Tanzania Medicines & Medical Devices Authority

# TMDA EXPERIENCE IN THE MAGHP PROCEDURE

## Swissmedic MAGHP - webinar
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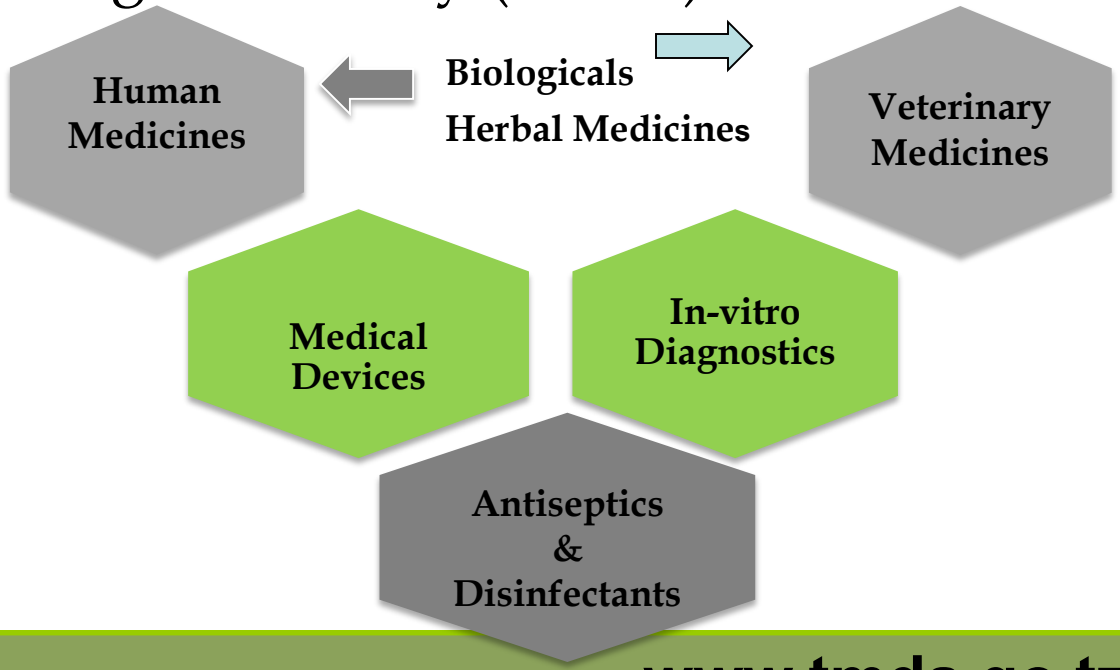
# Presentation outline

- Who is Tanzania Medicines and Medical Devices Authority (TMDA) ?
- TMDA medicines evaluation and registration process
- TMDA participation in MAGHP procedure
  - Experience
  - Challenges
  - Recommendations & Way forward

# Tanzania Medicines and Medical Devices Authority (TMDA)

- An Executive Agency
- Under The Ministry of Health, Community Development, Gender, Elderly and Children
- Established in July, 2003. TMDA was formerly known as Tanzania Food and Drugs Authority (TFDA)
- **Mandate**: Regulating Quality, effectiveness and safety of medicines, medicals devices and diagnostics.



**Mission**

- To protect and promote public health by ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products for all.

**Vision**

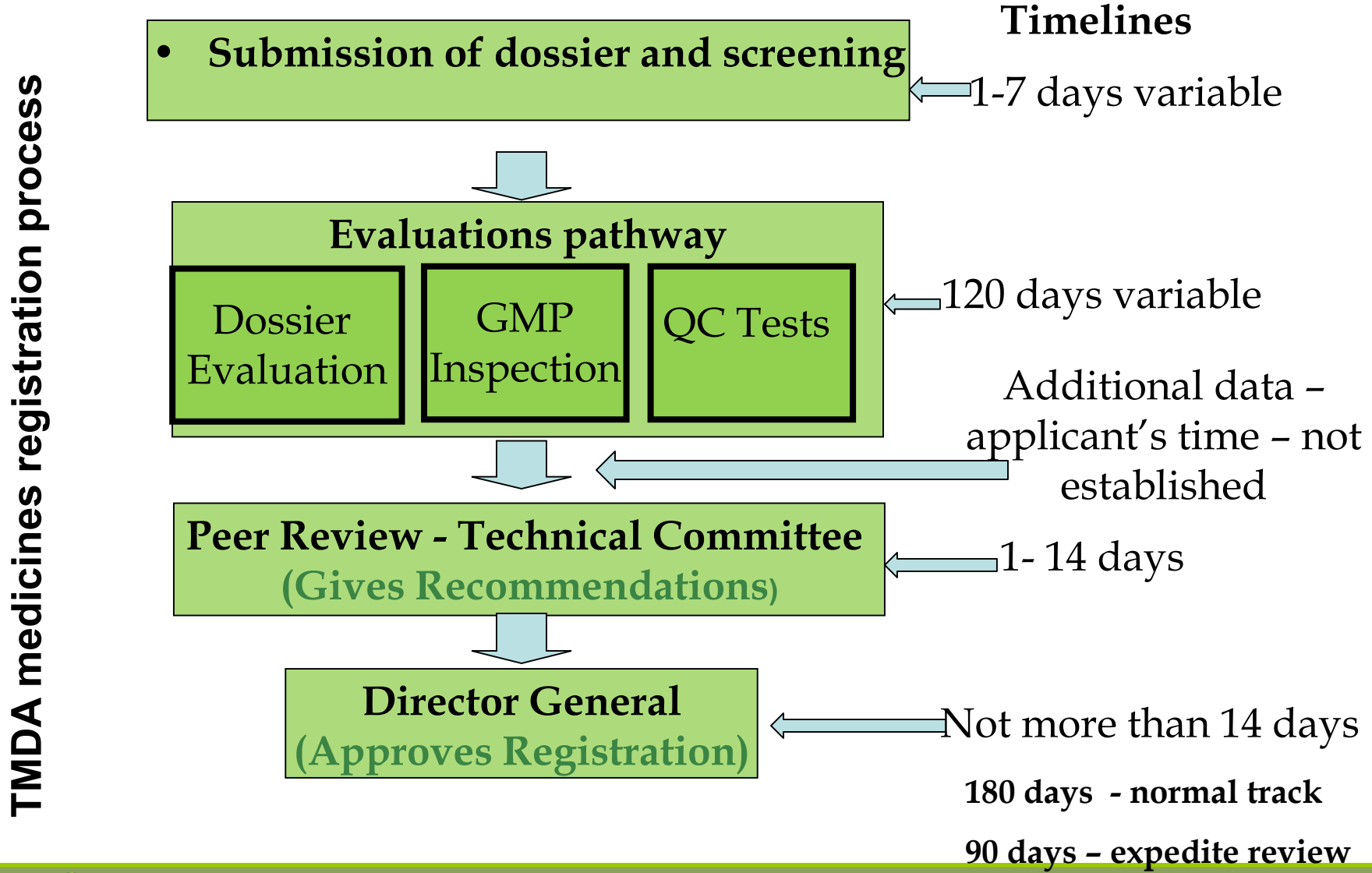
- To be the leading Regulatory Authority in ensuring safety, quality and effective medicines, medical devices, diagnostics and other health related products for all.

