EUROPEAN MEDICINES AGENCY

Update on EMA’s work on Patient Experience Data

ISG - 30 September 2025

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Relevance of PED

- Patient Experience Data (PED) is data reflecting patients' experience **without input or interpretation by others** (PROs, patient preferences, data from patient engagement activities).

- **Patients' views or preferences** on medicines or living with a condition is particularly important for many medicines, such as cancer medicines, where quality of life may matter most to patients than more established endpoints (e.g. overall survival).

- Collection of PED using reliable and validated methodologies **can contribute to benefit/risk evaluation** to complement primary or secondary endpoints

- In particular, PROs can contribute to decision-making in **cases when "harder endpoints" have not reached maturity** by the cut-off point.

- In the post authorisation phase, PED can be collected **as part of RWD (e.g. in registries) to generate supportive evidence.**

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 groups

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 update

2022

EMA workshop on PED

2023

PED expert group and action plan

2024

Drafting PED reflection paper*

Update CHMP AR

2025

Publication of PED RP for public consultation

Survey on therapeutic areas

2026

Publication of final PED RP

Survey analysis

Evaluation of updated CHMP AR

* Draft prepared by experts from CHMP, PRAC, PCWP, HCPWP, SAWP, MWP, ONCWP, RIWP, CVSWP, CNSWP, IDWP, VWP, NDSG, COMP, CAT, PDCO, CMDh, ETF and CTCG

EU Network expert drafting group for PED reflection paper

Multidisciplinary drafting group set up with experts from the **EU Network**

Covering expertise within each Committee/working party

Committee/experts	Examples of areas covered
CHMP	All aspects of benefit-risk assessment
PRAC	ADR reporting, preference for risk minimisation activities
COMP	Rare disease/orphan medicines/ major contribution to patient care for significant benefit
PDCO	Paediatric aspects (e.g formulation)
CAT	Advanced therapies aspects
Working parties: Oncology, Methodology, Scientific Advice, Network Data Steering Group Patients, Consumers and healthcare professionals' representatives	Specific aspects to each working party

Key aspects of reflection paper

It 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.

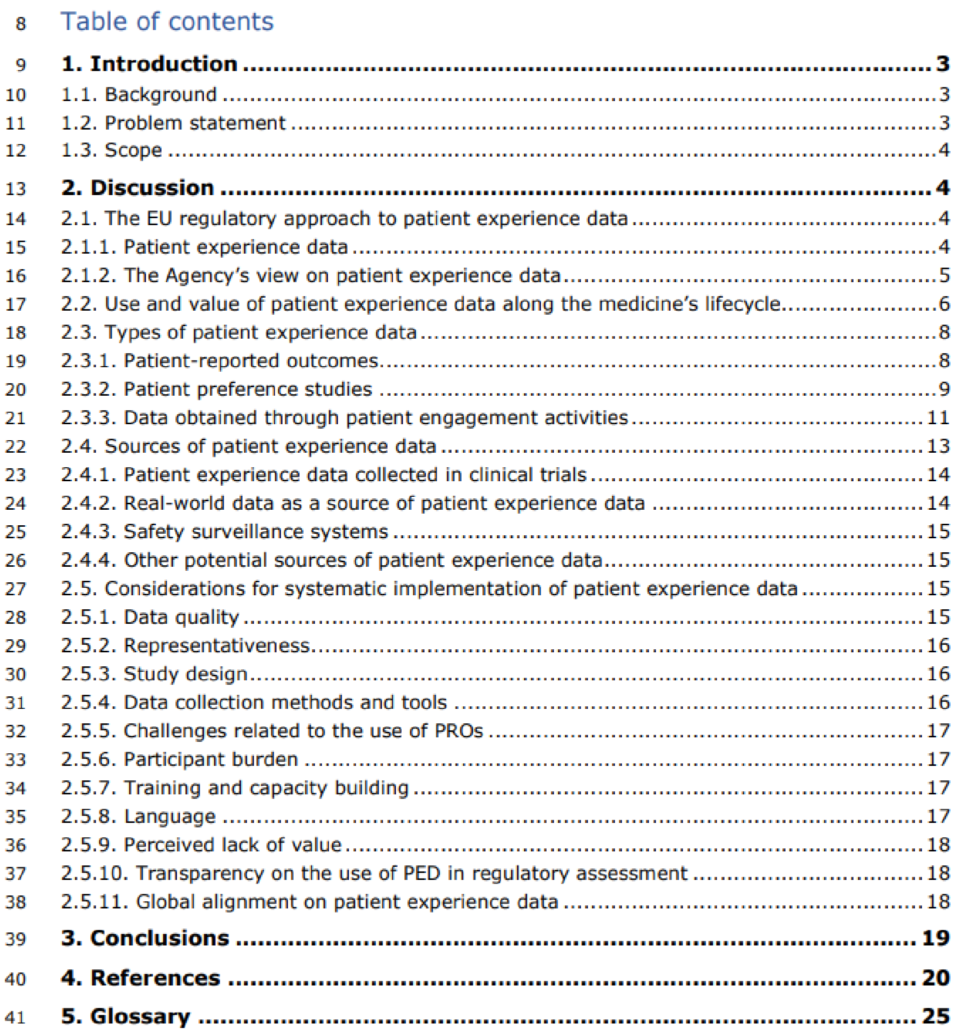
The reflection paper has been published on 29 September 2025:

