EMA
EUROPEAN MEDICINES AGENCY

Patient and HCP engagement highlights 2025

PCWP/HCPWP and all eligible organisations meeting

Presented by Melanie Carr on 18 November 2025

Head of Stakeholders and Communication Division

Stakeholder network

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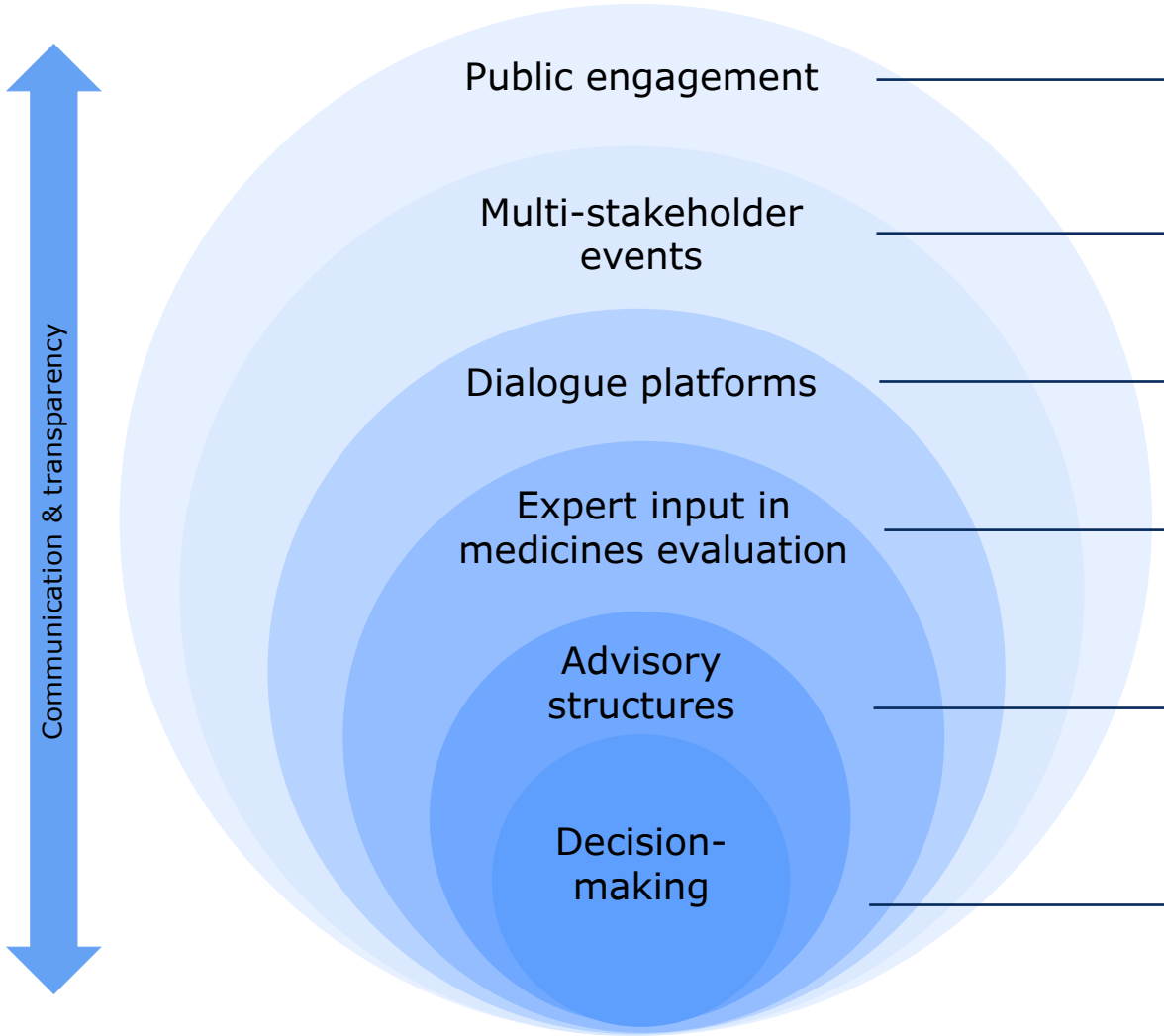
How do we engage our stakeholders in our work?



