ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINE FOR EMERGENCY USE AUTHORIZATION OF VACCINES AND THERAPEUTICS FOR MARBURG VIRUS DISEASE

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GUIDELINE FOR EMERGENCY USE AUTHORIZATION OF VACCINES AND THERAPEUTICS FOR MARBURG VIRUS DISEASE

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Abbreviation

Abbreviation: Meaning

CMC: Chemistry, Manufacturing and Controls

CoA: Certificate of Analysis

DS: Drug Substance

DP: Drug Product

EFDA: Ethiopian Food and Drug Authority

EUA: Emergency Use Authorization

GMP: Good Manufacturing Practice

MARV: Marburg virus

MVD: Marburg Virus Disease

NRA: National Regulatory Authority

RMP: Risk Management Plan

RRA: Reference Regulatory Authority

SRA: Stringent Regulatory Authority

SmPC: Summary of Product Characteristics

PIL: Patient Information Leaflet

WHO: World Health Organization

EUL: Emergency Use Listing

1. Introduction

Marburg virus disease (MVD) is a severe hemorrhagic fever with case fatality rates that can exceed 80%. The disease is caused by Marburg virus (MARV), a filovirus closely related to Ebola virus. Outbreaks are rare but highly lethal and can spread rapidly in healthcare and community settings.

As of November 2025, no vaccine or specific therapeutic is fully licensed for MVD worldwide. Several candidate vaccines (e.g., Sabin ChAd3-MARV, IAVI rVSV-MARV, and others) and therapeutics (monoclonal antibodies, remdesivir, favipiravir) are in advanced development or have been used under compassionate/expanded access protocols during recent outbreaks (Rwanda 2024–2025, historical outbreaks in Africa).

The Ethiopian Food and Drug Authority (EFDA) plays a critical role in protecting public health while enabling rapid access to promising medical countermeasures during public health emergencies. In accordance with Article 20(5) of Food and Medicine Administration Proclamation No. 1112/2019, EFDA may grant a permit for importation or use of unregistered medicines in compelling circumstances, including outbreaks of dangerous communicable diseases.

This guideline establishes a risk-based Emergency Use Authorization (EUA) pathway for investigational vaccines and therapeutics intended for prevention or treatment of MVD when a public health emergency is declared by the Minister of Health or when the benefit–risk profile clearly favors immediate availability over waiting for full registration data.

The EUA is time-limited, conditional, and revocable, and requires specific post-authorization commitments from the applicant.

This guideline is effective immediately and will be revised as needed based on evolving scientific evidence and outbreak situation.

2. Scope

This guideline applies to applications submitted to EFDA for emergency use authorization of:

- ✓ Vaccines intended to prevent Marburg virus disease
- ✓ Therapeutics (small molecules or biologics) intended to treat Marburg virus disease

Products already granted WHO Emergency Use Listing (EUL) or approved/EUA by a Stringent Regulatory Authority (SRA) may follow an abbreviated/verification pathway.

3. General Considerations

- The assessment is risk-based and flexible. The level of data required is proportional to the severity of the emergency and the availability of alternative options.
- Positive benefit–risk balance must be demonstrated, even with incomplete datasets.
- Reliance on assessments by WHO-Prequalification, SRAs (FDA, EMA, etc.), or WHO EUL is strongly encouraged and will expedite review.
- Animal Rule (21 CFR 314.610/601.91 equivalent) data may be accepted as primary evidence of efficacy when human efficacy studies are not ethical or feasible.
- Rolling submissions are accepted.
- Review timeline target: 5–21 working days from completeness of dossier (or faster in active outbreak).
- Waived or significantly reduced application fees during declared emergencies.

4. Requirements for Information and Data for EUA Application

Applications shall be submitted in CTD format where possible, or in structured electronic format acceptable to EFDA via email. Critical modules may be submitted in English; labeling in Amharic/English.

4.1. Administrative Information

- Cover letter declaring intent for EUA for MVD and emergency context
- Application Form (Annex I)
- Letter of Commitment (Annex II) signed by CEO or equivalent
- Proof of payment (or waiver request)
- GMP certificate or inspection report (or commitment for inspection within 6 months)

- Authorization letter if applicant is not the manufacturer
- Evidence of WHO EUL application status or SRA decision (if applicable)

4.2. Product Information

- Proposed Summary of Product Characteristics (SmPC)
- Patient Information Leaflet (PIL) / Instructions for Use
- Labeling and packaging mock-ups (English)
- Risk Management Plan (RMP) – Ethiopian-specific version
- Pharmacovigilance system description and local responsible person contact

