EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pre-submission interactions

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- EMA introduced improvements to the format of pre-submission interactions:
  - ✓ Increased dialogue – earlier (ahead of meeting), more focused and tailored to the application.
  - ✓ Provide high quality support in a timely manner.
  - ➢ Aim to better support applicants in the finalisation of their MA application.

- Improvements live on 22 November 2021 with a transition period until 31 December 2021.
- During this period, Applicants have the option to follow either of the models and should discuss with their Product Lead (PL) the best option. From January 2022 onward only the new model will apply.

Pre-submission interactions (1/2)

1. Applicants send their questions using the pre-submission meeting request form renamed: "MAA pre-submission interactions form" together with the necessary background documents

2. Simplified package:
   - Briefing document with updated guidance
   - Documents no longer required: Module 2 overviews, protocol & SAP for pivotal studies; overviews of pharmacology studies and paediatric studies and ERA.

3. Consolidated written responses prepared by the EMA product team will be circulated by the Product Lead to the Applicant within 3 weeks from the receipt of the questions via Eudralink.

Pre-submission interactions (2/2)

1. Upon receipt of the EMA's response Applicants can request a meeting (teleconference) with the EMA product team, through the Product Lead, to seek further clarifications. Selected product team members will attend based on the topics requiring discussion.

2. When complex applications are identified, in addition to written responses, EMA will suggest to organise a pre-submission meeting (teleconference) with relevant EMA product team members. Examples include concern with the legal basis chosen, ATMPs, a request for AA, request for CMA or MA under exceptional circumstances, PRIME products etc.

- Applicants are encouraged to meet with their appointed Rapporteurs at national level to present and discuss their upcoming MA applications.

- The PL should be informed by the applicant when such meetings take place and be invited to join the discussion via TC.

- In case an EMA pre-submission meeting has been suggested, a joint meeting with the Rapporteur(s) could be proposed. EMA will address the identified issues as part of this joint meeting.

Documents

Updated Form

[Marketing Authorisation Application (MAA) Pre-submission interactions form]

Updated Q&A

[2.09 on "How are marketing authorisation application pre-submission interactions structured at the EMA?]

Conclusion

- Streamlined interactions between EMA and applicants:
  - 1st written feedback within 3 weeks
  - Possibility of follow-up meeting.

- Allow EMA to identify complex applications and communicate accordingly with applicants for the finalisation of their upcoming MAA.

- Invite industry to review experience after 1 year to discuss further opportunities for improvements.

Any questions?

Further information

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