AMATA statement at the 75th Session of the WHO Regional Committee for Africa

Agenda Item: 16 - Information documents, 16.8 Progress report on the regional strategy on regulation of medical products in African Region, 2016–2025

The African Medicines Agency Treaty Alliance (AMATA) commends the progress made under the **Regional Strategy on Regulation of Medical Products in the African Region**. However, the African regulatory landscape remains fragmented and complex, with uneven capacities across countries. These disparities hinder the timely access to safe, effective, and quality medical products and continue to expose patients to the dangers of substandard and falsified medicines.

Furthermore, we **fully support and endorse the first Africa Continental Reliance Framework** which represents a significant advancement in fostering regulatory cooperation and enhancing efficiency across Africa. By enabling national regulatory authorities to rely on assessments and decisions made by trusted regulators—both within the continent and beyond—patient access to quality medical products can be accelerated without compromising safety or efficacy.

The framework provides clear guidance for leveraging prior regulatory work, thereby reducing duplication, conserving resources, and supporting timely, evidence-informed decisions. This is a technical innovation and bold expression for shared responsibility in public health and African solidarity.

Yet, a truly harmonized and effective system cannot exist without **continental coordination and leadership**. That is why we reiterate our strong support for the full ratification and implementation, of the **African Medicines Agency (AMA)**, in tandem with the rapid and swift transition of the AMRH technical activities to AMA operations.

The AMA, as a continental regulatory body, is *the vital tool we need* to unify Africa's fragmented regulatory space, reduce duplication, improve oversight, and ensure that *all* patients across the continent have access to quality, safe, and effective medical products in a timely manner.

We commend continued progress made on AMA's implementation through the recent appointment of Dr. Delese Mimi Darko as the Director General and we reiterate the importance of including in the governance of the future Agency, a mechanism to engage with patients and other relevant stakeholders who stand ready to contribute

We as AMATA, call on Member States that are yet to **sign and ratify the AMA treaty** to do so. Let us safeguard the health of our people, and take a decisive step toward an integrated and resilient African regulatory system.

Thank you.

AMATA Founding and steering committee members