4.3 Chemistry, Manufacturing, and Controls (CMC) Information

4.3.1 Manufacturing and Facilities

- Description of manufacturing process and process controls (flow diagram)
- Manufacturer(s) name, address, and responsibilities
- GMP certificate issued by SRA/WHO-listed authority or recent inspection report ≤3 years
- If no GMP certificate → commitment to GMP inspection within 6–12 months post-EUA
- For vaccines: seed lot/master cell bank characterization, adventitious agent testing

4.3.2 Control of Drug Substance and Drug Product

- Specifications for release (DS and DP) with justified acceptance criteria
- Analytical procedures and validation (or development data for novel platforms)
- Batch analysis data (≥3 batches for vaccines; ≥1 commercial-scale or representative batch for therapeutics)
- Reference standards
- Container closure system and compatibility data
- For vaccines: potency assay description and preliminary validation

4.3.3. Stability Data

- Real-time and accelerated stability data available
- Minimum 6 months real-time data strongly preferred for vaccines
- Proposed shelf-life and storage conditions with commitment to ongoing stability studies
- Post-constitution stability (vaccines) or in-use stability (therapeutics)

4.3.4. Process Changes and Comparability

- Description of any process changes from clinical batches to proposed commercial
- Side-by-side comparability data (or plan) for critical quality attributes
- Commitment to provide comparability protocol and data post-EUA

4.4. Nonclinical Data

- Pharmacology: proof-of-concept in relevant animal models (NHP challenge studies preferred)
- Safety pharmacology and toxicology studies (repeat-dose in ≥2 species)
- Developmental and reproductive toxicity (DART) data or pregnancy registry commitment
- For vaccines: evidence of immune response correlating with protection in NHP
- For therapeutics: PK/PD in animal models, including NHP efficacy studies
- Animal Rule justification (if applicable) with description of natural history model concordance

4.5. Clinical Data and Safety & Effectiveness Information

4.5.1. Vaccines

- Phase 1/2 safety and immunogenicity data (preferred ≥100 participants)
- Phase 3 efficacy data if available; otherwise, strong immunogenicity data + NHP protection data
- Immunobridging justification if surrogate endpoint used

- Safety database lock and statistical analysis plan
- Minimum 2 months follow-up safety data post-final dose for most participants
- Special populations data (pregnant women, children, immunocompromised) if available
- Evidence of no vaccine-associated enhanced disease in animal models or human data

4.5.2. Therapeutics

- Phase 1/2 safety and PK data
- Phase 3 controlled data if available; otherwise, compassionate use/expanded access data acceptable
- Animal efficacy data under Animal Rule (survival benefit in NHP challenge studies)
- Clinical safety database ≥100–300 patients preferred
- Compassionate use data from recent outbreaks (Rwanda 2024–2025) highly valuable
- Special consideration given to remdesivir, MBP091 (monoclonal), and other candidates with existing safety packages

4.6. Risk Management Plan and Pharmacovigilance

- Detailed RMP including additional pharmacovigilance activities (registry, Phase 4 studies)
- Local safety monitoring plan with named qualified in Ethiopia
- Commitment to report all serious adverse events within 24 hours
- Distribution and use restricted to designated treatment centers during outbreaks

5. Review Process and Decision-Making

- Dossier screened for completeness within 1 working day
- Rolling review possible

- Expert Advisory Committee (including NDAC and other relevant experts in infectious disease, virology, vaccinology) may be consulted within 7 days
- Reliance pathway: WHO EUL or SRA EUA → verification review within 7–10 days
- Full assessment: target 21 days maximum
- Possible outcomes: Authorization / Authorization with conditions / Rejection
- Authorization valid for 12 months or until emergency ends (renewable)
- Public list of authorized products published on EFDA eRIS website.

6. Post-EUA Obligations and Monitoring

- Submit variations for significant changes
- Ongoing stability data every 6 months (if applicable)
- Monthly safety reports first 6 months, then quarterly as per EFDA pharmacovigilance guideline requirements
- Final clinical study reports within agreed timelines (if applicable)
- Phase 4 commitments (effectiveness, special populations)
- Immediate reporting of safety signals
- Revocation possible if benefit–risk becomes negative

7. Considerations for Continuing Clinical Trials Following EUA Issuance

Sponsors encouraged to continue randomized controlled trials. EUA issuance does not justify stopping placebo-controlled studies. Ethical mechanisms (e.g., crossover, early unblinding only for treatment failure) shall be implemented to preserve trial integrity while providing access.

