

# Patient and HCP engagement highlights 2024

PCWP/HCPWP and all eligible organisations meeting

Presented by Melanie Carr on 20 November 2024  
Head of Stakeholders and Communication Division



# Network of eligible organisations maintained and expanded

## Eligible patients' and consumers' organisations

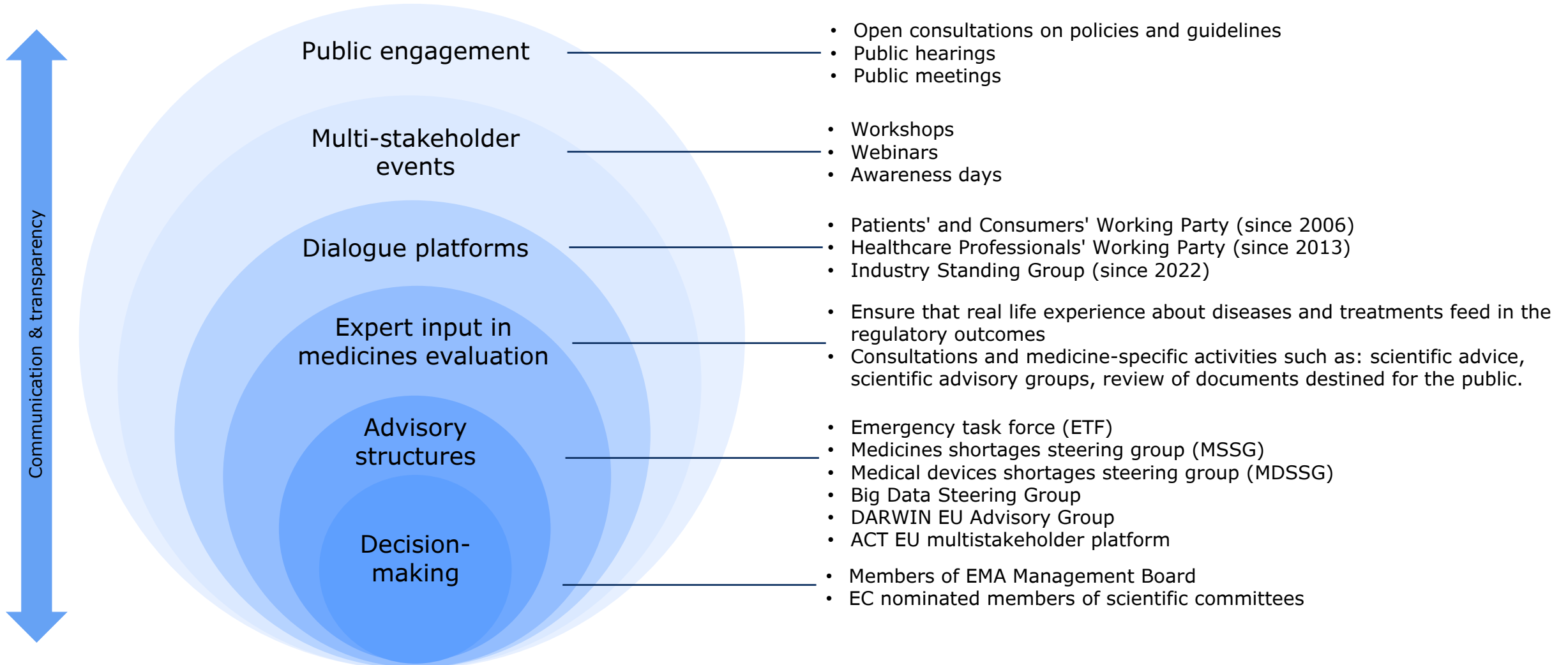


