



ZAMBIA MEDICINES REGULATORY AUTHORITY

IMPLEMENTATION OF THE MEMORANDUM OF UNDERSTANDING BETWEEN THE EGYPTIAN DRUG AUTHORITY (EDA) AND THE ZAMBIA MEDICINES REGULATORY AUTHORITY (ZAMRA)

Summary of the Procedure

1

ELIGIBILITY.CRITERIA

- ❖ Product MUST be registered with EDA and manufactured in Egypt



2

REQUIREMENTS

- ❖ Signed cover letter & ZAMRA Application Form
- ❖ Quality Information Summary (QIS) endorsed by the EDA
- ❖ Submission of CTD dossier approved by the EDA
- ❖ Product samples, Labelling & Information in English
- ❖ Valid cGMP Certificate from the EDA
- ❖ Proof of Payment of Prescribed Fees (see attached Annex)



3

EXPRESSION.OF.INTEREST

- ❖ Send your Expression of Interest and completed Quality Information Summary (QIS) to: export@edaegypt.gov.eg and foreign.affairs@edaegypt.gov.eg
- ❖ EDA will verify documents through: ma.reliance@zamra.co.zm



4

REVIEW.PROCESS

- ❖ Risk-benefit assessment conducted according to the Recognition Framework established by EDA and ZAMRA



5

DECISION.™ .NOTIFICATION

- ❖ Applicant notified of decision within 30 days



Annex 1: Prescribed Application Fees for Grant of Marketing Authorisation as Per Statutory Instrument No. 308 of 2016 (Fees Regulations)

Application type	Application fee
1. Application for Grant of Marketing Authorisation of Human Medicines Imported as Finished Products	
(a) New Chemical Entity	US\$ 2,800
(b) Generic Medicine	US\$ 2,000
(c) Biological product	US\$ 2,800
(d) Abridged applications	US\$ 1,700
2. Application for Grant of Marketing Authorisation of Human Medicines Imported as Finished Products	
(a) New Chemical Entity	US\$ 2,100
(b) Generic Medicine	US\$ 1,750
(c) Biological product	US\$ 2,100
(d) Abridged applications	US\$ 1,550
3. Application for Grant of Marketing Authorisation of Allied Substances Imported as Finished Products	
Allied substances (for Human or Animal Use)	US\$ 500

Annex 2: Link for the ZAMRA application Form for the Grant of Marketing Authorisation

<https://www.zamra.co.zm/wp-content/uploads/2025/06/APPLICATION-FOR-GRANT-OF-MARKETING-AUTHORISATION-OF-COSMETICS-FOR-USE-IN-ZAMBIA.pdf>

Annex 3: Link for the Quality Information Summary (QIS) Template

<https://www.zamra.co.zm/wp-content/uploads/2025/07/ZAMRA-QIS.pdf>