Opening Remarks by Margareth Ndomondo-Sigonda during a Study Tour to the Tanzania Medicines and Medical Devices Authority, 03-08 October 2022

- Dr Yonah Hebron representing Mr Adam Fimbo, the Director General, TMDA
- TMDA Management and staff
- Mr Bonaventure Chilinde, the Chairperson of AMQF TC of the AMRH Initiative
- Delegates from Burundi, Botswana, Mozambique, Senegal, Tunisia and Zambia represented here
- Distinguished gusts, Ladies and Gentlemen

Good morning

It gives me pleasure to give remarks and officiate the opening session of this very special occasion of a study tour of the 6 countries to the TMDA.

You will all agree with me that a access to good quality, safe and efficacious medical products is one of the key pillars of a well-functioning health care delivery system and an important component for countries to attain Universal Health Coverage (UHC).

While the continent has had challenges in it health care delivery systems for the longest, COVID-19 pandemic has further exacerbated the substantial inequities in access to care which has existed for many years within as well as between countries. Vulnerable populations have continued to face a higher burden of morbidity and premature mortality due to easily preventable and treatable causes. Their limited access to affordable and quality essential services, as well as underinvestment in primary health care systems, is a major impediment to achieving Universal Health Coverage.

The African Union has identified health as one of the critical priorities for achieving the continental development agenda. Agenda 2063 ten-year implementation plan has targeted healthy and well-nourished citizens as one of the priorities towards achieving "A Prosperous Africa, based on Inclusive Growth and Sustainable Development."

The aim is to improve access to medical products supporting the development and the distribution of treatments and vaccines, and the coordination of research on the development and production of new medicines and vaccines on the continent. This will be achieved through implementation of various AU Policy and Strategic Framework such as the Pharmaceutical Manufacturing Plan for Africa (PMPA) and the Partnerships for African Vaccines Manufacturing (PAVM), just to mention a few.

The study tour this week is therefore a result of a long term investment by African Governments and development partners on implementation of the African Medicines Regulatory Harmonization Initiative as part of the PMPA policy framework aimed to improve the fragmented regulatory systems on the continent.

It is important at this point that I recognise the contributions from various partners who have supported the initiative from its inception in 2009., They include the AU Organs (i.e. AUC & PAP), WHO, WB, BMGF and United States Pharmacopoeia Convention (USP), just to mention a few. I would particularly like to underscore the USP

contribution in constituting the African Medicines Quality Forum (AMQF) in 2017 as one of the AMRH TC from a network of national Medicines Laboratories (NOMCOL) in recognition of the need to ensure African ownership and sustainability of partner supported programs. The AMQF a collaborative effort of USP, AUDA-NEPAD and the West African Health Organization (WAHO). It plays a key role in assuring the quality of medicines circulating on the African markets

Access to a well-functioning laboratory for medical products testing is an important resource for the national regulatory system and one of the key indicators of the maturity of a national regulatory authority under the WHO Benchmarking Tool standards. The laboratory can either be under the responsibility of an NRA or a governmental or an external laboratory depending on a national policy and legal framework. While the performance of Laboratory function is critical, the NRAs are required to also ensure other 8 regulatory functions are equally robust to ensure a credible regulatory system in a country. These are Marketing Authorization, Vigilance, Market Surveillance and Control, Licensing of Premises, Regulatory Inspections, Laboratory Access & Testing, Clinical Trials, and Lot Release

This study tour comes at a time when Africa is making strides in its regulatory systems strengthening and harmonization efforts. While Tanzania Medicines and Medical Devices Authority was the first to attain WHO ML3 status in December 2018, the Ghana Food and Drug Authority followed in May 2020. This year alone in March we have witnessed 2 more NRAs attaining WHO ML Status i.e. The National Agency for Food and Drug Administration of Nigeria (NAFDAC) and the Egyptian Drug Authority attaining the WHO ML 3 status, the latter for vaccines producing country.

You may also wish to know that in 2019 USP assessed the capacity of NQCLs among the members of AMQF using the international standards of ISO/IEC 17025 and WHO GPCL as the criteria. The study showed that only twenty-five percent (25 %) of the labs were accredited hence the decision by the 4th annual AMQF meeting that three NQCLs which are not accredited would visit accredited NQCLs for training purposes.

We need strong NRAs to attain 60% vaccines self-sufficiency by 2040. We need strong NRAs to serve as an anchor for the African Medicines Agency and TMD is critical in this process.

Let me at this juncture thank the TMDA Management for accepting our request to host the 6 countries namely Botswana, Burundi, Mozambique, Tunisia, Senegal, and Zambia. Cross country learning and sharing experiences, collaborations and networking among NRAs, mutual recognition of regulatory decisions and laboratory results among NRAs and/or Laboratories are key for strengthening regulatory capacity.

I would like to commend the TMDA leadership for its commitment in setting the pace for the African NRAs to aspire global standard recognition and would like to implore the leadership to assist other less mature NRAs in their journey of growth. This study tour is a true testimony of TMDA leadership and commitment.

With these remarks, I would like to thank you all for your attention and wish you a productive study tour.