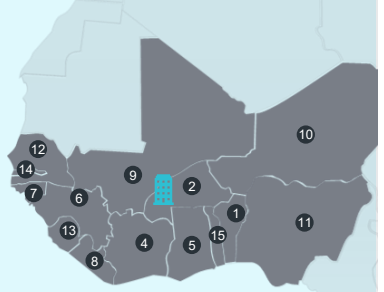
The ECOWAS Joint Assessment Procedure (ECOWAS JAP)

The **ECOWAS Joint Assessment Procedure (JAP)** is a collaborative initiative among 15 National Regulatory Agencies (NRAs) in West Africa that ensures harmonized and streamlined market authorization of medical products across the region.

Upon approval notification by the West African Health Organization (WAHO), the applicant has 2 years to apply to the 15 ECOWAS Member States that will grant marketing authorization within a maximum of 60 days.

1. Benin
2. Burkina Faso
3. Cape Verde
4. Côte d'Ivoire
5. Ghana
6. Guinea
7. Guinea-Bissau
8. Liberia
9. Mali
10. Niger
11. Nigeria
12. Senegal
13. Sierra Leone
14. The Gambia
15. Togo



ECOWAS Secretariat Headquarters

Key Features for Success

- Expression of Interest (EOI) all year round
- Pre-submission meetings
- Pre-admission screening and dossier validation
- Expert participation from across the region
- Joint evaluation with WHO, Swissmedic, and EMA (technical partners)

Objective

Increase access to and affordability of good quality, safe, and efficacious medicines

Through:
- Harmonized regulatory requirements
- Transparent and efficient regulatory processes

Timeline† (DAYS)

- **133** without queries
- **196*** including a single round of questions

**This timeline does not consider the time needed for applicants to reply to the comments and list of questions*

Scope of Products under the ECOWAS JAP

- WHO Essential Medicine List
- Programme Medicines
- Public Health Emergencies
- WHO Prequalified and Stringent Regulatory Authorities (SRAs) Approved†
- Life Saving Commodities
- Biological Products and Blood Products (Including Vaccines)
- WAHO Listed Medical Devices Covered in Calls for EOI
- Priority Medical Supplies Determined by WAHO

†For WHO Prequalified and Stringent Regulatory Authority (SRA) approved products the ECOWAS JAP procedure takes only 60 days.

ECOWAS JAP Process Flow

How the joint assessment procedure supports an efficient registration of medicinal products

ECOWAS-JAP Preliminary phase | ECOWAS-JAP Regular process | ECOWAS-JAP Decision-making | ECOWAS-JAP Step outcome | ECOWAS-JAP Extended timeline | National Market Authorization Procedure

Screening fee payment — *Evaluation fee payment*

START

- **STEP 1** Expressions of Interest (EOI)
- **STEP 2** Pre-submission meeting
- **STEP 3** Submission and dossier validation (screening)
- Letter of Deferral
- Letter of Acceptance

30 DAYS

14 DAYS

DAY 0
- **STEP 4** Dossier assignment for review

DAY 45
- **STEP 5** Phase I: Technical Evaluation — VIRTUAL
- Draft technical report and preliminary list of questions (LoQ#1)

DAY 66
- **STEP 6** Phase I: Joint Evaluation (by EWG & Technical Partners) — VIRTUAL or FACE-TO-FACE
- Outcome notification and list of questions (LoQ#1) delivery
- Endorsement and finalization of proposed technical report

APPROVAL

DAY 101
- **STEP 8** Phase II: Technical Evaluation — VIRTUAL
- Draft technical report 2 and, if applicable, preliminary list of questions (LoQ#2)

OPTIONAL
- **STEP 7** Joint GMP Inspection and Quality Control

Development of answers

DAY 138
- **STEP 9a** Phase II: Joint Evaluation (by EWG & Technical Partners) — VIRTUAL
- Endorsement and finalization of proposed technical report

APPROVAL

DAY 139
- **STEP A1** EWG member comments to applicant answers
- Outcome notification and list of questions (LoQ#2 or N) delivery

Development of answers

DAY 169
- **STEP A2**** Joint Evaluation (by EWG & Technical Partners)
- Draft technical report #N and, if applicable, list of questions (LoQ#N)

Additional questions

APPROVAL

DAY 152
- **STEP 9b** Development of the final report by EWG

FINAL REPORT

DAY 182
- **STEP 10** Report validation by WA-MRH Steering Committee

Beginning of NMAP

DAY 196 End of JAP
Recommendation by WAHO

Screening: *USD 500* *(as of March 2023)*

Evaluation fee: (as of March 2023)
- Applicants in the West Africa Region will pay USD 8,000
- Applicants in other regions of Africa will pay USD 10,000
- Applicants outside Africa will pay USD 12,000

Decision-makers
- EWG
- ECOWAS-JAP Steering Committee
- NRA Assessors
- Lead Coordinating Authority*
- Technical Partners

Actors involved
- Applicant
- ECOWAS-JAP Secretariat
- EWG Chairman

*On a rotational basis, one of the 15 NRAs acts as a Lead Coordinating Authority (LCA). As of March 2023, the Nigeria regulator serves as LCA.
If dossier is found unacceptable after **STEP A2, a re-submission will require an additional payment of 50% of the evaluation fee.

A win-win solution for the applicants and the NRAs:

- ✓ Transparency, efficiency and predictability
- ✓ Streamlined administrative procedures
- ✓ Single point of contact during product assessment
- ✓ Faster and harmonized regulatory approvals
- ✓ Timely access to any of the 15 ECOWAS Member State markets
- ✓ Use of reliance-based procedures

Tips for Success

- Attend pre-submission meeting
- Submit dossiers that meet regulatory requirements in ECOWAS CTD format
- Submit complete and timely responses to the LoQs

Abbreviations

CTD	Common Technical Document
ECOWAS	Economic Community of West African States
EMA	European Medicines Agency
EOI	Expression of Interest
EWG	Experts Working Group
GMP	Good Manufacturing Practice
LoQ	List of Questions
NMAP	National Market Authorization Procedure
NRA	National Regulatory Agency
WAHO	Western African Health Organization
WHO	World Health Organization

Useful resources

- ECOWAS JAP initiative portal
- ECOWAS JAP EOI portal
- Information on the WAHO Guidelines for GMP
- Information on the ECOWAS-WAHO eCTD & eSubmission
- African Medicines Regulatory Harmonization Programme

Contact information

WAHO - West African Health Organization
01 BP 153 Bobo-Dioulasso 01 / Burkina Faso
(226) 20 97 01 00 / (226) 20 97 57 75
(226) 20 97 57 72

https://www.wahooas.org/web-ooas/

wahooas@wahooas.org

IFPMA
http://www.ifpma.org/

https://waho-essmed.org/WAMRH

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