## Eligible healthcare professionals' organisations

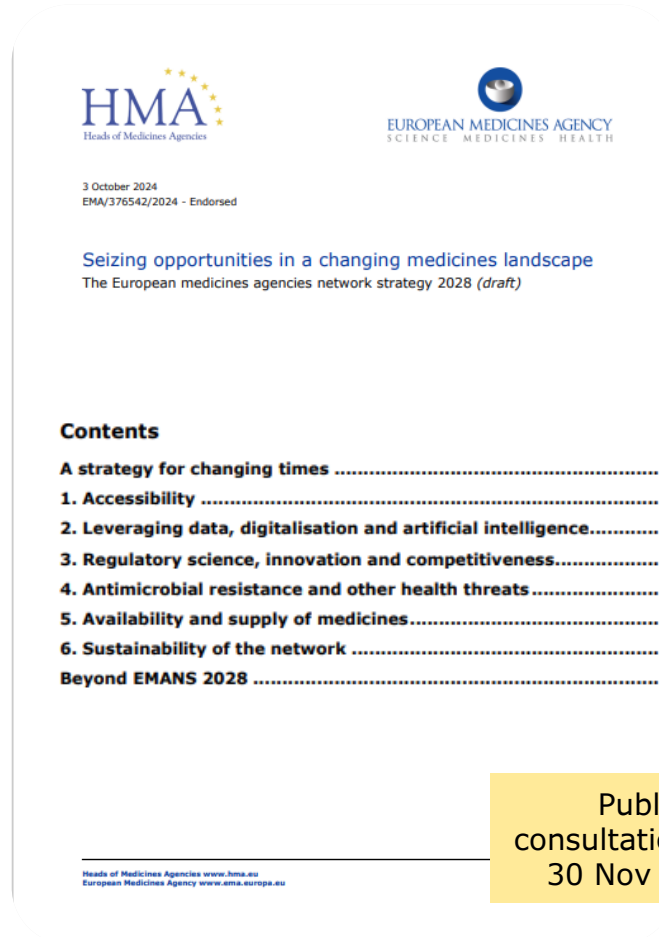


Re-assessment of eligibility 2024 ongoing (deadline 5 Nov)

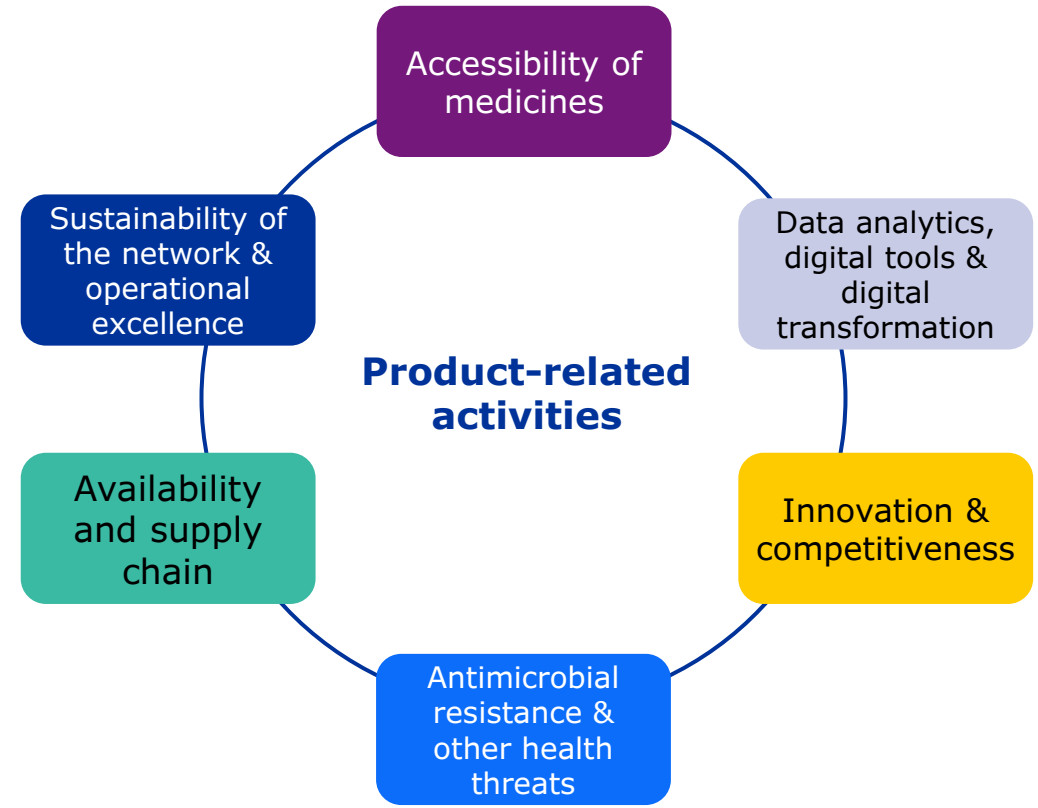
# How do we engage our stakeholders in our work?



# Protecting public health



Public consultation until 30 Nov 2024

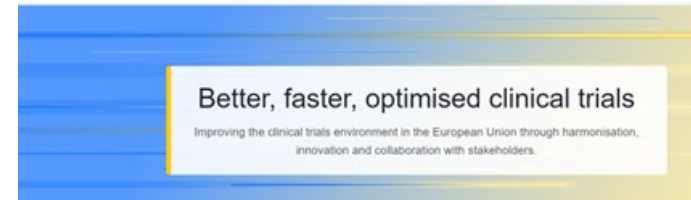


Engaging with stakeholders to:

