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

Details on required information for submission

In general:

MCA recommends that the request for consideration includes the following types of data, as appropriate and to the extent feasible given the exigencies of the circumstances:

1. Well-organised study reports that provide a complete assessment and analysis of available safety and effectiveness data and an interpretation of the findings. If final study reports are not yet available, any available interim study reports should be provided and clearly identified as such.
2. Any relevant statistical analyses and source data for clinical studies, nonclinical laboratory studies, and any animal studies demonstrating safety and efficacy of the product in the treatment of the underlying disease or condition or a closely related disease or condition, such as case report tabulations for key studies; case report forms for all patients who died during the clinical studies and for all persons who did not complete the study due to an adverse event, regardless of causality; relevant reports in the published literature; and notarised English translations of source materials in a language other than English.