# EAST AFRICAN COMMUNITY JOINT ASSESSMENT PROCEDURE

The East African Community (EAC) Joint Assessment Procedure (JAP) is an initiative aimed at having joint assessment of applications and harmonized regulatory approvals in the region. The process is available to **any industry applicants** to register different types of pharmaceutical products across the EAC region through a single application.

The procedure also allows for fast track registration of certain medicines.

## WHY APPLY VIA THE EAC JOINT ASSESSMENT PROCEDURE

- Transparency, efficiency and predictability
- ► Single point of Contact in submission of dossiers
- Efficient administrative team for the management of applications and queries
- Only 1 submission to all EAC National Regulatory Agencies (NRAs) = access to minimum 2 markets and up to 5
- Final decision valid in all EAC Partner States NRAs
- Faster and harmonized regulatory approvals in the region
- Enhance timely access to medicinal products in EAC countries
- Reduction of cost for all parties









## **OVERVIEW OF THE PROCESS**

DAY 0 Application submission to Tanzania Medicines and **Medical Devices Authority**  **DAY 10** 

Screening and validation by TMDA. Verification of GMP status EXTRA 180 DAYS Joint GMP Inspection led by Uganda National Drug Authority (GMP lead) if physical inspection is necessary **DAY 45 DAY 65** Peer review Initial review

**DAY 90** 6 Review followed by Joint **Assessment Session** Send List Of Questions to applicant maximum 3 rounds Responses to List Of Questions

**DAY 270** 

Compile documents and send recommendations to **EAC Secretariat** 

(each round = 180 extra days)

**DAY 300** 

**DAY 360** 

Publication of Marketing Authorisations by all NRAs and EAC Secretariat.

Issuance of the final EAC

registration. Confirmation

letter is sent to applicant

Approval at National Level

and issuance of Marketing

authorisation certificates

within 90 days

recommendation for

### MORE INFORMATION

Do you have further questions?

Would you like to submit an application for a product through the EAC Joint Assessment Procedure?

Please reach out to the EAC Secretariat for further assistance.



**East African Community** One people, one destiny

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#### **ACTORS**

**APPLICANT** 

ALL NRAs

Tanzania Medicines and Medical Devices Authority (TMDA)

NRA 2

**EAC SECRETARIAT** 

Uganda NDA

 $^*$ Applicable fees for EAC Partner States NRAs are available upon request.