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

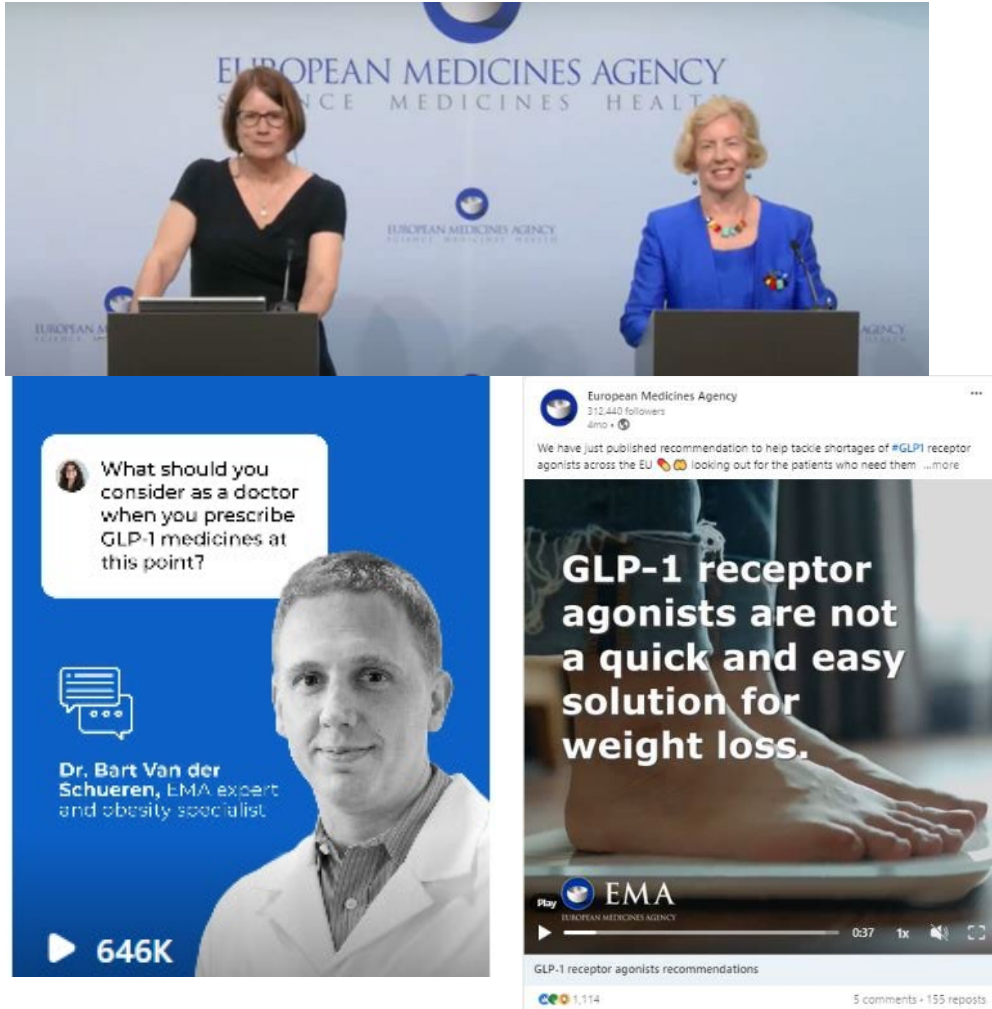
# Accelerating clinical trials in the EU (ACT EU)

- **Multistakeholder platform (MSP) Advisory Group** established, and co-chair elected
  - MSP Advisory Group meetings (Mar/Apr/Jul/Sep 2024)
  - **EU Multistakeholder platform** annual meeting (Oct 2024)
- **Clinical Trials Analytics** workshop (Jan 2024)
- Presentation of the Clinical trials information system (**CTIS**) **revised transparency rules** and **new version of the public portal** to PCWP/HCPWP (Jul 2024)



[https://accelerating-clinical-trials.europa.eu/index\\_en](https://accelerating-clinical-trials.europa.eu/index_en)

# Shortages



- Patient and healthcare professional representation in the **executive steering groups** on shortages of medicines (MSSG) and medical devices (MDSSG)
- Multistakeholder workshop on shortages of GLP-1 receptor agonists (Jul 2024)
- Communication activities (press briefing, Instagram LIVE, social media campaign)

# Multistakeholder workshop on shortages of GLP-1 receptor agonists

## Workshop objectives:

- Clarify needs and challenges of different stakeholder groups in the context of shortages of GLP-1 receptor agonists;
- Share experiences of ongoing activities to mitigate and prevent shortages of GLP-1 receptor agonists;
- Identify novel solutions to mitigate and prevent the shortages of these medicines;
- Strengthen cooperation amongst all stakeholders and improve coordination of activities;
- Discuss and agree on key messages for communication and how to best reach target audiences.



