For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

MEDICAL DEVICE REGULATION IN ZAMBIA

OUR JOURNEY

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PRESENTATION OUTLINE

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2. LEGAL MANDATE AND BASIS OF MEDICAL DEVICE INLUDING IVD‘s
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BRIEF INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is established under the Medicines and Allied Substances Act (No.3) of 2013 and is mandated to ensure that medicines and allied substances being made available to the Zambian people and animals consistently meet the required standards of quality, safety, efficacy and performance.

LEGAL MANDATE AND BASIS OF MEDICAL DEVICE INCLUDING IVD‘s

The Medicines and Allied Substances Act (No.3) of 2013 provides for the regulation of medicines and allied substances and Section 39, Part V further provides for grant of marketing authorisation of medicines and allied substances to be placed on the Zambian market.

The Act defines **“allied substances”** to include **medical devices** and has further defines **medical devices to include in-vitro diagnostics as per global definition**.

Based on this provision, the Authority is legally mandated to regulate medical devices, including in vitro diagnostics (IVDs), placed on the Zambian market in line with applicable regulatory requirements

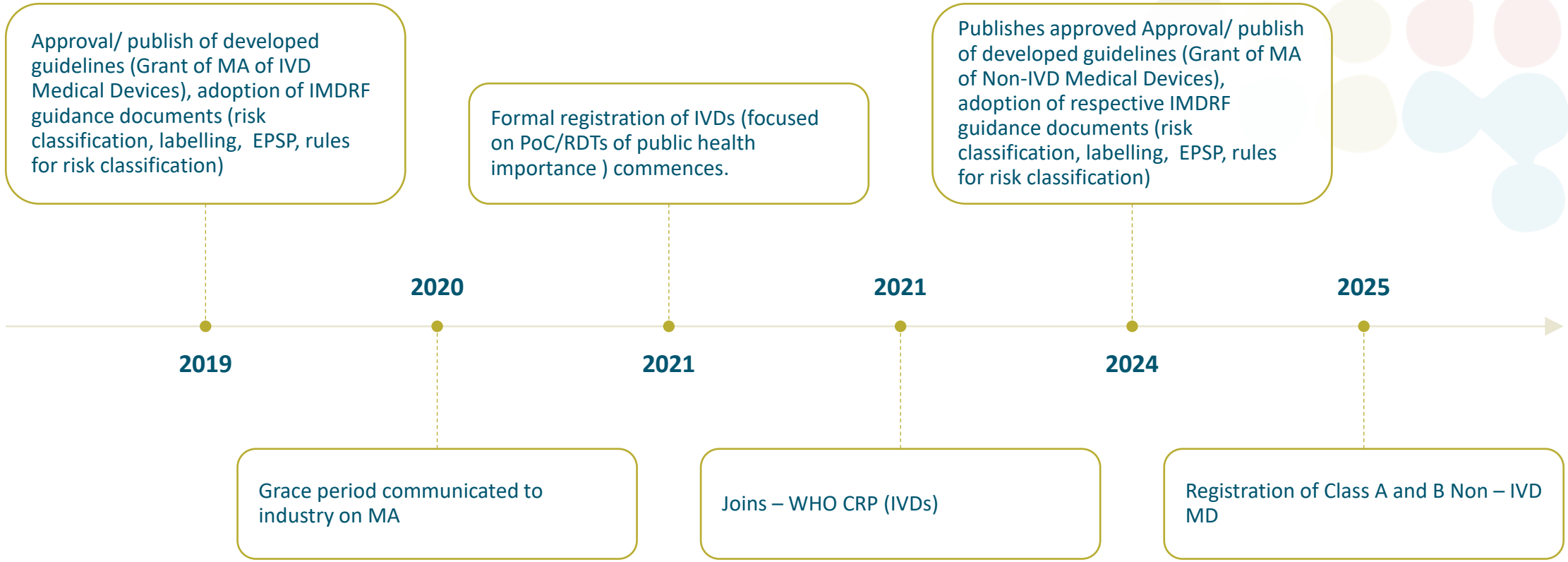
BRIEF OVERVIEW OF MEDICAL DEVICE AND IVD REGULATORY FRAMEWORK

- The Zambia Medicines Regulatory Authority (ZAMRA) has developed a comprehensive regulatory framework for medical devices, including in vitro diagnostics (IVDs), modeled closely on the World Health Organization (WHO) guidelines.