- 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

Elements of the reflection paper

- Introduction, Problem Statement and Scope
- The EU regulatory approach to PED
  - Scientific advice and qualification, Innovation Task Force, academia support
- Use and value of PED along the medicine's lifecycle
- Types and Sources of PED
  - Clinical trials (PROs, PPS), patient engagement, real-world data, safety surveillance systems, other potential sources
- Considerations for systematic implementation



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Scientific advice and qualification of novel methodologies

The EU approach is to encourage companies to liaise early with regulators during scientific advice or qualification to discuss best way to generate and collect PED and have a case-by-case discussion on their specific development plans

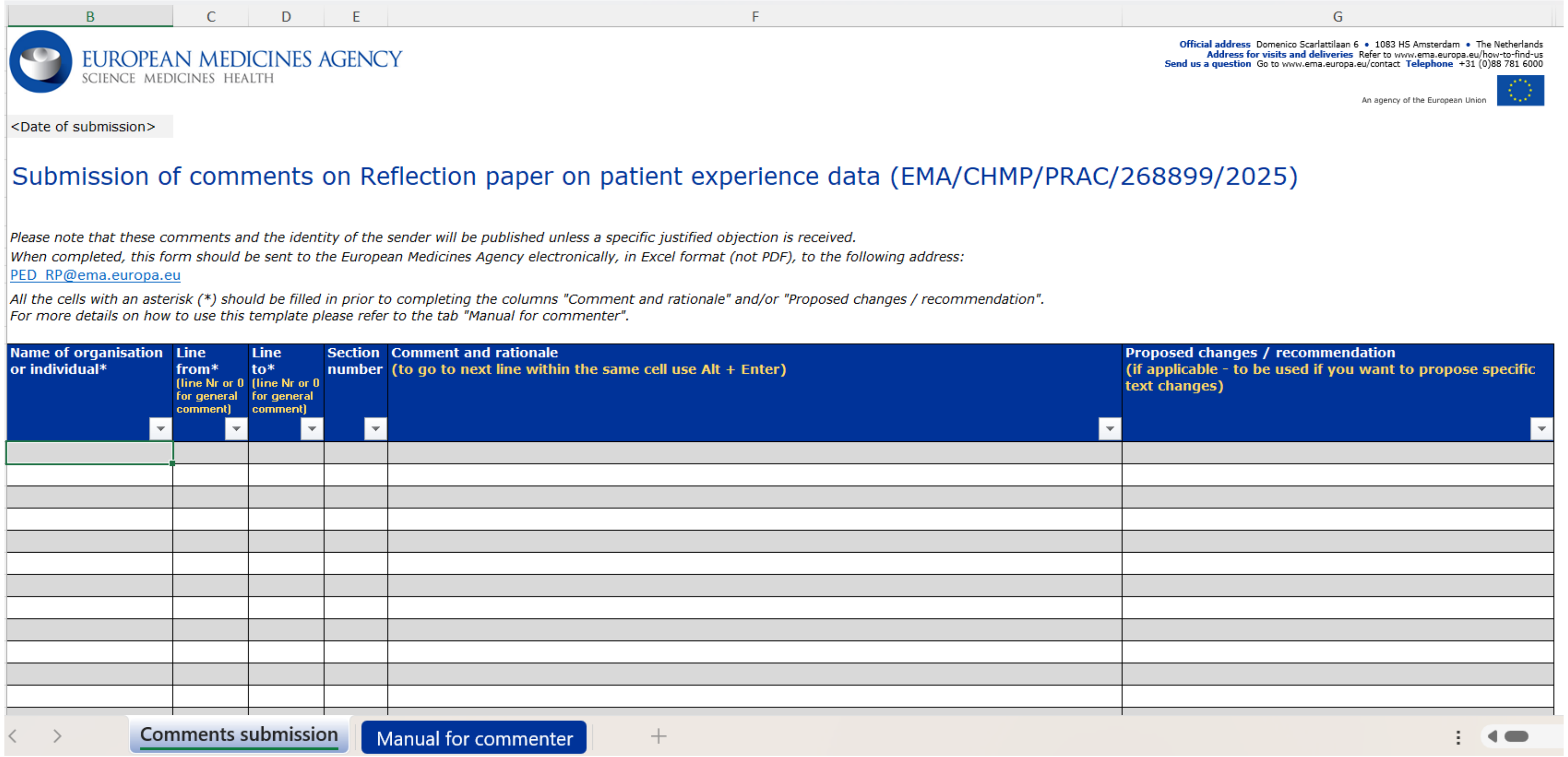
Scientific Advice

- Developer presents plans to develop a medicine and identifies questions and possible solutions
