EMA
EUROPEAN MEDICINES AGENCY

PROMS
A Joint Global Initiative

Update on Patient Experience Data (PED)

15th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

28 November 2025

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Public and Stakeholders Engagement Department

Disclaimer

The presenter does not have any conflict of interests.

EMA's Action Plan on PED – Priorities

Overall EU strategy and approach

- Agree overall approach on PED with the Network
- List of priorities
- Monitor implementation
- Network expert group

Regulatory guidance with stakeholder input

- **Reflection paper & Stakeholder consultation**
- PCOs/HCPs - populating EMA data catalogues
- PCOs/HCPs -Data Quality Framework
- **Therapeutic area priorities**

Improve alignment, data quality and methodologies

- Support ICH guidelines
- Mapping EU and international initiatives
- Support HTA/payer contribution to reflection paper
- Workshops on qualification, registries
- Ongoing projects

Increase transparency

- Inventory of PED use cases – scientific publications
- Update of CHMP AR template
- Exploring update of medicine overview
- Exploring update of OMAR template
- Link to AI coordination group

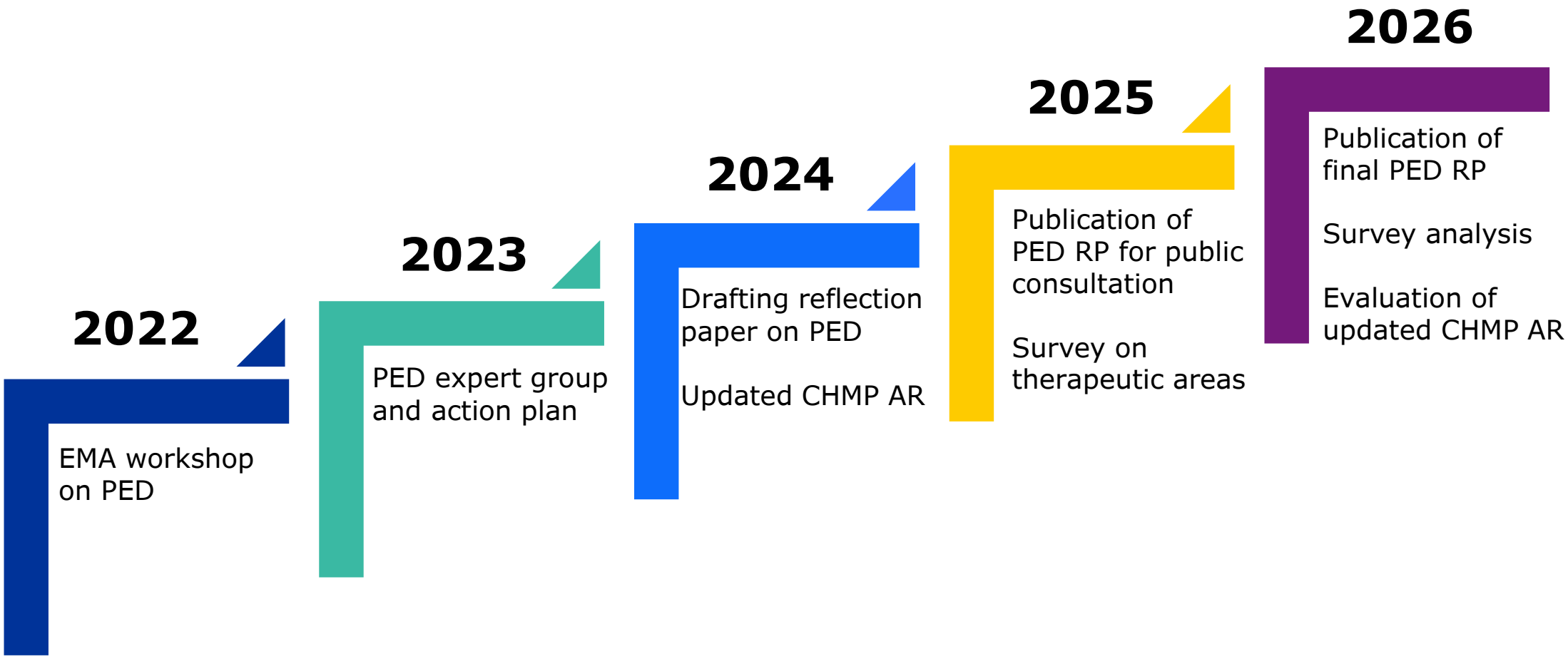
RWE and digitalisation

- Involvement of PCOs in Big Data
- Proof of concept studies
- Literature review of use of PED in non-interventional studies
- PED data sources in data catalogue
- Learnings from ongoing SMA study

