

MEDICINES CONTROL AGENCY

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

Pre-submission meeting request form

EUA ASSESSMENTS

Please complete each section of this application form and submit electronically as a Word document to the MCA. Attachments in electronic format that are 8MB or less in size can be sent by email with this completed application form, including a proposed agenda for the meeting. Attachments in electronic format that are larger than 8MB should be submitted on a USB flash drive, or else be printed and sent by courier or surface mail to the Medicines Control Agency, Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia.

| Applicant (name of manufac- turer) | | | | |
|--|--------------------|--|--|--|
| Contact person responsible for this application | | | | |
| Contact person's job title/position | | | | |
| Contact details - postal address: | Phone, fax, email: | | | |
| Meeting Details | | | | |
| Type of meeting requested: | | | | |
| □ Face-to-face □ Teleconference □ Videoconference | | | | |
| Brief statement of the intended dossier (INN/strength/dosage form), and the expected date for submission to MCA for E.U.A. | | | | |
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| Specific objectives/outcomes expected from the meeting | | | | |
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| Preliminary proposed agenda including estimated time needed for each agenda item (up to a maximum of 3 hours for the entire meeting) and designated speaker(s) | | | | |
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| List of specific questions: | | | | |

| List of all individuals (including titles) who will attend the proposed meeting from the applicant's organisation and/or consultants (up to a maxi- mum of 10 proposed participants). | 1. | | | |
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| Proposed date(s) and time(s) for the meeting | | | | |
| Additional information is attached: | | □ Yes | 🗆 No | |
| Additional information will be forwarded sepa- rately: | | □ Yes | □ No | |
| Completed by: | | Date: | | |