- EMA gives advice on developer’s proposals
- Scientific advice can be provided on any PED scientific question (e.g. collection PED in clinical trials)

Qualification of novel methodologies

- Opinion on the acceptability of a specific use of a PED collection method, such as use of a novel PRO
- Advice on protocols and methods intended to develop a novel method with the aim of moving towards qualification

Template to comment on the Reflection paper



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An agency of the European Union

<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)

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.

PED RP timelines

CHMP & PRAC adoption of draft
Sep 2025

Launch public consultation
end 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 identify potential gaps and unmet needs
- ✓ 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

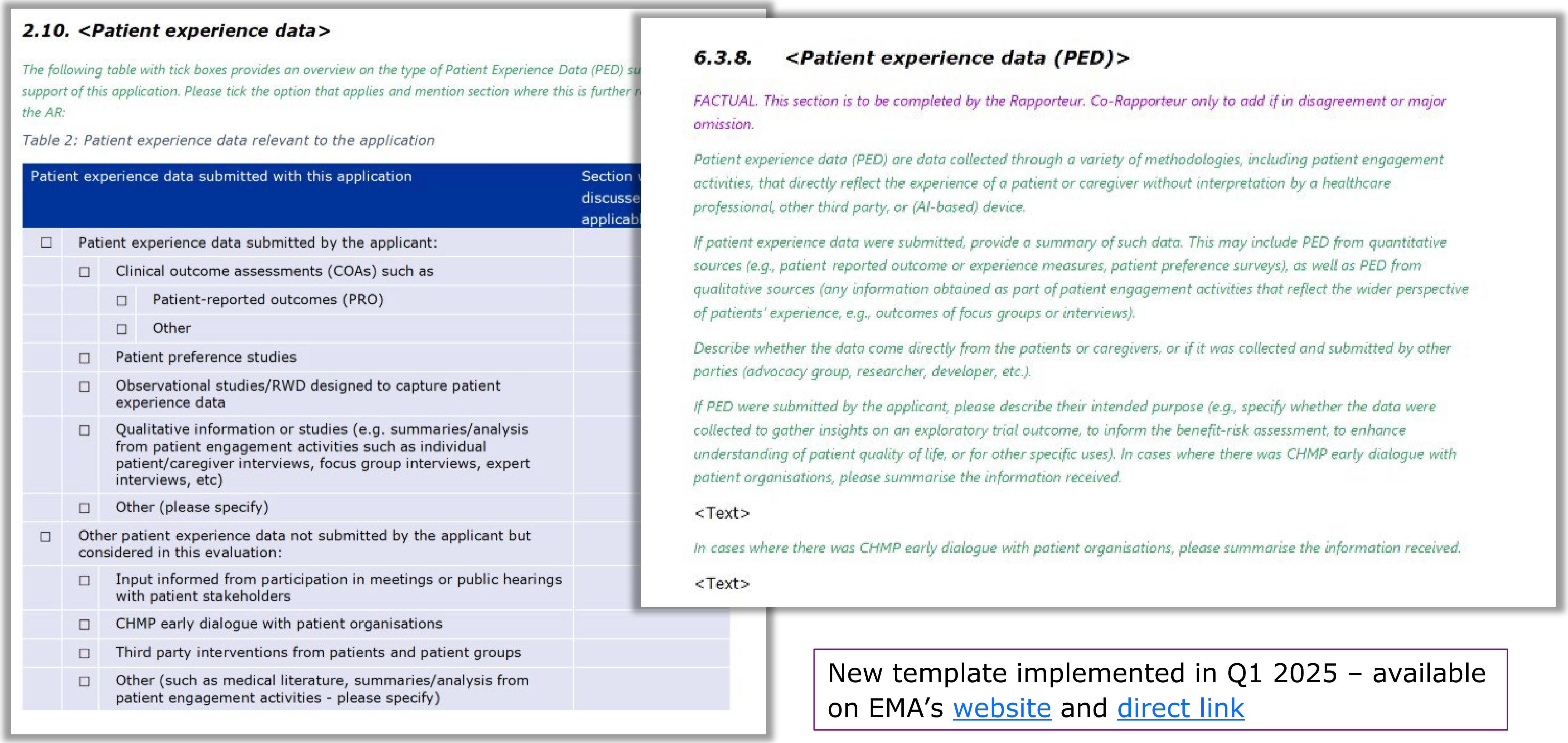
Participants :

