Annex to Letter of Intent (pre-submission request form)

Note: This form must be fully completed and submitted as an annex to the Pre-submission Request Form (LINK) only when the scope of the request is "centralised procedure – Intent to submit a MAA"

Active substance(s): <active substance>

EMA Product Number: <Product Number>
General guidance

Purpose

The purpose of this document is for the applicant to submit information related to their intended Marketing Authorisation Application (MAA) or EU-M4All\(^1\) submission.

Reminder

By submitting the Pre-submission Request Form – Centralised Procedure – Intent to submit a MAA and this annex (also known collectively as “Letter of Intent”) the Applicant is requesting EMA and the National Agencies to commit resources to the assessment of the dossier. As such, it is imperative that the indicated intended submission date is accurate.

Changes to the submission date may trigger a change of Rapporteurs if these have already been assigned. If the Applicant wishes to retain the Rapporteurs, the new submission date might need to be agreed with them. The Applicant will be asked to justify any changes to the intended submission date.

Guidance Text

Guidance on how to complete the sections below is provided in green text. Please remove this text before submitting this form. Click on Ctrl-Alt-Shift-S to view the “styles” window. Select “Guidance text” and click on the icon on the right, chose “Select all XXX instances,” press the “Delete” key on the keyboard.

\(^1\) EU-M4all’ was previously known as the Article 58 procedure, as the legal basis is Article 58 of Regulation (EC) No 726/2004.
Background on Development Programme

Clinical studies

Please provide information on the clinical studies completed or ongoing which will be included in the dossier by completing the table below (in line with eCTD m5.2 tabular listing).

Table 1 – Ongoing and completed clinical studies

<table>
<thead>
<tr>
<th>Study Identifier (link to study register)</th>
<th>Enrolment status (ongoing/completed) current number of subjects/ total number of subjects needed</th>
<th>Study phase, design &amp; Control type</th>
<th>Test product(s); Dosage regimen; Route of administration and duration of treatment/follow-up</th>
<th>Study population</th>
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Last LPLV and DBL dates

Please indicate the primary completion date (e.g., last-patient-last-visit) and the corresponding database lock date (actual or projected) for the last study data point to be included in the application. Please also indicate whether there is any other information (e.g., batch analysis data, GMP certificate, CE marking) or factors (e.g., difficulties in study conduct, lower than expected number of events, planned analyses etc.) which are on critical path or might affect the preparation of the dossier and therefore the submission date.

<Text>

Scientific advice

Please provide information on any relevant centralised scientific advice received by completing the table below.

Table 2 – Relevant centralised scientific advice

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic (quality/ nonclinical/ clinical)</th>
<th>Reference number</th>
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Quality dossier

Please indicate whether there has been a Quality-by-Design approach to the quality dossier. If so, please include details.
Modelling and simulation

*Please indicate whether the dossier includes extensive Pharmacokinetic modelling and/or simulations, in particular if these are relied upon for the main indication claims. If modelling and/or simulation are included, please include details.*

<Not applicable><Text>

Medical device/companion diagnostic

*Please indicate whether the product/indication is associated with the use of a medical device or companion diagnostic. If this is the case, please provide information on Notified Bodies opinions, where relevant.*

<Not applicable><Text>

Complex clinical trial methodology

*Please indicate whether your submission includes complex clinical trial methodologies, such as umbrella or basket trials, adaptive designs, multiple post-hoc analyses, use of external control, indirect comparisons, or real-world evidence, etc.*

<Not applicable><Text>

Regulatory information

*Please indicate whether you intend to apply for accelerated assessment, conditional MA, or MA under exceptional circumstances. For accelerated assessment, if applicable, please state the intended submission date of the request for accelerated assessment.*

<Text>

Planned lifecycle of the product

*Please indicate which line extensions, indication extensions and important variations (e.g., changes to manufacturing processes or sites) are planned following the potential approval of the MA, together with the expected submission date.*

**Table 3 – Planned lifecycle**

<table>
<thead>
<tr>
<th>Lifecycle type (Line Ext. or Ext. of Indication)</th>
<th>Brief description</th>
<th>Expected submission date (quarter and year)</th>
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