- Open consultations on policies and guidelines
- Public hearings
- Public meetings

- Workshops
- Webinars
- Awareness days

- Patients' and Consumers' Working Party (since 2006)
- Healthcare Professionals' Working Party (since 2013)
- Industry Standing Group (since 2022)

- Ensure that lived experience about diseases and treatments feed in the regulatory outcomes
- Consultations and medicine-specific activities such as: scientific advice, scientific advisory groups, review of documents destined for the public.

- Emergency task force (ETF)
- Medicines shortages steering group (MSSG)
- Medical devices shortages steering group (MDSSG)
- Network Data Steering Group
- DARWIN EU Advisory Group
- ACT EU multistakeholder platform

- Members of EMA Management Board
- Members of scientific committees

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Network of eligible organisations maintained and expanded

Eligible patients' and consumers' organisations

Eligible healthcare professionals' organisations

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PCWP and HCPWP

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PCWP and HCPWP new co-chairs and new mandates

Marco Greco

(PCWP co-chair)

Elected on 23 September

Piotr Szymański

(HCPWP co-chair)

Elected on 23 September

PCWP and HCPWP

expanded from 22 to 25 members

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PCWP/HCPWP meetings

April 2025

- EMA 30th anniversary
- Clinical trials
- EMANS to 2028
- electronic product information
- Shortages and the shortages platform
- DARWIN EU
- Revised EMA policy on competing interests
- Patient Experience Data
- Communication campaigns

September 2025

- Election of new co-chairs Assessment of medicines
- 30th anniversary scientific conference
- EMA's first public Open Door Day
- Medicine safety campaign
- Risk Minimisation Measures

November 2025

- New Pharmaceutical legislation
- Clinical trials
- Training activities
- International activities
- Availability and supply of medicines
- Product information
- Communications
- Members' voice

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Helping to shape strategic direction

The six themes in EMANS 2028

- Accessibility
- Leveraging data, digitalisation and artificial intelligence
- Regulatory science, innovation and competitiveness
- Antimicrobial resistance and other health threats
- Availability and supply
- Sustainability of the network

Engaging with stakeholders to:

- Create awareness
- Map expectations and identify gaps
- Learn and share knowledge
- Increase impact

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Key events for 2025

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EMA’s first Open Door Day – 9 May 2025

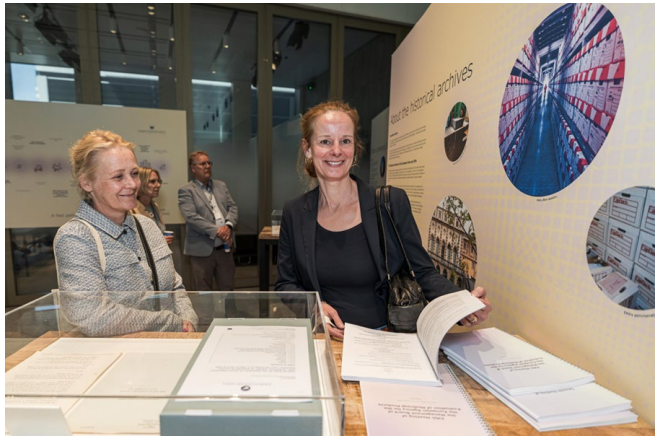
120 attendees included:

- general public,
- patients,
- academia,
- industry stakeholders,
- healthcare professionals

8 tours that included:

- Centralised procedure
- Safety of medicines
- One Health
- EMA building
- Archives

“The whole atmosphere was very welcoming and friendly. All EMA staff was very friendly.”



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Annual training for patients and healthcare professionals

- Both virtual and in-person training sessions
- Pre-webinar on 26 June:
  - Introduction to EMA
  - How EMA engages with stakeholders
- In-person training on 2 July:
  - Scientific advice
  - Review of documents
  - How to get involved in EMA activities
- 34 in-person participants: 23 patients/consumers and 11 HCPs
- Identified through eligible organisations, Stakeholder Database and “pool of patient and HCP experts”

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Remuneration

- EMA implemented **additional support** for patients and healthcare professionals.
- Open call was launched to create a pool of patient and healthcare professional **experts.**
- **Contracts** issued by EMA for a selected list of tasks
- First contracts and **payments** to experts made.
- The call remains open for the period of 2024-2029.