Four tailored surveys for

- patient representatives and individual patients and carers,
- healthcare professionals and academic researchers,
- assessors (NCA and HTA),
- and industry: https://ec.europa.eu/eusurvey/runner/PEDsurvey_Industry_Final

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

Transparency on PED – Dedicated sections



2.10. <Patient experience data>

The following table with tick boxes provides an overview on the type of Patient Experience Data (PED) su support of this application. Please tick the option that applies and mention section where this is further r the AR:

Table 2: Patient experience data relevant to the application

Patient experience data submitted with this application				Section w discusse applicab
☐	Patient experience data submitted by the applicant:			
	☐	Clinical outcome assessments (COAs) such as		
		☐	Patient-reported outcomes (PRO)	
		☐	Other	
	☐	Patient preference studies		
	☐	Observational studies/RWD designed to capture patient experience data		
	☐	Qualitative information or studies (e.g. summaries/analysis from patient engagement activities such as individual patient/caregiver interviews, focus group interviews, expert interviews, etc)		
	☐	Other (please specify)		
☐	Other patient experience data not submitted by the applicant but considered in this evaluation:			
	☐	Input informed from participation in meetings or public hearings with patient stakeholders		
	☐	CHMP early dialogue with patient organisations		
	☐	Third party interventions from patients and patient groups		
	☐	Other (such as medical literature, summaries/analysis from patient engagement activities - please specify)		

6.3.8. <Patient experience data (PED)>

FACTUAL. This section is to be completed by the Rapporteur. Co-Rapporteur only to add if in disagreement or major omission.

Patient experience data (PED) are data collected through a variety of methodologies, including patient engagement activities, that directly reflect the experience of a patient or caregiver without interpretation by a healthcare professional, other third party, or (AI-based) device.

If patient experience data were submitted, provide a summary of such data. This may include PED from quantitative sources (e.g., patient reported outcome or experience measures, patient preference surveys), as well as PED from qualitative sources (any information obtained as part of patient engagement activities that reflect the wider perspective of patients' experience, e.g., outcomes of focus groups or interviews).

Describe whether the data come directly from the patients or caregivers, or if it was collected and submitted by other parties (advocacy group, researcher, developer, etc.).

If PED were submitted by the applicant, please describe their intended purpose (e.g., specify whether the data were collected to gather insights on an exploratory trial outcome, to inform the benefit-risk assessment, to enhance understanding of patient quality of life, or for other specific uses). In cases where there was CHMP early dialogue with patient organisations, please summarise the information received.

<Text>

In cases where there was CHMP early dialogue with patient organisations, please summarise the information received.

<Text>

New template implemented in Q1 2025 – available on EMA's website and direct link

Conclusions

- The Network is progressing a number of initiatives on PED
  - The reflection paper has been published for a 4-month public consultation, following PRAC and CHMP adoption

- The reflection paper discusses types and sources of PED, general principles and elaborates on the use and value of PED across the medicine lifecycle
  - 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, in order to enable case-by-case discussions on specific development plans and regulatory submissions

- EMA is planning to evaluate the updated CHMP AR template with dedicated PED sections
- EMA is seeking stakeholder input on PED priorities in the different therapeutic areas

Thank you

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