MEDICINES CONTROL AGENCY

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia,
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Discussion of Risks and Benefits

Products to be used in PHE, in response to recognised health threats, may provide particularly important benefits, therefore higher risks related to the absence of some data may be acceptable. In such cases an E.U.A. can be granted also if preclinical or pharmaceutical data are not comprehensive.

MCA recommends that a request for consideration for an EUA includes a discussion of the medicine's known and potential risks and benefits, which includes a synthesis of the data and information requested above, including:

1. Measures taken to mitigate risks or optimise benefits (how the anticipated benefits to public health in the context of immediate availability outweigh the risks (also taking into account the as yet missing information)).
2. Limitations, uncertainty, and data gaps (risks inherent in the fact that additional data are still required).
3. A description of circumstances, if any, under which the product should not be used (e.g., contraindications).
4. Benefits to public health of the immediate availability of the medicinal product on the market.