Training and resources

- Collaborating experts
- EU Network training centre
- Coordinate stakeholder requests
- Overview of projects on PED with EMA involvement

Progress overview



Scope and key aspects of reflection paper

The reflection paper has been published on 29 September 2025:

- A path to better include patients' perspectives in the regulation of medicines | European Medicines Agency (EMA)
- Patient experience data (PED) reflection paper | European Medicines Agency (EMA)

Public consultation is open until **31 January 2026**

The RP is a **framework for discussion** or clarification particularly in areas where scientific knowledge is fast evolving or regulatory experience is limited

It describes **general principles** – it is not a methodological guidance.

It is **complementary to ICH** guidance work

It encourages **systematic consideration of PED** in medicine development programmes and regulatory submissions.

Target audience:

- medicine developers,
- regulators,
- Researchers, and
- patient groups who generate, collect and review PED

Reflection paper timelines

CHMP & PRAC adoption of draft
Sep 2025

Launch public consultation
29 September 2025

End public consultation
31 January 2026

Implementation comments
February-March 2026

CHMP & PRAC adoption of final text
Q2 2026

Publication of reflection paper
Q2 2026

Survey on the use of PED in different therapeutic areas

Objectives

- ✓ To gain a clear view on key stakeholders' experiences with the use of PED across all therapeutic areas
- ✓ To allow for comparative analysis between the different stakeholders' views and the different therapeutic areas.
- ✓ To identify potential gaps and unmet needs and further develop PED

Timelines: launched on 22 September, closed on **19 October 2025**

Respondents:

- 26 responses from Industry,
- 75 from patients,
- 21 from NCA-HTA,
- and 111 from HCP-academia

Results to be communicated in 2026 either through industry organisations or in the form of a published report

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Thank you

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https://www.ema.europa.eu/en/patient-experience-data-ped-reflection-paper

