CHMP early dialogue with healthcare professional organisations

Latest updates, one-year report, and EPAR discussion

HCPWP meeting

Presented by Cécile Henrot on 03 July 2024
Public and Stakeholders Engagement Department

Revised input template

HEALTHCARE PROFESSIONAL EXPERIENCE OF:

indication

Please include below any aspects that are of particular importance to healthcare professionals, such as information on:

- the standard of care or available treatments and to what extent they cover the intended indication;
- the treatment duration; and, if in your view, the duration needs to be optimised;
- any possible therapeutic/unmet medical needs;
- what benefits you would hope for in new medicines; as well as what level of side-effects you would consider manageable for patients;
- considerations for pregnant people/people of child-bearing potential, where applicable.

Please also mention any aspects about the condition or its treatment that you feel are not well-understood or not sufficiently considered.

Please include anything else you feel is important for EMA to know. Please try to keep your main points to 1-2 pages; if necessary, include more details in an appendix.

REMINDER:
Early dialogue does **NOT** aim to collect positions on the medicinal product under assessment

Clarification on input (and organisation name) sharing

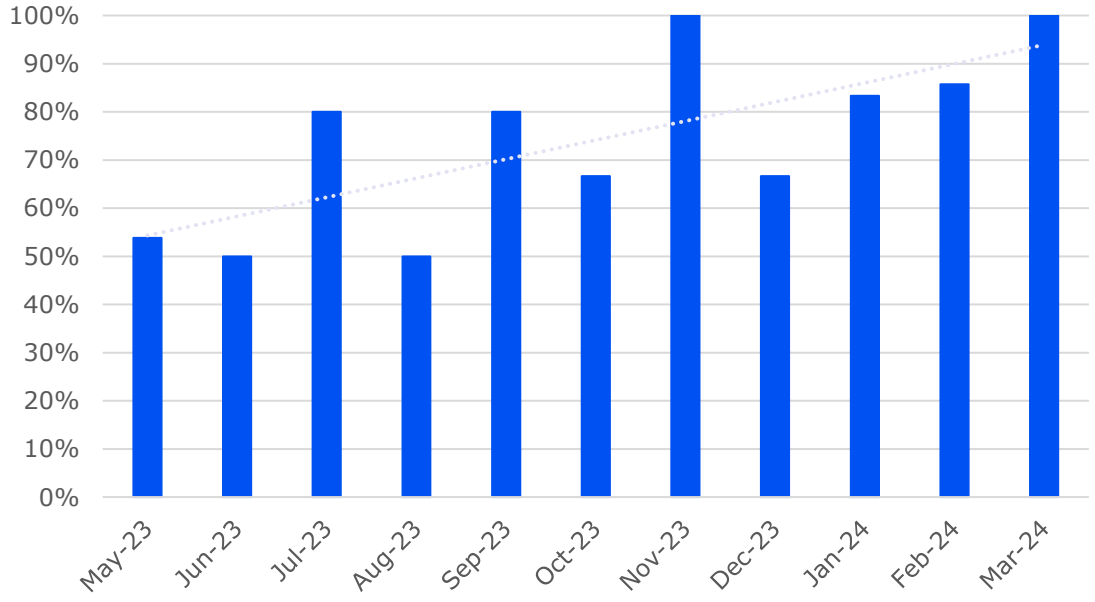
- Systematically shared with CHMP (and other relevant EMA committees, working parties and expert groups)
- Systematically shared with pharmaceutical company who submitted the marketing authorisation application
- **May be shared with another pharmaceutical company** for an application with the same indication + in the frame of an Access to Document request
  - For similar indication, EMA will endeavour to contact organisations to proactively ask whether the input can be shared and should be modified
  - **Please keep this in mind however when providing input**
- Goal is to reflect input in the assessment report that will be made public at the end of the procedure *(see last slide)*

Figures for the first year

Month/year of start of evaluation	Number of products selected for consultation	Number of HCPOs contacted	Number of inputs received
May 2023	7	13	**7**
June 2023	2	4	**2**
July 2023	3	5	**4**
August 2023	6	10	**5**
September 2023	4	10	**8**
October 2023	6	9	**6**
November 2023	2	3	**3**
December 2023	4	6	**4**
January 2024	3	6	**5**
February 2024	4	7	**6**
March 2024	3	4	**4**
April 2024*	0	0	N/A

**There is no start date in April for initial, full (non-accelerated) marketing authorisation applications.*

Percentage of inputs received vs inputs requested from HCP organisations



Published information

- CHMP early contact with patient and healthcare professional organisations: process and FAQs
- New question **5.1.13** in pre-authorisation guidance

Next steps

- One-year report to be published (see next slide)
- Update of process/FAQs
- Continuously learn from each other, raise awareness and update each other

One-year report structure

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Date
EMA/225343/2024
Stakeholders & Communication Division

Early dialogue with healthcare professional organisations for marketing authorisation applications: 1-year report

- Background/rationale
- Purpose and methodology
- Outcome:
  - % inputs received *vs* inputs requested (see slide 4)
  - Distribution per therapeutic area
  - Content of input
  - % inputs reflected in assessment documents
- Discussion of results
- Conclusion and next steps

Discussion on proposal for EPAR

Proposal to consult organisations when European Public Assessment Report (EPAR) is being prepared

What would you prefer to see in the EPAR?

1) Harmonised text:
   - Stating that patient and HCP organisations have been consulted in the context of this evaluation and input has been received
   - This could include the names of the organisations consulted
2) A contextualised summary of the input received that can be reviewed by the organisations prior to finalisation?

Any questions?

Further information

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