EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance on the revised Pre-Submission Interactions model

1. Purpose and scope

This document outlines the high-level process for applicants, rapporteurs and EMA for pre-submission interactions (PSI) under the revised PSI model during the voluntary pilot phase.

The aim of this new model is to introduce earlier and more comprehensive dialogue between all stakeholders to strengthen interactions. Expected outcomes are to optimise submission readiness, identify "premature" applications and assessment issues, and support alignment on submission timelines. The initiative introduces shared ownership between the applicant, rapporteurs and EMA on submission timing, as well as enhanced planning visibility.

The pilot is planned to run for 18 months, and applicants planning marketing authorisation application (MAA) submissions between **February 2027 and September 2028** are eligible to participate. The applicant, rapporteurs and EMA shall jointly agree on the applications to be included in the pilot.

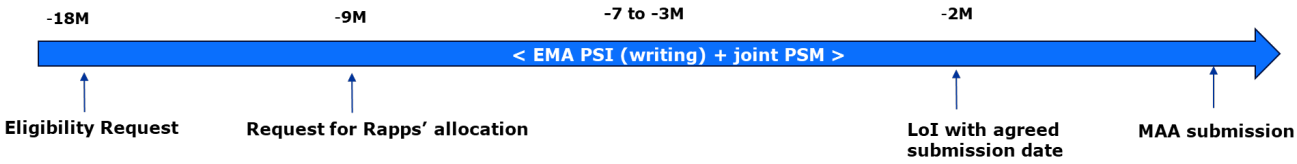
For the scope of this guidance PSI is understood as ranging from request for appointment of the rapporteurs to the submission of the MAA i.e. excluding the eligibility step.

2. Overview of the revised PSI process

This section provides a high-level process summary of the revised PSI model.

- The eligibility request by applicants remains unchanged and takes place 18 months prior to the intended MAA submission date.
- The request for rapporteurs' allocation should be submitted 9 months prior to the intended MAA submission date.
- PSI comprise two elements: a written interaction with EMA, followed by a joint pre-submission meeting between the applicant, CHMP, PRAC or CAT rapporteur(s) and EMA.
- After the joint PSM, applicants are requested to submit their Letter of Intent (LoI), reflecting the agreed MAA submission date, at the latest 2 months before the initially intended MAA submission date.

The flowchart below provides a visual representation of this high-level process.



3. Step-by-Step Process

3.1. Request for rapporteurs' allocation

The applicants shall submit the request for rapporteurs allocation 9 months before the intended submission date along with the up-to-date status overview attached as an email sent to rapporteurshippilot@ema.europa.eu. By submitting the request, the applicant is asking the EMA and the National Competent Authorities to commit resources for the assessment of the dossier. Hence, it is imperative that this request is received in timely manner before of the intended submission date. Please see the published submission dates for Rapporteurship assignment (section 2.5, Pre-authorisation guidance | European Medicines Agency (EMA))

3.2. EMA pre-submission interactions

Upon allocation of the rapporteurs, applicants should plan for the EMA pre-submissions interaction in writing with EMA so they occur ideally at least 5 months prior to the intended MAA submission date.

Applicants should use the revised EMA PSI form (see link in web announcement) and follow the instructions provided therein. Feedback from the EMA product team will be provided in writing within 3 weeks of submission.

The EMA PSI form has been revised to include enhanced guidance for applicants and questions on procedural, compliance and regulatory affairs aspects. This enables the EMA to identify potential topics for applicants to address and to better support effective validation guidance and evaluation of the application.

The EMA PSI form needs to be filled in electronically and sent to EMA via the IRIS portal. The background documents listed in the pre-submission interactions form should be provided at the same time.

3.3. Joint pre-submission meeting with Applicant, Rapporteurs and EMA

Following rapporteurs' allocation, applicants should plan the joint PSM to take place at the latest 3 months prior to the intended MAA submission date.

Applicants are responsible for organising the joint PSM. Early engagement is encouraged (i.e. by the time the EMA PSI is submitted), including initiating contact with both Rapporteurs and EMA in a single email, to facilitate agreement on the most suitable meeting date.

Applicants should use the EUSTART list (see link in web announcement) and follow the instructions provided therein). This document aims to support participants for the joint PSM and to identify issues for discussion and allows the rapporteurs to determine the application maturity. Applicants should cover all points raised in this form, when relevant to their application, in their briefing package.

The applicant should also address any open major issues raised in the context of the EMA PSI for EMA check.

The briefing package should be submitted, via Eudralink, to all participants 3 weeks prior the meeting. The supporting presentation for the meeting should be provided at least a week before the meeting. The duration of presentation should not exceed 20 minutes in order to allow sufficient time for the discussion.

The meeting starts with a welcome and introductory remarks, followed by the applicant's presentation and the subsequent discussion. The meeting is chaired by the rapporteur. The applicant should be prepared to address all dossier-related issues.

During the meeting, the rapporteurs shall present their feedback on the questions/topics raised and express their views on the degree of submission readiness and maturity of the application, and on whether the initially intended submission date can be agreed upon. Further exchanges may take place later on, where appropriate, to support alignment on the submission date. The rapporteurs may, where appropriate, seek input from the CHMP. Such instances are expected to be exceptional, and the applicant should be provided with the CHMP's feedback as soon as possible

After the meeting, the applicant provides the meeting minutes within two weeks, including conclusion on dossier maturity and the anticipated submission date.

3.4. Submission of the Letter of Intent

Following the joint PSM, applicants are requested to submit their Letter of Intent (LoI), reflecting the agreed MAA submission date, at the latest 2 months before the initially intended MAA submission date.

The LoI should be submitted to EMA via the IRIS portal.

4. Submission readiness and application maturity

A submission may be considered insufficiently mature where the available data package is not yet adequate to support a robust benefit-risk assessment and efficient conduct of the procedure within the applicable timelines. This may include, for example, significant missing, incomplete data; reliance on interim results that do not yet provide a sufficiently comprehensive view of the benefit-risk balance; unresolved major quality, manufacturing or compliance issues; absence of key supportive analyses or justifications; or anticipated major objections likely to require extended clock-stops or generation of additional data not feasible within the standard procedural timelines. Consideration may also be given to the overall readiness and completeness of the dossier, including whether pending data are expected during the procedure that can impact the assessment outcome.

Applicants are encouraged to assess the overall maturity and completeness of the application prior to confirmation of the intended MAA submission date. In particular, applicants should consider whether the data package and dossier readiness are expected to support an efficient assessment within the applicable procedural timelines. To support preparation for the joint PSM and evaluation of submission readiness, applicants are asked to use the EUSTART questions document.

The following aspects may be considered when evaluating submission readiness at the time of submission:

- Availability and completeness of pivotal clinical, non-clinical and quality data;
- Extent to which the available evidence is complete, robust, relevant, and consistent to support the proposed indication and benefit-risk balance
- Reliance on interim or evolving datasets expected to materially impact the assessment outcome;
- Known quality, manufacturing or compliance issues;

- Availability of key supportive analyses, validations or justifications;
- Anticipated need for substantial additional data generation during the procedure;
- Alignment with previous scientific advice or regulatory interactions, where applicable.

5. Conclusion

This guidance describes the revised PSI model to be implemented during the pilot phase. The model aims to strengthen early dialogue, improve submission readiness and enhance predictability of submission timelines through shared planning between Applicants, Rapporteurs and EMA. The implementation of the pilot will be monitored through defined KPIs. A report based on the analysis of these KPIs will be prepared to support evaluation of the pilot and inform potential refinements of the model.