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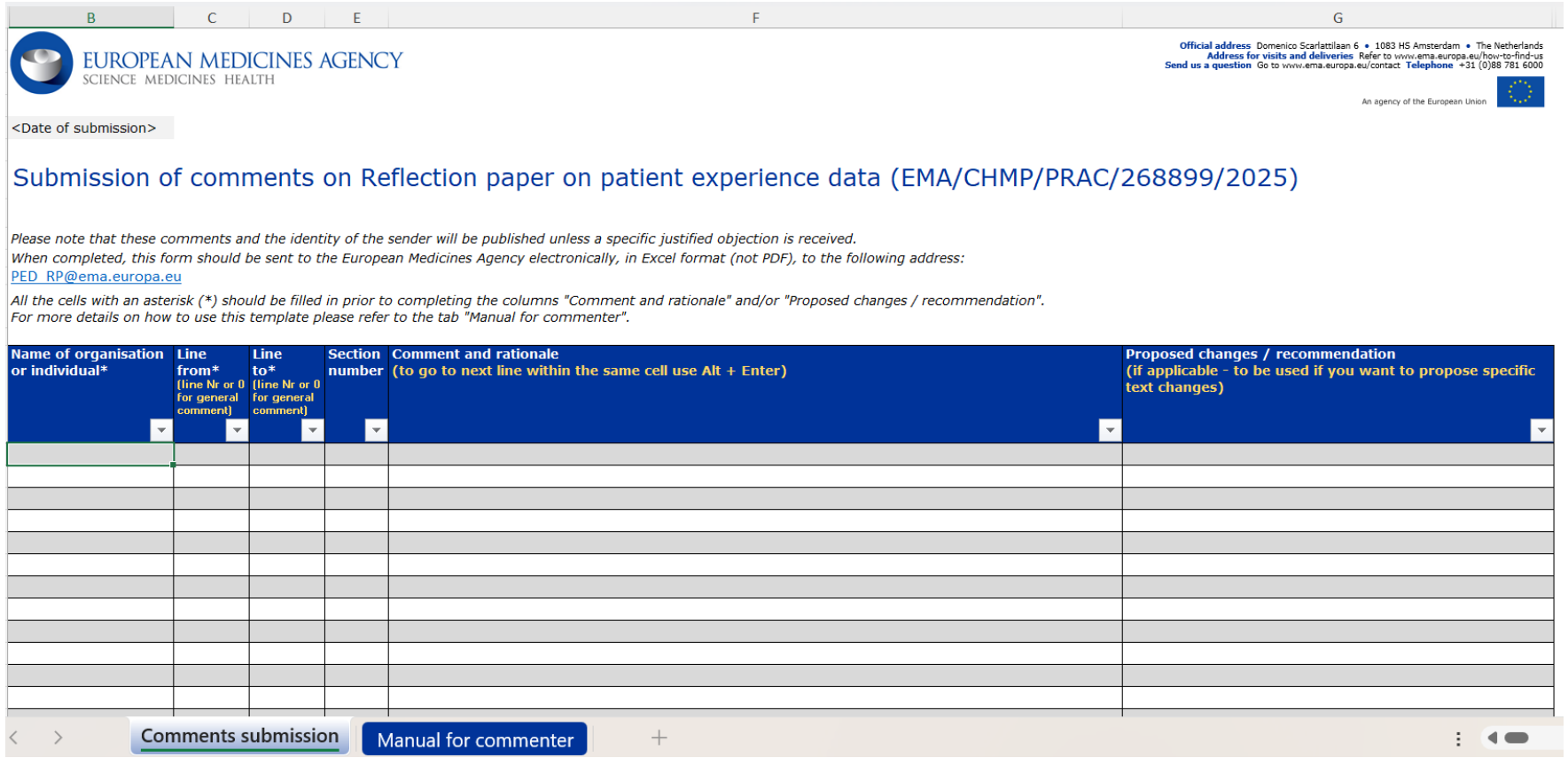
Template to comment on the Reflection paper



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<Date of submission>

Submission of comments on Reflection paper on patient experience data (EMA/CHMP/PRAC/268899/2025)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.
When completed, this form should be sent to the European Medicines Agency electronically, in Excel format (not PDF), to the following address:
PED_RP@ema.europa.eu
All the cells with an asterisk (*) should be filled in prior to completing the columns "Comment and rationale" and/or "Proposed changes / recommendation".
For more details on how to use this template please refer to the tab "Manual for commenter".

Name of organisation or individual*	Line from* (line Nr or 0 for general comment)	Line to* (line Nr or 0 for general comment)	Section number	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes)

Comments submission | Manual for commenter

https://www.ema.europa.eu/en/documents/template-form/submission-comments-reflection-paper-patient-experience-data-ema-chmp-prac-268899-2025_en.xlsx

The template for submitting comments during the public consultation is provided in **Excel**.

It is user-friendly, features expandable cells for ease of input and it includes a user manual.

Conclusions

- The EU Network is progressing several initiatives on PED
  - ✓ A reflection paper has been published for a 4-month public consultation closing on **31 January 2026**
- The reflection paper discusses types and sources of PED, general principles and elaborates on the use and value of PED across the medicine lifecycle
  - ✓ In addition to well-established ways to collect PED (e.g. PROs, PPS) data obtained through patient engagement activities are also an important contributor to the totality of evidence
- It is complementary to ICH work on patient focused drug development guidelines
- PED can inform medicine development and regulatory submissions, by providing patient insights that can be valuable for the assessment of marketing authorisation applications, as well as in the post-marketing setting
- Stakeholders are therefore encouraged to embed PED across all stages of medicine development
  - ✓ This can be achieved by liaising early with EMA through scientific advice/qualification of novel methodologies, to enable case-by-case discussions on specific development plans and regulatory submissions