Currently:

  - 178 applications were received,
  - 88 included in the pool of experts,
  - 68 contracted experts
  - 77 tasks have been assigned to contracted experts.

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Quick guide to competing interests for patients and healthcare professionals

- At a glance explanation of restrictions for competing interests
- Information for experts with interests in:
  - Pharmaceutical companies
  - Medical device companies
  - Research organisations

More information

- Handling competing interests at EMA
- EMA's policy on the handling of competing interests of scientific committees' members and experts
- Procedural guidance to scientific committees' members and experts on completing EMA's declaration of interests in the Experts Management Tool

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Quick guide to competing interests for EMA experts

To be involved as an expert in EMA activities, you need to complete a declaration of interest and curriculum vitae.

This guide provides an overview of what is expected to be declared and what EMA considers to be a competing interest.

Who is this for?

It has been developed for **patients, consumers or healthcare professionals** who may be involved as experts in EMA activities such as scientific advice, review of product information or who may participate in a scientific advisory group (SAG).

What is the aim?

It will help you **identify** whether you hold interests that would prevent you from working with EMA altogether or on a specific activity.

If you are currently employed by a **pharmaceutical company or a medical device company**, you cannot participate in EMA activities.

For other interests, please refer to the tables in this factsheet and the policy to see how it may impact your participation.

Where can you find more information?

The factsheet is not comprehensive and should be read in conjunction with EMA's policy on handling competing interests and the related procedural guidance.

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If you have questions about your involvement in a specific activity, please reach out to your contact at EMA.

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Publication of EMA reflection paper on PED for public consultation

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**

Scope and key aspects

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

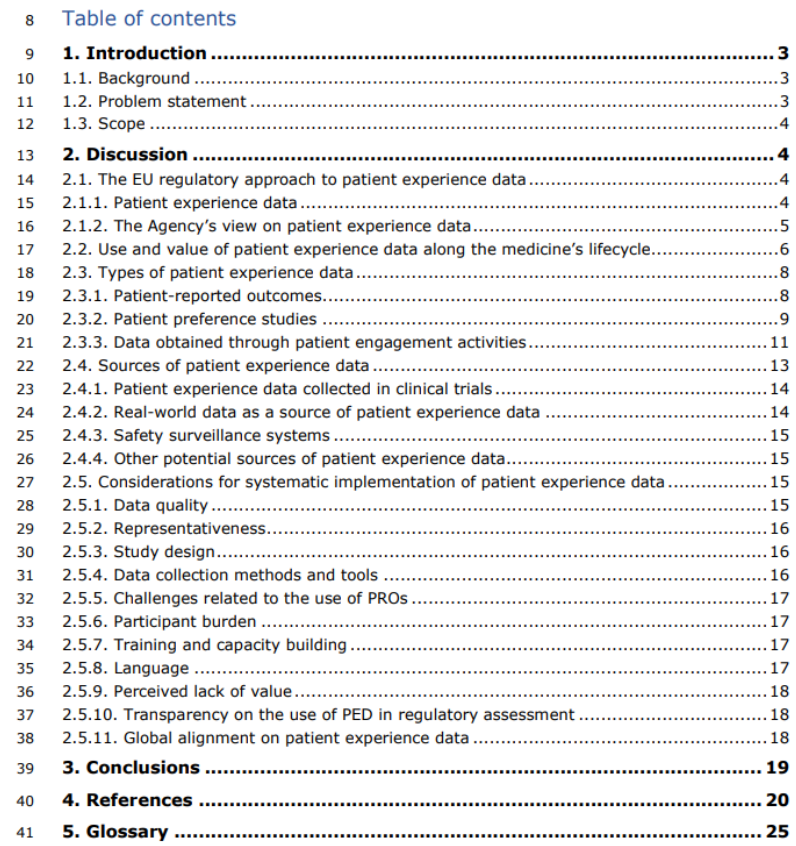
It describes general principles – it is not a methodological guidance.

