EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA experience on pre-submission interactions for initial marketing authorisation applications

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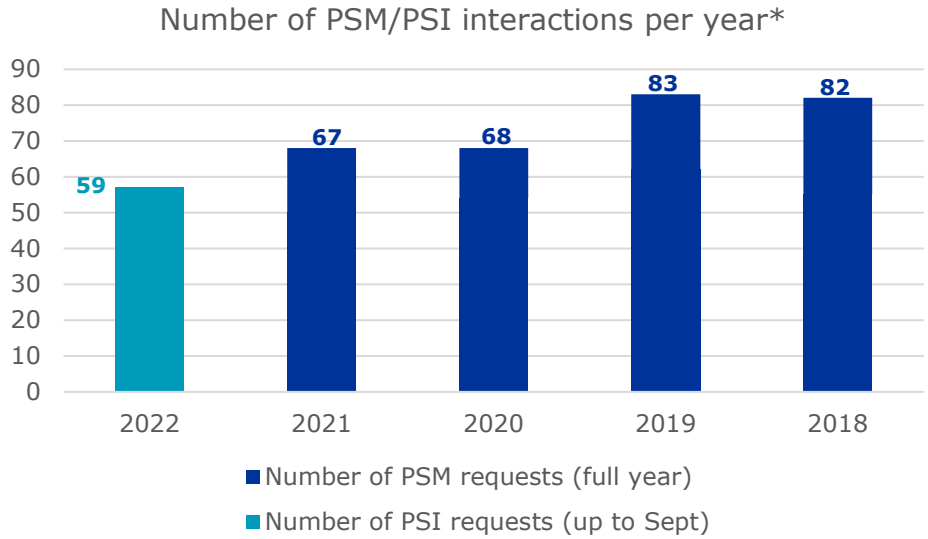
Pre-submission interactions

- In November 2021, EMA introduced **improvements to the pre-submission phase** by reshaping the format and timing of the pre-submission interactions.
- **Main change: written feedback** to applicants within 3 weeks after receiving the briefing document and annexes.
- **Possibility for follow-up TC** upon applicants or EMA request when clarifying questions remain.
- **With the new format:**
  - ✓ **Quicker responses** to applicant (3 weeks instead of at least 6 weeks).
  - ✓ **Less documents** requested (e.g. overviews, SAP, ERA no longer required.)
  - ✓ **Increased dialogue** & **earlier** than before
  - ✓ **When TC become necessary:** allow for a more **focussed dialogue** on identified issues or complex applications

Revision of pre-authorisation guidance

- **Pre-authorisation guidance | European Medicines Agency (europa.eu) (Q.2.9)** has been updated to:
  - reflect the format of the new process and,
  - the list of documents to be prepared by applicants.
- **No change** to pre-submission meeting with (co-)rapporteurs and assessment teams:
  - Applicants are encouraged to meet with their Rapporteurs at national level to discuss their upcoming MAA.
  - PL should be informed by the applicant and be invited to join the discussion.
  - In case an EMA pre-submission meeting takes place, a joint meeting with the Rapporteurs could be proposed. EMA will address the identified issues as part of this joint meeting.

Number of pre-submission meeting/ interaction requests



Observations:

- From Jan to Sept 2022, **59 PSI requests** were received.
- This is **similar** to the number of PSM requests received in **previous years up to Sept (cut-off)** (50 in 2021, 54 in 2020, 62 in 2019 and 55 in 2018 up to Sept).
- Fewer PSM requests in 2020-2021 compared to 2018-2019 (could be attributed to COVID-19 pandemic?)

PSM: pre-submission meeting
PSI: pre-submission interaction
* Exclude Covid-19 related procedures

Timing of written responses

Timing of written responses (Jan- Sept 22)

Time to respond	% (n=59)
< 3 weeks	54% (32/59)
< 1 month	75% (44/59)
< 2 months	93% (55/59)
< 3 months	100% (59/59)

- **54%** of the written responses were provided within the 3 weeks deadline window.
- **100% of responses** were given in less than 3 months.
- Time to respond ranged from **9 days to 77 days**.
- Main reason for delays: **internal consultation** needed before finalisation of the consolidated responses.
- Room for improvement on the timing but overall, feedback is provided earlier than in previous process (PSM were taking at least 6 weeks to be organised).

EMA pre-submission meetings following writing responses

- From January to Sept 2022: no follow-up meetings were considered needed following receipt of the EMA written responses,
- Except, **one PSM** was organised upon the request of EMA:
  - ✓ It was **1 hour TC** focussing on identified **issues** that **could raise major objections** during the evaluation.
  - ✓ Issues raised were related to quality aspects and new medical device regulation.
  - ✓ It was a joint meeting with the Rapporteurs/ assessors.
- When applicable, issues identified by EMA are also followed-up in the Rapporteurs' PSMs.
- Few cases where applicants were encouraged to come for PSI but considered not needed by applicants. Issue at time of validation.

EMA experience after 9 months

- **Similar number** of pre-submission interactions **requests** with new format compared with previous years: new process did not impact the number of requests.
- Above half of the written responses were given < 3 weeks and 100% in < 2.5 months. Overall, responses provided quicker to applicants. Room for improvement on the timing of responses.
- **One follow-up meeting** requested by EMA
  - After written responses allowed a **more focussed discussion** on specific issues with relevant product team members, industry participants and Rapporteurs.
- Internal actions taken: trainings, active follow-up, internal guidance updated to improve consistency.
- EMA will continue to monitor and discuss further opportunity for improvements

Any questions?

Further information

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