MEDICINES CONTROL AGENCY

54 Kairaba Avenue, P.O. Box 3162, The Gambia, Phone: +220 4380632, email: info@mca.gm, www.mca.gm

Annex I of the Guideline for Emergency Use Authorisation: Request for Consideration for an EUA

Product under Development ☐ **Approved product** ☐

MCA Product Registration Number, if applicable .....

INN or Generic Name .....
Route of Administration .....
Dosage form / strength .....

MANUFACTURER

Name. .....
Premises/Business Address .....
Tel ..... Email ..... Website .....

APPLICANT

Name .....
Address + Full Contact Details .....
Tel ..... Email ..... Website .....

STATUS OF APPLICANT

Manufacturer ☐	Marketing Authorisation Holder ☐	Pharmaceutical Company ☐
Importer ☐	National Representative ☐	Ministry ☐
Other ☐ (please specify)		

a) Description of the product and its intended use

b) Identification and explanation of unmet need(s)

c) Description of the product's international registration / Marketing Authorisation (MA) status

d) List of each manufacturing site and the GMP status of the manufacturer

e) Identification of any approved alternative products (including availability and adequacy for the proposed use)

f) Available safety and efficacy information for the product

g) Discussion of risks and benefits

h) Description of information for healthcare providers/authorised dispensers and recipients of the product including feasibility of providing such information

i) Information on chemistry, manufacturing, and controls

j) Please provide the Certificate of Analysis of the EUA medicine

k) Instructions for use as EUA product

l) Proposed labelling including batch number, manufacturing date and expiry date

m) Name of reference substance/material (if applicable)

DECLARATION:

I, the undersigned certify that the information in the accompanying documentation concerning the request for consideration for an emergency use authorization of the product indicated herein is true and reflects the total information available.

I also agree that I am obliged to comply with the requirements of the Agency related to the stated product at any time in the future.

Signature of Applicant: ..... Date: .....