It is complementary to ICH guidance work

It encourages systematic consideration of PED in medicine development programmes and regulatory submissions because PED can be a relevant contributor to the totality of evidence throughout the medicine lifecycle

Target audience:

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



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Medicine Shortages Communication (MSC)

- Medicine Shortages Communication (MSC)
- Process: a new procedure to communicate on shortages to healthcare professionals was adopted by the MSSG in October 2024.
- The MSC replaces Direct healthcare professional communications (DHPCs) for shortages not related to a quality, safety or efficacy issue.
- The MSC was implemented through a pilot programme which started in October 2024 and is currently under review.
- During 2025, HCPs have reviewed 10 MSCs prior to publication.

#ItTakesATeam campaign

EMA, together with consumer and healthcare professional organisations, is running the #ItTakesATeam campaign to highlight how different actors work together to help patients during medicine shortages.

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Accelerating clinical trials in the EU (ACT EU)

- Multistakeholder platform (MSP) Advisory Group dialogue on priorities to boost clinical trial environment in the EU
  - MSP Advisory Group meetings (Mar/June/Sep 2025) and Multistakeholder platform annual meeting (Oct 2025)
  - Focus groups/targeted consultations on CT training needs; CTIS and CTR training material; risk-based approaches; auxiliary medicinal products in CTs, problematic requests for information.
- Key achievements:
  - Launch of Trial map
  - Key performance indicators and quarterly reports to monitor EU CT performance
  - CTIS master handbook
  - Consolidated advice pilots

https://accelerating-clinical-trials.europa.eu/index_en

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Public webinar on shortages

500 people followed via WebEx

Feedback received was positive

97% of respondents said webinar was very useful (55%) or quite useful (42%)

Objectives

- To inform patients, consumers and healthcare professionals about the EU regulatory processes in place to manage shortages
- To help patients, consumers and healthcare professionals find information about shortages
- To discuss how they can help prevent and manage shortages
- To listen to their needs, expectations and concerns

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EMA booklet: safety of medicine

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Stakeholder Engagement

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Activities with patients and consumers

Participation in procedures during the assessment of a medicine at the EMA

In 2025 patient/consumer representatives:

- contributed to 52 scientific advice procedures.
- participated at 9 oral explanations at the CHMP, COMP and CAT.
- participated in 7 scientific advisory group meetings (SAG).

Review of EMA documents

In 2025 patient/consumer representatives reviewed

- 53 package leaflets (out of 57 requests received)
- 47 medicine overviews (out of 50)
- 15 shortage entries (out of 15)
- 4 public health communications (out of 5)

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Activities with healthcare professionals

EMA activities

In 2025 HCPs representatives:

- participated in 9 SAG meetings
- input 20 early dialogue procedures
- reviewed 12 safety communications
- Reviewed 21 shortage communications.

Promoting outreach of safety information

- A call to prevent inappropriate prescribing of fluoroquinolones from the European Medicines Agency (EMA) and the EAU Guidelines co-authored by EMA in collaboration with the European Association of Urology (EAU).
- Meningococcal B Vaccines as a Paradigm of Safe and Effective Vaccines for Children co-authored by EMA in collaboration with European Academy of Paediatrics (EAP).
- The case for more prudent prescribing of fluoroquinolones in primary care co-authored by EMA in collaboration with EAU and GPs organisations (WONCA EUROPE, UEMO, and EFPC).

HCP Policy Officers Group (POG) meetings

- Fourth year of operation
- The group met five times in 2025.
- Topics: Clinical trial updates, Availability and supply of medicines, the use of artificial intelligence in healthcare and associated HCPO's position papers, engagement with academia, scientific publication strategies, and communication activities,...

Bilaterals

- **First** formal bilateral meetings with the European Society of Cardiology (ESC), the European Association for the Study of Diabetes (EASD), the European Association of Urology (EAU) and the European Respiratory Society (ERS).
- Annual meeting with GP organisations' representatives (UEMO, EFPC and WONCA EUROPE)
- Annual meeting with the European Association of Hospital Pharmacists (EAHP).

