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Dear Dr. Hill:

Thank you for the regular opportunities for the Global Medical Technology Alliance (GMTA) and the Global Diagnostics Alliance (GDA) to correspond with your office, offering perspectives on the World Health Organization (WHO’s) Model List of In Vitro Diagnostics (EDL). As consideration is being given to updating the EDL, per an open comment period just concluded, we once again commend the WHO for recognizing that diagnostic tests are an essential component in advanced universal health coverage, address health emergencies, promote healthier populations and help sustain efficient healthcare systems. Diagnostic tests are critical tools for health care, providing vital information that impacts the prevention, detection, diagnosis, treatment, management of disease, surveillance and epidemiology. We strongly support WHO’s goal of increasing access to safe and effective diagnostics in underserved regions of the world.

The GMTA is comprised of national or regional medical technology associations, which represent innovative companies that currently develop and manufacture over 85 percent of the world’s medical devices, diagnostics and equipment. It provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients’ health care needs. The WHO recognizes the GMTA as an NGO with official relations.

The GDA is an international group of the leading industry associations representing manufacturers of in vitro diagnostics and related analytical instruments and software. The associations currently participating in the GDA are AdvaMedDx from the United States, CBDL from Brazil, Pathology Technology Australia, JACRI and JAIMA from Japan, Mecomed from the Middle East and Africa, MEDEC from Canada, and MedTech Europe.

The position of the GMTA and GDA on the WHO’s EDL is informed by continual feedback from member companies and associations given experience to date with the first edition of the EDL.
as well as the pending second edition and its potential impact on access to safe and effective diagnostic tests.

**Patient Access to Diagnostic Tests: Laboratory Infrastructure Support Critical**

The EDL presents the potential to improve access to safe and effective diagnostic tests, critical to patient and public health. Indisputably, any EDL implementation will only have the potential to be as successful if its laboratory infrastructure is strong. As such, we continue to encourage WHO to also focus efforts on helping member states build up their laboratory infrastructure, update training of laboratory technicians, and establish a framework for simplified accreditation, to improve overall access to diagnostic tests and implement their own EDL in a manner consistent with what WHO has stated are the overarching goals of the EDL, to expand access and improve quality of care.

**Proposed Second Edition EDL**

The first edition of the EDL was initially focused on general laboratory tests for routine patient care as well as for the detection and diagnosis of HIV, tuberculosis, malaria, hepatitis B and C, human papillomavirus, and syphilis. For the second edition, WHO has indicated an interest in receiving applications for categories of tests for antimicrobial resistance, neglected tropical diseases, noncommunicable diseases, outbreaks/emergencies and sepsis. The SAGE IVD will consider a draft set of stakeholder recommendations later this month. The draft list represents a broad range of tests. We encourage the WHO to approach with careful consideration augmentation of the list, providing a clear rational for any expansion item. As we have in the past, we ask WHO to ensure a narrow scope of the EDL is maintained at while a robust and transparent, evidence-based process of assessing the impact of the EDL on access to diagnostics is put in place. Only after a full assessment of the EDL on patient access to effectively utilized diagnostics is performed, and there is evidence to indicate that access is improving in a sustainable way, should consensus-based consideration of broadening the disease areas take place.

**Ensure Robust Assessment of Member State EDL Implementations**

We ask WHO to take the opportunity during the early stages of the EDL to establish a standardized, regular, robust and transparent evidence-based process of assessing the impact of the EDL on patient access to diagnostics. The evidence-based process should be predictable and rooted in the fundamentals of diagnostics tests. A publicly released assessment would bolster decision making processes regarding the EDL implementations and WHO policy toward EDL modifications. We would be pleased to be of assistance in developing any such assessment tool.
Ensure Support of Diagnostic Access and Innovation

The GMTA and GDA as you know, maintain concern that a poorly designed implementation of the EDL by member states could result in reduced access to diagnostics. Taking lessons learned from the implementation of the Essential Medicines List of many decades, we understand that member states have utilized the EML to implement restrictive pricing of medicines to drive down their cost. The implementation of price controls on diagnostic tests, particularly if laboratory infrastructure and outreach to patients is inchoate, could lead to stifled innovation and reduced access to diagnostic tests. The diagnostics industry has undertaken many agreements to offer critical diagnostic tests at reduced prices to low and middle-income countries (LMICs).

The true value of diagnostic tests goes well beyond price. Effective use of high-quality diagnostic tests that meet global standards of safety, quality and performance can save lives, lower treatment costs through early detection, and set clear, efficient clinical pathways for care and improve patient outcomes. The EDL should consider the quality of assays – as for instance assessed by the WHO pre-qualification programme for diagnostics. Beyond the test, country implementation should incentivize IVD manufacturers for high-quality customer support necessary to realize the full potential of diagnostics.

With a longer-term vision, there should be a clearer pathway for the EDL to encourage the development of the new innovative diagnostic technologies which are needed in different healthcare settings from LMICs to emerging health threats. Appropriate implementation of an EDL would ensure the diagnostics industry is practically incentivized to continue research and development in innovative diagnostics for conditions that disproportionately impact LMICs. We urge WHO to work with member states to ensure any methodology to implement an EDL considers not only the unique role of diagnostic tests as different from medicines, but also fully accounts for the broad value of diagnostics within the healthcare system.

EDL Should be Organized by Specific Targets

In consideration of the list of tests proposed to be included in the second edition of the EDL, the GMTA and GDA believe the EDL should not be designed to advantage one testing technology over another. The EDL should be organized by specific testing targets and offer guidance on how to best achieve those test results. While not named, company-specific systems and technologies are clearly referenced in the EDL. We strongly encourage the WHO to ensure the EDL meets the goal set forth in the Report of the first Strategic Advisory Group on In Vitro Diagnostics (SAGE-IVD) indicates that “the EDL refers to tests according to their biological targets and does not use brand names.”

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WHO and SAGE IVD Consultation with Stakeholders: Recommendation for Technical Advisory Process Beyond the SAGE IVD

We encourage increased transparency in WHO and SAGE IVD deliberations, in recognition of the value open consultation with stakeholders who have a background and expertise in the development, commercialization, and global distribution of diagnostic tests can bring to the EDL.

We recommend the WHO establish a technical advisory process that would include diagnostics and medical experts, separate and apart from the SAGE IVD. The diagnostics industry is continuously innovating in response to science and public health needs, among other reasons. Ensuring experts with keen knowledge of the latest advances and capabilities of the diagnostics industry is indispensable to sound policy determinations on the EDL.

Prequalification and EDL: Separate and Distinct Processes

As we have previously stated, we appreciate the WHO keeping the EDL and the list of prequalified diagnostic tests as two distinct processes. As the list of tests included in the EDL are based on disease areas and test category, it has a much wider scope that the list of prequalified diagnostics, which are identified by brand.

More basically, the prequalification program functions as a regulatory system that can aid member states in making procurement determinations. The EDL, in contrast, can function as a policy guidance for member states seeking to contemplate a minimum standard of diagnostics tools and tests that may suit the health care delivery needs of their populations.

Thank you for the opportunity to provide you our comments on the EDL. We look forward to continuing to engage with you and others at WHO to help increase access to safe and effective diagnostics around the world.

Sincerely,

Global Medical Technology Alliance
Global Diagnostics Alliance

Cc: Dr. Francis Moussy, Essential Diagnostics List Secretariat