8. References

1. The Food and Drug Administration Proclamation 1112/2019
2. WHO Emergency Use Listing Procedure (9 August 2022)
3. EFDA Guidance for Emergency Use Authorization of COVID-19 Vaccine (January 2021)
4. EFDA Guideline for Conditional Approval of Medicines (2023)
5. FDA Emergency Use Authorization guidance documents
6. WHO Target Product Profiles for Marburg vaccines and therapeutics

Annex I: Application Form for Emergency Use Authorization (EUA) of Marburg Virus Disease Products

ETHIOPIAN FOOD AND DRUG AUTHORITY (EFDA)

P.O. Box 5681, Addis Ababa, Ethiopia

A. Product Details

Proprietary name (trade name)			
Approved generic name(s) (use INN if any)			
Standard claimed (BP, Ph.Int, Ph. Eur., USP, IH, etc.)			
Strength(s) per dosage unit			
Dosage form			
Route of administration			
Shelf life (months)			
Storage condition			
Visual description			
Description of container closure			
Packaging and pack size			
Therapeutic category (e.g., vaccine for prevention, antiviral for treatment)			
Complete qualitative and quantitative composition (indicate per unit dosage form, e.g., 5ml per vial, etc.) Add/delete as many rows and columns as needed.	Composition	Strength	Function
Regulatory situation in other countries (Provide a list of countries in which this product has been granted a marketing authorization or EUA, and			

any restrictions on sale or distribution, e.g., withdrawn from the market, etc.)	
Reliance pathway (if applicable): WHO EUL status, SRA EUA/approval reference	

B. Details of Applicant

Name	
Business address	
Street number and postal address	
Telephone number	
Fax number	
E-mail and website address	
Contact person in the company	Name:
	Position:
	Postal address:
	Telephone number:
	Fax number:
	E-mail:
Details of Manufacturer (if different from above)	

C. Details on Active Pharmaceutical Ingredient(s) (API) or Antigen(s)

Name of manufacturer	
Street number and postal address	
Telephone number	
Fax number	
E-mail	

Name of the drug substance/antigen	
Retest period/Shelf Life	

D. Details on Local Agent (Representative) in Ethiopia

Name of local agent	
Sub-city and postal address	
Telephone number	
Fax number	
E-mail	
Contact person in the company	

CERTIFICATION BY A RESPONSIBLE PERSON IN THE APPLICANT COMPANY

I, the undersigned, certify that all the information in the accompanying documentation concerning an application for an emergency use authorization for:

Proprietary name (trade name): _____

Approved generic name(s) (INN): _____

Strength(s) per dosage unit: _____

Dosage form: _____

Applicant: _____

Manufacturer: _____

... is correct and true and reflects the total information available.

Signature: _____

Name: _____

Position in company (print or type): _____

Date: _____

Annex II: Commitment Letter Template

[Company Letterhead]

[Date]

Director General

Ethiopian Food and Drug Authority (EFDA)

P.O. Box 5681

Addis Ababa, Ethiopia

Subject: Commitment Letter for Emergency Use Authorization (EUA) of [Product Name] for Marburg Virus Disease

Dear Director General,

We, [Company Name], represented by [Name and Position of Authorized Signatory], hereby commit to the following obligations in support of the Emergency Use Authorization (EUA) application for [Product Name] (INN: [Generic Name]), intended for [prevention/treatment/post-exposure prophylaxis] of Marburg virus disease (MVD):

1. Data Submission and Updates: We will provide all required data in CTD format, including rolling submissions of ongoing clinical trial results, stability data, and manufacturing updates. We commit to submitting ongoing or final Phase 3/4 study reports whenever available post-EUA.

2. Pharmacovigilance and Safety Monitoring: We will implement an Ethiopia-specific Risk Management Plan (RMP), including active surveillance, pregnancy registry, and effectiveness studies. All serious adverse events will be reported to EFDA within 24 hours, with monthly safety summaries for the first 6 months and quarterly thereafter.

3. Manufacturing and Quality Assurance: We commit to GMP compliance, with allowance for EFDA inspection within 6–12 months post-EUA. Any process changes will be notified as variations, with comparability data provided.

4. Post-EUA Obligations: We will continue clinical trials to generate data for full registration, including long-term safety and efficacy (e.g., evaluating for enhanced disease). We agree to restricted distribution to designated MVD centers during the emergency.

5. Revocation and Termination: We acknowledge that this EUA is conditional and time-limited (12 months or until emergency ends), and may be revoked if benefit–risk changes.

6. Ethical and Legal Compliance: We confirm compliance with Ethiopian laws, WHO guidelines, and international ethical standards. Informed consent will be required for all recipients.

This commitment is binding and ensures the product's safe and effective use in Ethiopia's public health emergency.

Sincerely,

[Authorized Signature]

[Name]

[Position]

[Company Name]

[Contact Information]

CC:

[Local Representative in Ethiopia] [if any]