**ISO 9001:2015 Certified**

**ISO/IEC 17025:2005 Accredited**

**WHO Pre-Qualified Laboratory**

# TMDA evaluation and registration process



# TMDA participation in MAGHP procedure (1)

**MAGHP procedure participated**

1. Carbetocin Ferring, Solution for injection for the prevention of uterine haemorrhage due to postpartum uterine atony after vaginal delivery for IM or IV administration;
   - application for a new indication and alternative route of administration

*Application proposal*

1. Artemether:Lumefantrine (A:L) 2.5:30 mg Dispersible Tablets fixed-dose combination formulation for neonates and infants of body weight below 5 kg;
   - application for a new AL 2.5:30 mg fixed-dose combination to provide a maximum dosing flexibility for <5 kg BW.

# TMDA participation in MAGHP procedure (2)

**Participation**

- Objective and scope of the procedure were clearly communicated to experts.
- Actively participated in the review of for all the two applications
- One expert was involved

- Confidentiality forms for each application agreement was signed

# TMDA participation–Experience (1)

**Experience**

- Sharing of knowledge and experience among experts during team meeting, Swissmedic, WHO-PQ & NMRAs

- Sharing of in-depth review reports and documents related to the application through SharePoint - sharing of confidential information between Swissmedic experts, NMRA experts, through SAGHP procedure.

# TMDA participation –Experience (2)

- Comprehensive initial assessment reports by Swissmedic experts on in depth review of preclinical and clinical data and pertinent issues which were raised on studies objectives, evaluation/analysis of the data – **This was teaching notes to experts.**

- Learning experience from marketing procedures placed by Swissmedics; including administrative ordinances, guidelines, communications with applicants, approval decision and conditions of approval.

# TMDA participation – Experience (3)

- Assessment report from MAGHP procedure was used for the approval process at TMDA.

- The review and approval of the application within 90 days was fulfilled for Carbetocin Ferring solution with a GMP desk review. Timelines requirement was in line with TMDA approval of priority medicines.

- TMDA submission; 25 September 2020 and granted marketing authorization on 18 November, 2020. Less than 60 days.

# TMDA participation – Challenges

- Participation of all involved members was not possible due to time zone context/overlapping of activities particularly for the NMRA experts.

- The telephone conferences meeting had unstable connection and background noise

- Few applications so far

- Lack of formal signed agreement between TMDA and Swissmedic for participation – Legal provisions for regulatory decision reliance

- Expected challenges with regards to management of post approval changes/variations

# TMDA participation – Way forward (1)

- Flexibility for including additional assessor/expert from NMRA during dossier review session – This will provide room for participation of experts specific for some specialized products such as biotec products - vaccines.

- Means of communication especially for the session of **case team meeting** should be improved e.g. to use Zoom, WebEx etc. particularly for the SAGHP procedure which involves more participants.

- Meeting need to be pre-aligned in order to secure higher participation of experts from WHO and NRAs particularly for the SAGHP meeting.

# TMDA participation – Way forward (2)

- Establish standards of sharing information on approval of priority medicines from WLA countries ( i.e. Swissmedic) for timely availability to the needed group of population.

- More advocacy of the procedure: manufacturers/applicants

- Expand scope of applications

- To have formal and legal agreement – signing of MoU between Swissmedic, TMDA on regulatory decision reliance. A clear agreement or consent from applicant to share the information with NMRAs.
- Mechanism should be in place to ensure the same dossier submitted to Swissmedic is submitted to NMRAs.

# Thank you
# (Asante)