



EAC MRH Programme

12 DEC 2019





GOAL

To improve access to safe, efficacious and good quality essential medicines for the treatment of diseases of economic importance within EAC region and beyond.





MRH PARTNERS

WHO & SWISSMEDIC

Technical Assistance (TA) to EAC Secretariat and Partner States NMRAs

NEPAD

Advocacy and political commitment in enactment of relevant policies and regulatory framework

WORLD BANK

Financial Management and oversight for the MRH Grant

BMGF- Provides Financial Support

PARTNER STATES





MRH MA

Harmonization process



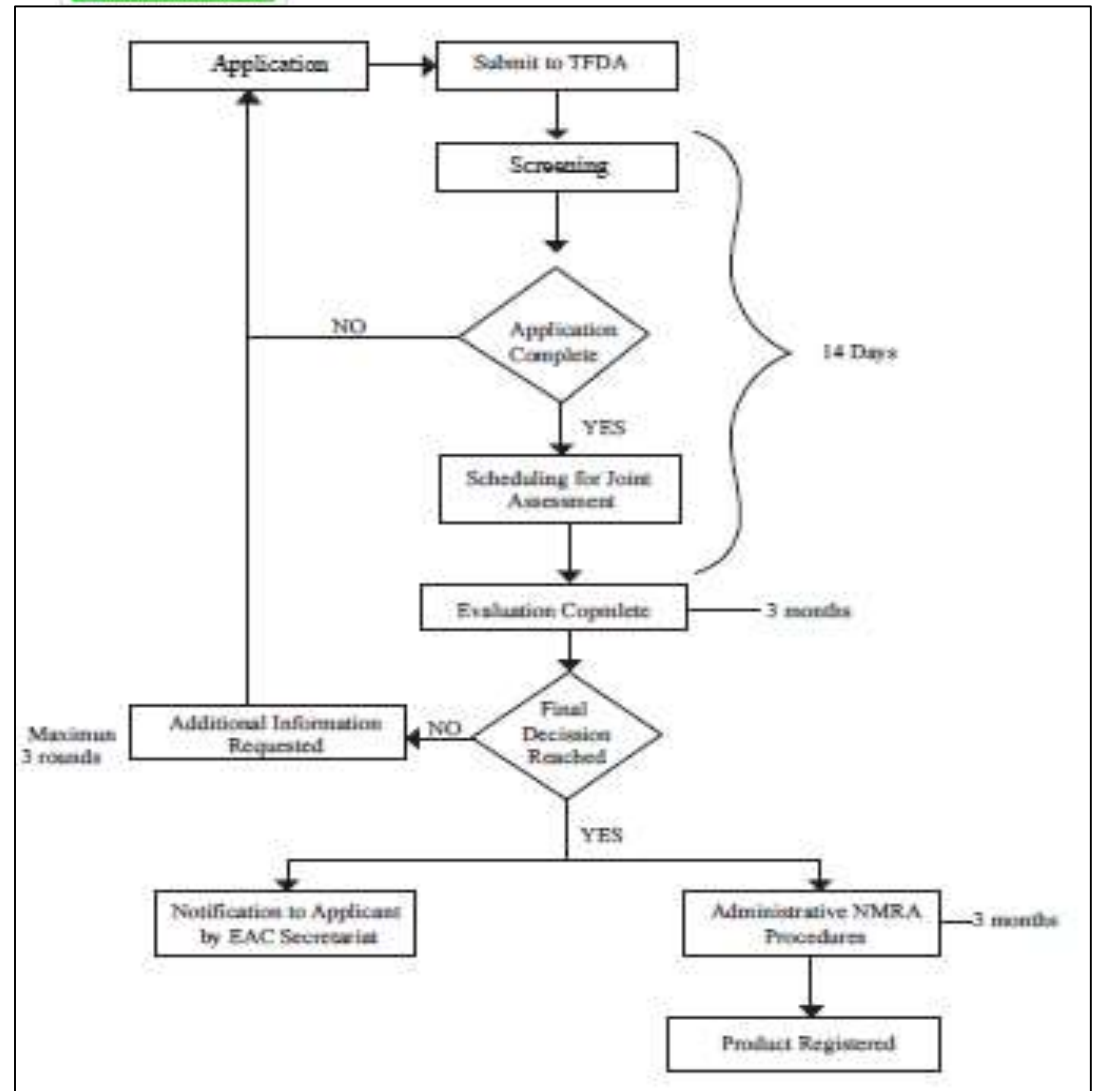
- Harmonized technical guidelines developed- 2012-2014
- Approved in Sep, 2019 by EAC Council of Ministers
- 2015 Adoption and domestication by EAC Partner States
- 1st EOI for MA issued in Nov, 2015 - reproductive health products included





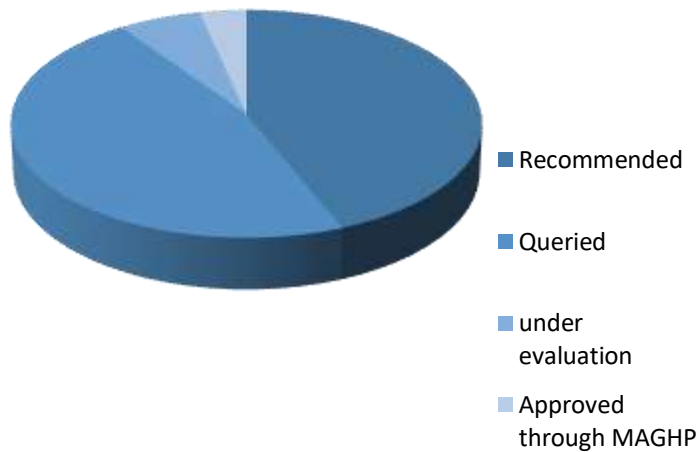
Joint assessment

Process Flow chart including timelines





JA PROGRESS



- Total applications: **106**
- Total assessed: **101**
- Total recommended: **50**
- Queried: **53**
- Under evaluation: **7**
(Distributed to Assessors)
- *Approved through MAGHP-4*





EAC-SWISSMEDIC COLLABORATION

2015

- Revision of existing harmonized guidelines on MER and GMP-2018
- Participation of swissmedic and WHO experts in JA sessions -for clinical and quality review of dossiers
- Training of EAC experts on MER and GMP
- Training on case/project management





MAGHP

EAC Engagement



Global-

- EAC is a member and participates at ICH and ICDRA (International Conference of Drug Regulatory Authorities) meetings
- EAC experts participates in WHO PQ assessment procedure

Regional

- Developed abridged guidelines to guide on the assessment of products already approved through WHO PQ collaborative procedure to fast track and reduce registration timeline- within 90 days
- Convene joint dossier assessment sessions -13 sessions
- Coordinates approval and registration of recommended medical products
- Capacity building of PS experts -participate in the WHO PQ program





MAGHP

PS Engagement



Global

- Participate in WHO PQ process

Regional and national

- Domestication of harmonized guidelines
- Participation in EAC-MRH joint medical product assessment and Good Manufacturing Practice Inspections
- Registration of the approved products
- Monitoring of Safety and quality of products granted MA
- Sharing of skills, experience, knowledge and expertise through twinning programs





CONCLUSION

Access of medicines is a collaborative process that require harmonized efforts



- WHO and Swiss medic-Technical Expertise
- EAC Experts-Technical expertise/capacity building
- PS- Commitment / Financial and technical Support
- EAC Sec-Staffing/Commitment, coordination/technical expertise/ capacity building
- Partners- financial/ Technical Commitment





One People, One Destiny
Asante