

The Secretary of the 21st Expert Committee on the Selection and Use of Essential Medicines
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

23 February 2017

Open letter re: Support for the proposed WHO Model List of Essential *In Vitro* Diagnostics (EDL)

Dear Expert Committee,

We are writing to acknowledge the value of the World Health Organization (WHO) Model Lists of Essential Medicine (EMLs) for adults and children and to express our support for the establishment of a similar list for diagnostic technologies. In an open letter previously sent to the WHO Department of Essential Medicines and Health Products, we encouraged the WHO's leadership in establishing a list of essential diagnostics.¹ As members of the civil society organizations and community groups, working to improve access to tuberculosis (TB) diagnosis and treatment, we are encouraged by the prospect of a WHO Model List of Essential *In Vitro* Diagnostics (EDL) and its potential to support our efforts to hold country governments accountable for providing access to essential diagnostic tools and medicines for TB.

Model Lists are a powerful advocacy tool for improving the availability of included products and technologies, and maximizing the impact of health resources. In the same way the EMLs provide accountability for the provision of essential medicines, an EDL would support activists' efforts to hold country governments accountable for providing access to important diagnostic tools. In instances where country governments and regulatory bodies allow the marketing and use of inappropriate diagnostic tests– in some cases, while simultaneously failing to implement those that are evidence-based and quality assured– an EDL would serve as a critically important reference for activists' as they push for policy and practice reforms at the country-level.

The WHO EMLs have been fundamental in guiding countries on the inclusion of appropriate medicines in national programs and procurement decisions. An EDL would offer the same helpful guidance to national programs and procurement agencies for diagnostic tests crucial for the management of all forms of diseases (both communicable and non-communicable), surveillance of emerging infections, and maintenance of public health.

Given the well established link between accurate diagnosis and access to appropriate treatment, an EDL would complement the EML by helping to improve the rational and appropriate use of medicines, especially important given rising rates of antimicrobial resistance. Additional benefits that might be expected from the establishment of an EDL include increased uptake, which could lead to volume based cost reductions, further improving access to testing in low and middle-income countries. An EDL might also help

policy makers prioritize laboratory testing and infrastructure needs, leading to improved health care delivery systems and better patient outcomes.²

As advocates for access to evidence-based, quality diagnosis and treatment for TB and other health conditions, we are very supportive of the establishment of an EDL and eagerly await the response of the Expert Committee on the WHO's proposal. Since the WHO already hosts the EML and develops guidance on diagnostic tests and laboratory accreditation schemes for low income countries,³ we believe that it is extremely well-poised to lead the development and maintenance of an EDL.

We welcome the recent developments and reiterate our support for WHO and other partners to hasten the establishment of an EDL. Should the Expert Committee approve the WHO's proposal, we look forward to further consultations with key stakeholders, including civil society organizations and community groups to inform the process, scope, and organization of the EDL. If you have any questions or interest in further discussion, please direct your response to Wim Vandeveldde at wim@eatg.org.

Sincerely,

ACTION Global Health Advocacy Partnership
The Global Coalition of TB Activists (GCTA)
Infectious Diseases Society of America (IDSA)
The European AIDS Treatment Group (EATG)
The Global TB Community Advisory Board (TB CAB)
McGill Global Health Programs
McGill International TB Centre
TB Proof
Treatment Action Group (TAG)
University of Michigan Medical School Global Reach Program

¹ Open letter re: Urgent need for an Essential Diagnostics List. 24 October 2016.

Available from:

www.treatmentactiongroup.org/sites/default/files/Essential%20Diagnostic%20List_WHO_Final.pdf

² Schroeder LF, Guarner J, Elbireer A, Castle PE, Amukele TK. Time for a Model List of Essential Diagnostics. *N Engl J Med*. 2016 Jun 30;374(26):2511-4. doi: 10.1056/NEJMp1602825.

³ *Ibid.*