



## **MEDICINES CONTROL AGENCY**

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia,  
Website: [www.mca.gm](http://www.mca.gm); E-mail: [info@mca.gm](mailto:info@mca.gm)

### **Format of Submissions**

The MCA expects material to be provided in a reviewable form in Common Technical Document (CTD) format and sufficiently complete to permit substantive evaluation.

Submissions shall be made in an electronic format:

1. One (1) copy saved on a USB flash drive together with an application letter addressed to the Executive Director of the MCA.
2. MCA recommends that the submission begins with a section that describes the contents and organisation of the included materials. The applicant or anyone with a right of reference may refer to data or other information previously submitted to the MCA in a marketing authorisation (registration) application.
3. The MCA expects material to be provided in a reviewable form and sufficiently complete to permit substantive evaluation. Nevertheless, the MCA recognises that, in rapidly developing or unexpected emergency circumstances, or when previously unanticipated or unavailable medicinal countermeasures are being considered, it may not be possible for an entity to provide all of the requested data or to provide it in the format suggested in a timely manner. In such circumstances, the MCA will accept and evaluate the request for consideration for an EUA. based on data in the form an entity is able to submit. Missing data and poor documentation may lead to a request for additional information and thus, may cause a delay in the decision-making process or even the decision not to authorise emergency use of the medicine.
4. The address for submission of a request for consideration for an EUA. is:  
Medicines Control Agency  
Off Bertil Harding Highway  
Kotu East  
Kanifing Municipality  
P.O. Box 3162  
Serekunda, The Gambia