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Consultations-product information activities

- Review of the **package leaflet template** (QRD template)- package leaflet improvement.
  - Public consultation on QRD template version 11
  - Public online survey on **'key information section'** to seek stakeholders' views.

- **Medicine overviews: survey on target audience awareness and satisfaction**. In addition, a series of **interviews** with patients and healthcare professionals was carried on the EMA's plain language summaries of medicines (also known as "medicine overviews").

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Publications and communication

- Agency's Stakeholder Engagement Report 2024-25 will be published in Q1 2026
- Public Engagement Highlights 2024
- Stakeholders Database mailings:
  - 23 CHMP/PRAC communications
  - 50 public consultations
  - 36 communications related to EMA events
  - 17 communications about DHPCs
  - 8 calls for expressions of interest
  - 54 other communications (newsletter, shortages, surveys, etc.)

2024

Public engagement highlights

Annual overview of patients and healthcare professionals involvement in EMA's work

In 2024, representatives of patients, consumers and healthcare professionals (HCP) actively contributed to better EMA's work in many ways. They participated in multistakeholder workshops and other initiatives, and continued to provide valuable input on EMA documents to ensure that these documents are clear to the patients and healthcare professionals who read them. They also engaged in early dialogue with CHMP, contributed to the EMANS strategy to 2028 and joined the ACT EU Multistakeholder platform advisory group as members. Finally, this year also saw the launch of the revamped Human Medicines Highlights newsletter and an Open Call aimed at remunerating patients, consumers and HCP experts for their work with EMA.

Stakeholder involvement in medicine-related activities

Patient contribution to EMA's work

Patient membership numbers	39
EMA Management Board	2
Scientific committees	15
Patients' and Consumers' Working Party	22
Active patient experts	186
Patients/consumers eligible organisations	41

HCP contribution to EMA's work

HCP membership numbers	36
EMA Management Board	2
Scientific committees	12
HCP Working Party	22
Active HCP experts	155
HCP eligible organisations	41

Working party meetings

February
Third-party interventions, activities in cancer area, PED, pharmacovigilance, shortages, policy on competing interests, EMA Working Party operations
Access meeting documents

July
EMANS to 2028, Clinical trial (CT) activities, product information, transparency activities, shortages, vaccine related updates, biosimilar medicines
Access meeting documents

November
CTs updates, sustainability of the network, shortages, medical devices, EMA data-related initiatives and digitalisation, artificial intelligence, communication activities
Access meeting documents

Queries by stakeholder

Total number queries: 1450
Overall satisfaction: 77%

Common topics:
COVID-19 vaccines, availability, ADRs, GLP-1 receptor agonists

Key events

Multistakeholder workshop on psychedelics

In April 2024, a multi-stakeholder workshop brought together patients, HCPs, academia, regulators, and industry to discuss the development and therapeutic use of psychedelic substances to address unmet medical needs in the area of mental health.

View event summary | Workshop documents

Multistakeholder workshop on shortages of Glucagon-Like Peptide-1 (GLP-1) receptor agonists

In July 2024, the multistakeholder workshop aimed to clarify the needs and challenges of different stakeholder groups in relation to shortages of GLP-1 receptor agonists, share experiences of ongoing activities to mitigate and prevent these shortages, identify novel solutions, strengthen cooperation among stakeholders, and agree on key messages for communication to effectively reach target audiences.

View event summary | Workshop documents

Patient and HCP engagement in medicine-specific activities

Patients in scientific advice procedures	70
Patients in scientific advisory groups	27
Patients in committee consultations	25
Responses to CHMP early dialogue	21
Review of documents by patients	98

HCP experts in scientific advisory groups	186
Responses to CHMP early dialogue	35
Review of documents by HCP	52

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Other meetings

- Fifth joint meeting of the PCWP and Patient Engagement Collaborative (FDA-CTTI) (June 2025)
  - How shortages are handled in EU/US
- Annual meeting with Civil Society representatives (October 2025)
  - Onboarding of committee members
  - New pharmaceutical legislation
  - Patient experience data reflection paper

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Thank you all for the hard work and support throughout the year

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Thank you. Any questions?


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Send a question via our website