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**
1. Application submission to Tanzania Medicines and Medical Devices Authority

**Day 10**
2. Screening and validation by TMDA. Verification of GMP status

**Day 45**
3. Initial review

**Day 65**
4. Peer review

**Day 90**
5. Review followed by Joint Assessment Session
   - Maximum 3 rounds (each round = 180 extra days)
   - Send List Of Questions to applicant
   - Responses to List Of Questions

**Day 270**
6. Compile documents and send recommendations to EAC Secretariat

**Day 300**
7. Issuance of the final EAC recommendation for registration. Confirmation letter is sent to applicant

**Day 360**
8. Approval at National Level and issuance of Marketing authorisation certificates within 90 days
9. Publication of Marketing Authorisations by all NRAs and EAC Secretariat.

**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.

**Actors**

- **APPLICANT**
- **Tanzania Medicines and Medical Devices Authority (TMDA)**
- **Uganda NDA**
- **ALL NRAs**
- **NRA 1**
- **NRA 2**
- **EAC SECRETARIAT**

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