



statement

R&D-based biopharmaceutical industry welcomes United Nations Declaration on TB

New York, 26 September 2018

Statement by the International Federation of Pharmaceutical Manufacturers and Associations at the High Level Meeting of the General Assembly on ending Tuberculosis

Mr Chairman,

IFPMA congratulates the United Nations General Assembly in holding the first-ever high-level meeting on the fight against tuberculosis and welcomes the UN Political Declaration on TB.

The global R&D-based biopharmaceutical industry is fully committed to the fight against tuberculosis and has been active in research, prevention, treatment, and access programmes to eliminate TB. The first new drugs to treat TB in more than 40 years were developed by our industry and companies continue to invest in R&D, individually and collectively through public-private partnerships.

We stand ready to partner with the WHO End TB strategy's three pillars of: integrated, patient-centred care and prevention; bold policies and supportive systems; and, in particular, intensified research and innovation.

To be impactful, diagnostics, medicines, and vaccines cannot operate in a vacuum. The scale-up of effective TB treatment and preventative therapy remains poor - even though most current drug regimens are comprised primarily of low-cost generics and supported by donation programmes and international donor funding. There is therefore an urgent need to strengthen health systems in high-burden countries to enable scale-up of existing tools, while ensuring appropriate use to prevent the continued emergence of drug-resistance.

The global R&D-based biopharmaceutical industry firmly supports the premise that progress towards universal health coverage, as defined in WHA Resolution 67.1 would significantly contribute to end TB.

Global guidelines for TB diagnosis and treatment need to be rapidly translated at the local level. Effective on-the-ground health systems strengthening supported by sound public policy is needed to support a holistic approach to ending TB. Public awareness, prevention, early diagnosis, adequate primary hospital care, and ending stigma are all key.

Development of future TB regimens will need to look at both new combinations of current drugs to make treatment shorter and less toxic, as well as the development of entirely new molecules from novel chemical classes with unique mechanisms of action for which there is no risk of resistance.

Publicly funded research is important to understand the science of this evolving disease. In addition, partnership with the private sector will be needed to deliver and sustain the much-needed innovation in TB. In addition to delivering the first two new TB drugs in over 40 years, industry is



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currently engaged in a total of 82 TB R&D projects many in partnership with other public and nonprofit actors.

Continued innovation is particularly important given the growing levels of drug resistance. To nurture and leverage industry's skills and incentivize companies to invest further in TB R&D, a mix of push and pull mechanisms, and simplified regulatory pathways will be needed. Intellectual property rights are also a key incentive to secure long-term private-sector investment in lengthy and costly TB drug and vaccine development trials and subsequent regulatory pathways. Without action to establish the right incentives and policies for the next wave of innovation, we risk losing precious opportunities to accelerate impact on this disease.

Working in an area like TB, which is under-resourced and under-incentivized, requires strong, multisectoral partnerships, from development all the way through launch and roll-out.

We believe the UN Political Declaration on TB has identified key challenges and indicated a constructive way forward where all stakeholders can unite to make this disease history.

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