

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH



SEVENTY-SIXTH WORLD HEALTH ASSEMBLY

Agenda item 13.7

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Standardization of Medical Devices Nomenclature

1. The United Republic of Tanzania (URT) commends and applauds the Secretariat of the Executive Board for the efforts and stride made towards standardization of medical devices nomenclature system. We reckon the endeavors made by the Secretariat in the extensive analysis of the existing nomenclature system and the proposal put forward to introduce the internationally accepted naming system to be adopted by WHO Member States.
2. In the URT medical devices are regulated by the Ministry responsible for health through the Tanzania Medicines and Medical Devices Act, Cap 219 and regulations made thereunder. The current legislation provides for the definition of medical devices including classification of these products into four risk categories in tandem with the International Medical Devices Regulatory Forum (IMDRF) classification arrangement.
3. The URT had also adopted the Global Medical Devices Nomenclature (GMDN) system through which the National Regulatory Authority (NRA) has subscribed to and given access. The same have been instrumental and quite helpful in grouping and classifying medical devices for regulatory approval processes.
4. Notwithstanding, the URT supports the proposed international nomenclature system as it would affirmatively streamline and converge the nomenclature and coding of devices globally resulting into expedited marketing authorization and access to good quality and safe medical devices.
5. In wrapping-up, the URT proposes for the adoption of the report on progress made in standardization of medical devices nomenclature as recommended by the Executive Board under provisional agenda item 13.7.
6. **I thank you.**