THE EAST AFRICAN COMMUNITY JOINT ASSESSMENT PROCEDURE: ACHIEVEMENTS, CHALLENGES AND WAY FORWARD

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Outline

• Overview of the EAC Joint Assessment Procedure
• Achievements
• Challenges and Way forward
  • Technical challenges
  • Administrative challenges
• Results
• Conclusion
• Acknowledgement

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
Overview of the EAC - MRH Joint Assessment Procedure

- Started in 2015
- 7 NMRAs

All communication is done by TMDA until a final recommendation is reached. The Secretariat notify applicants of the outcome.
OBJECTIVE 1: Harmonize technical requirements

Achievements

- CTD implemented in all NMRAs
- 2nd Edition of the Compendium of Guidelines for MER
  - Introduced QIS, guideline on naming, APIMF procedure
- Guidelines for registration of human vaccines, biotherapeutics, biosimilars
- Guidelines for variation (pharmaceuticals & vaccines)
- SOPs & assessment tools developed and implemented
- Assessment templates (new, query response & variations)
OBJECTIVE 2 & 3

- Regular meetings of EWGs to inform and exchange ideas
- Drafting and implementation of Cooperation framework agreement
- 12 JA sessions (13th session planned for 1st week of August)
  - Total applications 106
  - Total assessed: 83
  - Total recommended: 36
  - Queried: 47
  - Under evaluation: 21
  - Pending payment: 2
OBJECTIVE 4

- Strengthen Regulatory Systems of EAC Partner State
- Regular Forum of HNMRAs and Steering Committee
- 7 NMRAs have functional MIS at different levels
  - Functional MIS modules for registration in 3 NMRAs
- Development of regional MIS portal (in progress)
- 4 NMRAs are ISO 9001:2015 certified
- 1 NMRA attained WHO ML3
OBJECTIVE 5

- Capacity building and training
  - Twinning program
  - NMRA funded trainings
  - Aiding DFCA in domestication of guidelines
  - Other trainings:
    - QMS (60 experts, 35 lead auditors)
    - MER (over 30 assessors)
    - 12 experts trained in CROs inspections
    - 20 experts trained in BE
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Technical Bottlenecks

**Challenge**

- Delay in assessment
- Poor quality of submissions & delay in submission of query responses

**Solutions**

- Implementing SOPs and adhering to timelines;
- Engagement of HODs for MER;
- Implement abridged assessment procedure;
- Engage EWG – GMP at screening stage; and
- Sharing assessment reports (after consent)

- Engage industry (1 meeting in April 2019);
- Strengthen screening process;
- Start API – MF procedure;
- Set deadline for submission of additional info (180 days for first round and 120 days for subsequent rounds); and
- Limit rounds of assessment
## Administrative bottle necks

### Challenge

- Few number of applications
- Applicants unwilling to pay in all Partner States
- Lack of human resources
- Unassured financial sustainability

### Solution

- Improve/speeding up processes;
- Developed M & E tools (MER and GMP);
- Mapping of common applications;
- Share schedule with all stakeholders;
- Allow applicants to pay in at least 2 Partner States initially;  
  **(ongoing)**
- Consider having a single regional fee
- Hire staff dedicated to MRH and Joint activities

**Focus on sustainability of the Programme:**
- NMRAs to cover cost of conference facilities during joint meeting;
- NMRAs to fund GMP inspectors;
- Consider having a “top up” or administrative fee  
  **(proposal)**
Results

• Metric M & E tool was developed

• 6 sections:
  • Application Details, Screening Process, Evaluation Process (4 cycles), Final Recommendations, NMRAs Implementation, Post Approval Process

• Monitor regulators time i.e. time taken for screening, evaluation, final recommendation and registration at country level

• Monitors applicant time; time taken to respond to queries (*recommendation: monitor time taken to pay fees in each NMRA*)

• Data for 36 products jointly recommended have been analysed
**Results**

- **Overall timelines from 2015 to 2019**
  - 36 recommended

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<th>PS NMRA</th>
<th>Number of products registered</th>
<th>Time taken (days) to implement recommendations</th>
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- **Overall process took 372 days; regulator’s time 202 days; manufacturers’ time to respond to queries 170 days**

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• Timelines from January – September 2019
  • Total applications 54 (37 new + 17 query)
  • Finalized applications 8

<table>
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<tr>
<th>Partner State NMRA</th>
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• Submission to end of assessment for all products 240 days; regulator’s time 150 days; manufacturers’ time to respond to questions 90 days
CONCLUSION

• Identification of challenges and implementation of proposed solutions has led to increase in number of applications and creation of streamlined processes

• Monitoring and evaluation of the processes is essential in ensuring consistency in quality

• Overall time lines have been reduced by 35%; regulatory time lines and manufacturer’s have been reduced 26% and 47% respectively

• Shorter timelines will be recorded through monitoring of the process along six areas of the M&E framework
Acknowledgement

- TMDA management & staff particularly MRE Section
- EWG on MER & Technical Partners (WHO, Swissmedic, USP)
- EAC Secretariat
- AMRH development partners
- MCAZ

THANK YOU ... Questions??

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