating transparency and accountability regarding access to essential health products.' This is welcome especially given the important work WHO have led in the area of transparency including establishing the Vaccine Product, Price, Procurement (V3P) Project, which promotes transparency on vaccines prices worldwide; and the recently launched International

Clinical Trials Registry Platform (ICTRP), which aims to improve transparency in clinical trials – a critical component of R&D.

- These initiatives should be strengthened and expanded in line with recommendations of the UN HLP which further calls on WHO to establish an accessible international database of prices of patented and generic medicines and biosimilars.<sup>iv</sup>
- The Roadmap should be more explicit as to which specific tools and platforms it will develop and maintain. The above mentioned tools will require sustained investment to ensure they continue to be updated and useful.

## **7. The importance of comprehensively including work on diagnostics within the Roadmap**

MSF's work on access to medicines covers drugs, diagnostics and vaccines. Currently the Roadmap focuses on vaccines and drugs, and it is unclear how comprehensively the Roadmap covers the work currently being undertaken and planned in the area of improving access to diagnostics. We note that diagnostics and 'other health technologies' are referred to at various points in the narrative and deliverables of the Roadmap<sup>v</sup>, but it would be worth explicitly mentioning work on diagnostics across the board.

## **8. Accountability, Timelines and Target Indicators**

The draft roadmap contains no commitment to the production of technical reports or progress reports detailed in WHA resolutions. These reports, which are key deliverables for the WHO and form a core component of monitoring and evaluation mechanisms, should be outlined in the roadmap.<sup>vi</sup>

The draft roadmap establishes timelines for each of the deliverables in its ten strategic areas, categorising these as 'ongoing', 'mid-term' or 'long-term'. While 'ongoing' is a useful designation for certain continuous activities; 'mid-term' and 'long-term' are unspecific and risk creating a document that does not serve to hold the WHO accountable to the work it is mandated by Member States to undertake. It is worth noting that the GSPOA, agreed in 2008 and 2009 by all Member States, sought to provide a 'medium-term' framework and yet many of the elements have not yet been fulfilled. We therefore urge WHO to include specific timelines for the completion of the outlined deliverables.

The draft roadmap sets out five key targets and indicators for assessing success. This list is clearly non-exhaustive, and omits a number of targets established in WHA resolutions. Omitted targets include those relating to the elimination and eradication of malaria, poliomyelitis, measles, rubella and neonatal tetanus. Targets relating to vaccine coverage, measured by coverage for diphtheria-tetanus-pertussis-containing vaccines are also omitted.

Furthermore, the roadmap does not include the targets laid out in the SDG framework. SDG target 3b stresses the importance of supporting R&D for diseases primarily affecting developing countries, the importance of access to affordable medicines and vaccines in accordance with the Doha Declaration on the TRIPS Agreement, and the need to provide access to medicines for all.<sup>vii</sup> The two indicators for measuring the achievement of this target are the proportion of the population with access to affordable medicines and vaccines on a sustainable basis, and the total net official development assistance to medical research and basic health sectors. The roadmap presented by WHO should

outline the ways in which target 3b will be achieved and integrate SDG indicators as a measure of success.

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<sup>i</sup> In WHA resolution 61.15, 'Global immunization strategy', WHO is mandated 'to take measures, as appropriate, to assist developing countries to establish and strengthen their capacity for vaccine research, development and regulation, for the purpose of improving the output of vaccine production with the aim of increasing the supply of affordable vaccines of assured quality.'

In WHA resolution 69.21, 'Addressing the burden of mycetoma', WHO is mandated 'through the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, to support the strengthening of research capacity in order to meet the need for better diagnostics, treatments and preventive tools for mycetoma.'

In WHA resolution 70.14, 'Strengthening immunisation to achieve the goals of the global vaccine action plan', WHO is mandated 'to continue to strengthen the WHO prequalification programme and provide technical assistance to support developing countries in capacity building for research and development, technology transfer, and other upstream to downstream vaccine development and manufacturing strategies that foster proper competition for a healthy vaccine market.'

<sup>ii</sup> UN HLP recommendation to WHO:

2.6.1 (a)(ii) These multilateral organizations [UNCTAD, UNDP, WHO, WIPO, WTO] should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

<sup>iii</sup> The GSPOA mandates WHO to:

'facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.' (GSPOA, element 5.1.c)

<sup>iv</sup> UN HLP recommendation to WHO:

'4.3.4 (b) Building on the Global Price Reporting Mechanism (GPRM), V3P and others, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.'

<sup>v</sup> for example under the first activity area, 'Research and development for medicines and vaccines that meet public health needs' there is a deliverable on analysing and publishing 'a list of prioritized research and development needs... [including] in-vitro diagnostics'..

<sup>vi</sup> For example, in WHA resolution 70.12, 'Cancer prevention and control in the context of an integrated approach', WHO is mandated 'to prepare a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on the availability and affordability of medicines for the prevention and treatment of cancer, including any evidence of the benefits or unintended negative consequences, as well as incentives for investment in research and development on cancer and in innovation of these measures, as well as the relationship between inputs throughout the value chain and price setting, financing gaps for research and development on cancer, and options that might enhance the affordability and accessibility of these medicines.'

<sup>vii</sup> Sustainable Development Goals Target 3b:

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'Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.'