MEDICINES CONTROL AGENCY

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

Recommended Safety Data

In general:

The amount and type(s) of safety data that MCA recommends to be submitted as part of a request for consideration for an EUA. will differ depending upon a number of factors, including whether the product is approved for another indication and, in the case of an unapproved product, the product's stage of development. MCA will interpret safety information in light of the seriousness of the clinical condition, alternative therapies (if any), and the specific circumstances of the emergency. MCA strongly encourages any person or entity with an EUA medicine to discuss with the MCA at the earliest possible time (even before a determination of actual or potential emergency) the nature and type of safety data that might be.

a) Unapproved uses of approved products

If the new indication uses a similar dose, duration, route of administration, and/or mechanism of action (as appropriate given the nature of the product), and the intended patient population is similar to that for which the product is approved, MCA recommends references of the approved application if the requester submitted the approved application or has a right of reference. If the new use poses a different risk to the patient population (e.g., suggesting the possibility of increased toxicity), the MCA recommends that information from relevant in vitro studies, animal toxicology studies, and (if available) human clinical data and experience be provided to support such a use.

b) Unapproved products

The range of available data for such products will differ widely. MCA recommends that any request for consideration for an EUA includes available preclinical testing data, such as in vitro and animal toxicology data. The MCA also strongly encourages that safety information in humans from clinical trials and individual patient experience should be provided, if available. MCA further recommends that data submitted in the request attempt to link the likely patient exposure to any relevant existing preclinical data. Similarly, where animal data are used, sufficient information should be provided to link the results of these data to expected exposures related to the proposed use in humans. Any information on safety associated with use in humans of this or related compounds or devices of a similar design should be also submitted.

c) Approved products by another NMRA or reference institution

For data requirements for this approach reference is made to the "Guideline on Reliance".