



## **MSF: Open statement on the launch of the Global AMR R&D Collaboration Hub**

**22 May 2018**

Médecins Sans Frontières (MSF) welcomes the official launch of the Global antimicrobial resistance (AMR) Research and &Development (R&D) Collaboration Hub at the 71st World Health Assembly, as the Hub may prove to be an important catalyst to close the gap in R&D for urgently-needed new health tools to tackle one of the preeminent global public health concerns: antimicrobial resistance.

MSF witnesses first-hand the challenges caused by AMR: from war-wounded patients from Syria undergoing reconstructive surgery in Jordan, to burn patients in Haiti; from newborn babies in Pakistan to patients with multidrug-resistant tuberculosis (MDR-TB) in South Africa, India and Eastern Europe. Some of the hardest parts of our medical teams' jobs are diagnosing and treating these notoriously difficult conditions. We see patients suffer severe side effects from current standard treatments, such as deafness from drugs to treat MDR-TB. At worst, we encounter drug-resistant infections that are impossible to treat because of the lack of any other effective antibiotic options.

To address these urgent public health needs, the Hub must recognize that AMR poses a challenge that cannot be overcome with business-as-usual measures. We propose the following recommendations so that the Hub makes political and financial commitments and is able to catalyze patient-needs-driven R&D for new health tools that address the AMR crisis in an equitable, cost-effective, and sustainable way.

### **Patient-Centered Priority Setting**

The Hub should promote a truly global response to AMR and cover the unmet needs of patients and health systems worldwide. Therefore, the Hub should define a priority research agenda based on the WHO's priority pathogen list, including drug resistant tuberculosis (DR-TB). This agenda should also, and specifically, meet the needs of populations globally, with an R&D focus on new health tools that are affordable, accessible, and adapted for use in even poorly-resourced health settings.

In terms of disease focus, microbes causing diseases with high public health impact need to be prioritized. Research should include exploring opportunities to better use existing, possibly forgotten, sidelined, or withdrawn antibiotics, as well as identifying promising new drug candidates, and where appropriate assess the value of using drug combinations. In terms of treatment delivery, oral formulations instead of injectables and fixed-dose combinations of drugs would improve people's ability to adhere to complex treatment regimens. Simple paediatric formulations are needed to better treat children. Heat-stable products that do not require refrigeration (cold chain) would be indispensable.

With more than half a million new cases each year and around a quarter of a million deaths, DR-TB needs to be a key focus of the Hub, as acknowledged by the original founders of the Hub, the G20, in their 2017 Declaration. The goal is an effective and affordable short-course, all-oral cure.

### **Coherence of R&D Principles and Policy**

The Hub should promote R&D that adheres to the principles agreed upon by all countries under the 2016 UN High Level Declaration on AMR. The declaration affirmed that "all research and development efforts should

be needs-driven, evidence-based and guided by the principles of affordability, effectiveness, efficiency and equity.”

The medical products and technologies resulting from the AMR Hub should be considered public goods, ensuring public return on investment through affordability and accessibility for all, in resource-limited settings.

The Hub should also adhere to global best practices, standards, and norms and be fully aligned with the WHO Global Action Plan on AMR, the WHO Global Development and Stewardship Framework, and the work of the Interagency Coordination Group on AMR. As such, the WHO needs to play an important role in providing advice to inform R&D priority setting and funding-related discussions and decisions at the Hub.

### **Incentivize R&D Based on Need, Not Profit**

New incentive mechanisms to finance R&D should not rely on the sales proceeds of the final health product, either through high prices or high volumes – a principle commonly referred to as de-linkage. In fact, there is no connection between the prices charged for new medicines and the R&D costs. R&D financing mechanisms need to address people’s health needs even if there is no potential for significant profits, providing maximal public return on investment.

In addition, R&D incentives should foster R&D collaboration and accelerate delivery time of a new product from “bench to bedside”, through the sharing of research results, clinical trial data, and compound libraries, as well as the pooling of intellectual property rights. These conditions will speed up development, reduce costs, and increase efficiency.

MSF is particularly concerned about discussions on Market Entry Rewards (MER) and transferable intellectual property as incentive mechanisms. Such incentives are ill-suited to ensure adequate and appropriate public returns on public investments, and instead serve to perpetuate the cycle of profit focus, expensive drugs, and limited patient access. High prices are not an effective tool to promote appropriate use of antibiotics; on the contrary, high prices undermine the ability of countries to implement adequate stewardship measures.

To achieve sustainable access to effective antibiotic treatments, the Hub should adopt a transformative portfolio approach to R&D that enables the creation of a robust innovation ecosystem to deliver effective treatments including combination regimens, as opposed to drug-by-drug, company-by-company bets.

MSF believes the aim of “balancing innovation and access,” as put forth by the Hub, creates a false dichotomy of a trade-off between the two goals, when in fact both innovation and access are possible. A new, effective medical tool is of absolutely no benefit to those people who need it but cannot afford it.

### **Governance Voice of Developing Countries**

To best inform discussions and decision making, the perspectives and guidance of LMICs should be ensured. The Hub should also strongly and continually involve civil society organizations (CSOs), including patient groups and non-governmental treatment providers like MSF, in these processes. The inclusion of the voice of these stakeholders is not only important due to their experience and expertise, but also helps assure the Hub’s response to AMR puts the needs of people at the centre of all efforts.

Following these recommendations, we believe the Global AMR R&D Collaboration Hub can jumpstart the development of game-changing health tools that will transform for the better the lives of people caught in the global AMR crisis.