Executive Board, 138th Session, 2016
Agenda Item 9.1
Sharing on diagnostic, preventive and therapeutic products and for enhancing WHO's capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers

Background

In spite of unprecedented collaboration to accelerate research and development (R&D) of new tools for Ebola, the scientific harvest, two years after the start of the outbreak in West Africa, is relatively meagre.

Many clinical studies started too late after the peak of the epidemic has passed. The delay was due to a general lack of R&D 'preparedness' for Ebola: for example, VSV-EBOV, a very promising vaccine, had not yet been tested in healthy volunteers when the outbreak started although the animal studies were finalized more than four years earlier; the availability of only a few grams of ZMapp, a very promising therapeutic, precluded its prompt evaluation in a clinical trial in the field. Major dissensions between stakeholders on key issues such as trial designs also slowed down the research. Now that the Ebola outbreak has come to an end, the lessons and shortcomings of the Ebola response should not be repeated with respect to other emerging pathogens with epidemic potential. Several initiatives have been launched by some governments, research institutes, pharmaceutical companies and philanthropic foundations. The most advanced, holistic and comprehensive proposal is the one supported by WHO under the name "A Blueprint for Research and Development" and has been developed by the Secretariat with R&D stakeholders, including MSF, since December 2015.

Taking forward the R&D Blueprint

MSF believes that the development of products to address emerging diseases with a potential to cause major outbreaks should be treated as 'global public goods'.

As a result, R&D efforts and access strategies need to be coordinated by a multilateral organization, that is held accountable to all Member States, and that can promote incentive mechanisms which foster R&D in such a manner. The WHO is best placed to play that role. Previously, the WHO Consultative Expert Working Group on R&D (CEWG) recommended progressive norms and policies to spur innovation while safeguarding access, and in particular to develop products in a manner that separates cost of research and development from the promise of high prices. The R&D Blueprint should aim to be as closely aligned as possible to the processes, outcomes and approaches utilized by the CEWG, including alignment or even integration of incentive, governance and oversight mechanisms that both processes seek to establish. The following are some of the key components of the R&D Blueprint which MSF wishes to emphasize and noting in particular its linkages to the CEWG.

1. Needs assessment, priority setting and target product profiles. The WHO has a truly *global* approach for those pathogens most likely to emerge in new territories. WHO has already taken steps to determine some initial priorities as well as a procedure for priority setting. Likewise, WHO is best placed to determine the preferred characteristics of the product, so that they are adapted to the rural developing country settings where several of the priority pathogens are likely to emerge in the first place. The WHO was given a mandate by the World Health Assembly to set priorities for new R&D investments based on public health needs. To enable WHO to fulfil

this role, the Global Observatory on Health R&D (and more broadly the WHO secretariat) should be fully supported and financed by Member States to be part of the Blueprint.

2. Data sharing and sharing of samples: MSF is already supporting WHO to establish a collective biobank of Ebola specimens, in association with an open repository of clinical data collected in affected countries over the last two years. However, the vast majority of specimens that have been collected from patients in West Africa are currently stored in the few existing BSL4 laboratories around the world and it has been extremely difficult for scientific teams not affiliated with one of these labs to access the specimens and carry out research projects. Sharing of data and samples, as quickly as possible, if not in real time, is crucial to accelerate product development during an outbreak or after an outbreak. It is also crucial to ensure that the fruit of research that uses such samples and data complies with appropriate access and benefit sharing frameworks. In the absence of a multilateral policy, the BSL4 laboratories and their affiliates may be tempted to continue to work in silos.

3. Access to end-products: Under the predominant R&D financing model, pharmaceutical companies are incentivized to undertake R&D through the promise of high prices that can be charged for selling these products under monopoly conditions created through the granting of patents. . This model is not effective at financing R&D for the emerging infectious diseases listed in the Blueprint, because most of these disease targets (Ebola, Marburg, Lassa, CCHF) primarily affect rural populations in resource-limited settings, and timing of outbreaks are unpredictable. The Blueprint needs to follow a two-fold objective: spur innovation while ensuring that end-products are affordable and rapidly accessible in resource-limited settings. The Blueprint should clearly promote open licensing policies and financing mechanisms based on the 'de-linkage' of R&D costs from the prices of the end-products. Conversely, the resources mobilized with the Blueprint process should not be used to leverage investments in favor of highly-priced products that would be protected by patents and stockpiled only in countries which can afford them. The principles and approaches developed and now being taken forward under the CEWG can be of relevance to guide the design and roll-out of R&D projects to address these disease targets.

4. Capacity building: The Ebola epidemic in West Africa occurred in settings with very limited capacity to conduct clinical trials. Programmes like TDR, the Special Programme for Research and Training in Tropical Diseases supported by the WHO and other multilateral organisations, have for decades trained scientists from developing countries on good clinical practice, ethics, and trial designs. These training programmes need to be expanded. The capacity of the pharmaceutical companies including in developing countries to manufacture some of the medical products that will be tested within the Blueprint (i.e. viral vector-based vaccines, monoclonal antibodies),also needs to be supported through appropriate transfers of technology.

5. Funding: Significant funding, although still difficult to quantify, will need to be provided to implement the R&D Blueprint. Several scenarios with respect to governance of such funding should be explored. MSF prefers a pooling of contributions from Member States under the stewardship of WHO, where in such resources may be held by WHO or through a 'virtual pooling' of resources. Scientific, though not monetary, contributions of the pharmaceutical industry should also be considered. For innovations to be truly considered as global public goods, such financing should be drawn in a predictable and sustainable manner from the international community as a whole. In addition, pooled funding may be more effective than other mechanisms at rapidly mobilizing resources once an outbreak has occurred, as well as harnessing resources from non-traditional donors. It can stimulate transnational research collaborations and can be deployed rapidly. Finally, such pooled funding may be 'large enough' to cover high expenses such as clinical trial liabilities. A Pooled Fund, under the auspices of WHO TDR, which is expected to be finalized this year under the mandate of the CEWG, and which covers all diseases of public health relevance to developing countries, should be expanded to include all research processes undertaken with the framework of the Blueprint.

MSF recommendations:

MSF fully supports WHO's intention to play a pivotal role within the R&D Blueprint to accelerate R&D of new health products for infectious diseases with epidemic potential. MSF recommends integration where possible, and at a minimum coherence and alignment, between the Blueprint and other WHO-supported R&D initiatives, particularly the CEWG.

- For tracking, monitoring and identifying R&D gaps, the Blueprint should work through the Global Health R&D Observatory.
- Priority setting should also be under WHO auspices.
- Norms recommended and taken forward or inspired by the CEWG and developed by the blueprint under the WHO, including sharing of data and specimens, avoidance or removal of intellectual property barriers, and the separation of R&D costs from the price of end-products, should be instituted for all projects developed and taken forward under the auspices of the WHO secretariat including the Blueprint.
- Funding and other relevant resources to conduct R&D should be pooled, and every effort should be made to integrate such funding and resources from the Blueprint projects within the TDR pooled R&D Fund that is being considered under the CEWG. A pooled fund should be complementary to other funding sources.