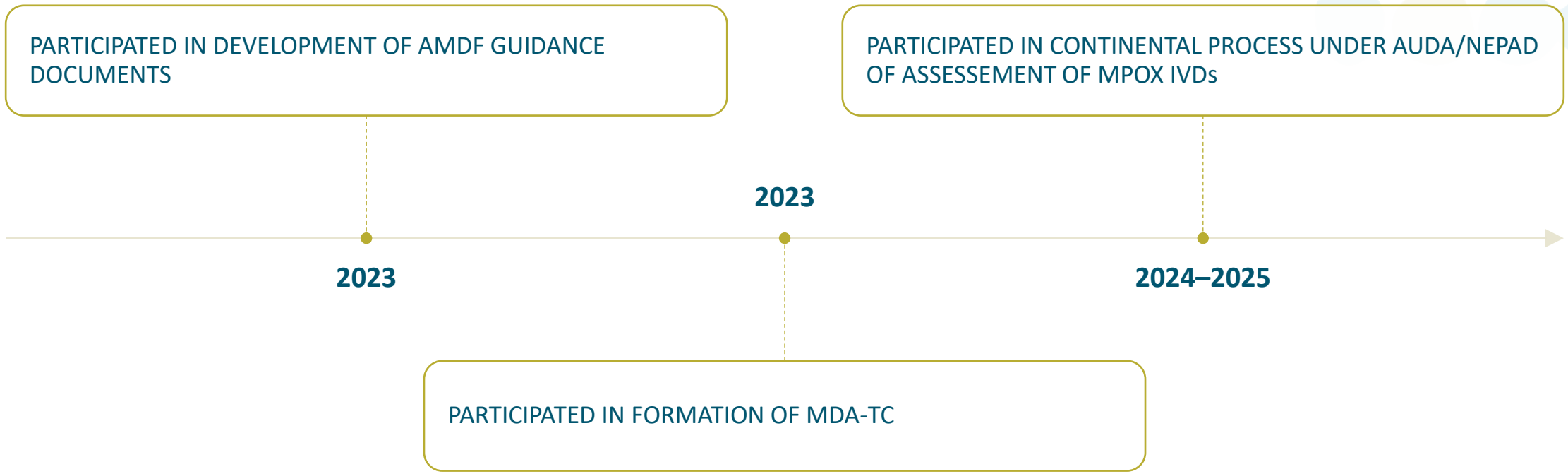
- The framework aims to ensure the safety, performance, and quality of medical devices placed on the Zambian market. It emphasizes a risk-based classification system for medical devices and IVDs, establishing clear pathways for pre-market evaluation, registration, and post-market surveillance. ZAMRA's regulation incorporates WHO principles by requiring manufacturers to demonstrate compliance with Good Manufacturing Practices (GMP) and ISO 13485: QMS

- The framework further emphasizes the importance of robust clinical evaluation, proper labeling, and adverse event reporting mechanisms.

2019 TO PRESENT, FOCUS ON ZAMRA'S RECENT ACTIVITIES



Participation in the Continental Process – AMDF/MDA TC



Implementing ISO 13485 QMS Audits

2023 –Capacity Building & Training. Train ZAMRA staff and designated auditors on ISO 13485 standards and audit procedures.

Collaborate with international bodies or consultants for technical expertise.

2024 – Planning on commencement/implementation of ISO 13485 QMS Audits

2025 – Develop tools for ISO 13485 QMS

Challenges Faced on this journey

- Resource constraints and technical expertise gaps

- Limited infrastructure for testing and certification

- Industry compliance hurdles

- Ensuring consistent enforcement and surveillance

Recommendations for Strengthening Regulation

- Increase investment in regulatory infrastructure
- Foster regional collaborations and data sharing
- Capacity building for regulators and industry
- Promote local manufacturing and innovation
- Develop a more predictable and transparent registration process

Future Directions

- Full implementation of regulation for all device categories
- Continued regional, continental and global integration efforts
- Regular stakeholder engagement and training
- Sustainable capacity development

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