<https://www.ema.europa.eu/en/events/multistakeholder-workshop-shortages-glucagon-peptide-1-glp-1-receptor-agonists>

# Multistakeholder workshop on psychedelics

## Workshop objectives:

- Hear the views of stakeholders and experts on the therapeutic potential of psychedelics;
- Provide further clarity on defining the safe and effective use of psychedelics;
- Inform on regulatory challenges associated with the development and evaluation of psychedelic medicines;
- Define areas for which further regulatory guidance is required.



<https://www.ema.europa.eu/en/events/ema-multi-stakeholder-workshop-psychedelics-towards-eu-regulatory-framework>

# Vaccine update

## **Vaccines Outreach Strategy (VOS) updated and Vaccines outreach group restarted**

- Update of messaging on COVID-19 vaccines with focus on reassuring on the safety, following MEP's questions
- Working on new ways of communicating on vaccines for the public
- Proposal for information ecosystem management to identify misinformation and knowledge gaps on vaccines
- Scientific publications on vaccines

## **EVIP**

- European Vaccination Information Portal (EVIP) communication plan and content review progressed
- EVIP Steering Committee - Communication Plan and content review to be further progressed



# Patient experience data (PED)

## Reflection paper on PED

- Drafting ongoing of the Reflection paper of the EU approach to Patient Experience Data
- Drafting group contributions on content, including from patients and healthcare professional representatives
- Next steps & timelines: review by PCWP/HCPWP and EMA Committees and WPs

## Increasing PED transparency in the CHMP AR

- CHMP assessment report (AR) template has been updated to better include reference to what PED is assessed by regulators

## Participation in Collaborare project

- EMA contributed to define the research proposal for the Collaborare project



# Consultations (surveys)

- Review of the **package leaflet template** (QRD template): package leaflet improvement. Survey to patients, consumers and healthcare professionals on **'key information section'** and benefits/risks balance in March 2024. Responses received from 96 patients/HCPs.
- **Biosimilars:** Surveys to HMA, patients, consumers, HCPs and industry on biosimilars completed in May and being analysed. Responses received from 64 patients and 168 HCPs.
- Upcoming surveys on the **use of Patient Experience Data** (PED) within the different therapeutic areas (planned for end of Nov / beginning of Dec).



# Publications and communication

- Agency's Stakeholder Engagement Report 2022-23
- Public Engagement Highlights 2023
- Revamped Human Medicines Highlights launched in May 2024
- One-year report of CHMP early dialogue methodology with HCP organisations
- Stakeholders Database mailings:
  - 18 CHMP/PRAC communications
  - 50 public consultations
  - 38 communications related to EMA events
  - 17 communications about DHPCs
  - 8 calls for expressions of interest
  - 54 other communications (newsletter, shortages, surveys, etc.)



# PCWP/HCPWP meetings

## February 2024

- Third-party interventions
- Activities in cancer area
- Patient Experience Data
- Pharmacovigilance
- Shortages
- EMA Working Party operations

## July 2024

- Clinical trial activities
- Product information
- Transparency activities
- Updates on biosimilars
- Shortages
- Vaccine related updates
- Biosimilars

## November 2024

- Clinical Trials updates
- Sustainability of the network
- EMA data related initiatives
- Artificial intelligence
- Communication activities at EMA

## PCWP only

- Patient involvement in EMA activities
- EMA international activities and patient engagement
- PCWP operations

## HCPWP only

- HCP involvement in EMA activities
- HCPWP operations
- One year report from early dialogue

# Other meetings and training activities

- Fourth joint meeting of the PCWP and Patient Engagement Collaborative (FDA-CTTI) (June 2024)
- EMA bilateral meetings
  - with the European Society of Cardiology (ESC; Jul 2024),
  - with the European Association of Hospital Pharmacists (EAHP; Nov 2024)
  - with GP organisations (UEMO/EFPC/WONCA; Nov 2024)
- Stakeholder meeting on the revision of the Paediatric Addendum to the Pulmonary Arterial Hypertension (PAH) guideline (Sep 2024)
- Annual meeting with Civil Society representatives (Sep 2024)
- Webinars:
  - Collaborare project (Apr 2024);
  - EUNTC introduction and navigation (Oct 2024);
  - Package leaflet review (tbc - Q4 2024)
- Annual training for patients and healthcare professionals (Dec 2024)



# Thank you. Any questions?



[ema.europa.eu](https://ema.europa.eu)



[@EMA\\_News](https://twitter.com/EMA_News)



[European Medicines Agency](https://www.linkedin.com/company/european-medicines-agency)



[public-engagement@ema.europa.eu](mailto:public-engagement@ema.europa.eu)

Send a question via [our website](https://ema.europa.eu)