



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Highlights 2023

PCWP/HCPWP and all eligible organisations meeting

Presented by Ivana Silva and Maria Mavris on 15 November 2023
Public and Stakeholders Engagement Department

An agency of the European Union



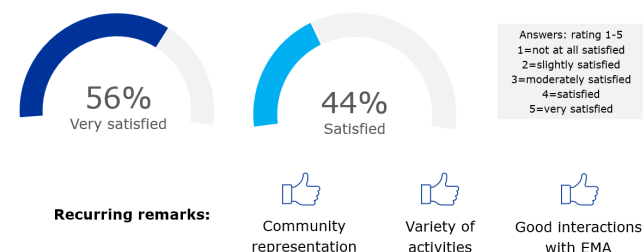
Eligible patients' and consumers' organisations



2023 Satisfaction survey to all eligible organisations

- Run from 23 Feb to 24 Mar 2023
- Goals:
 - Assess organisations' satisfaction
 - Gather feedback on interactions
 - Improve engagement activities
- Key findings
 - Generally high satisfaction and positive comments
 - Topics of interests and engagement methodologies reflective of Agency's priorities and ongoing work
 - Survey participation rates could be improved

Patient/ consumer organisations



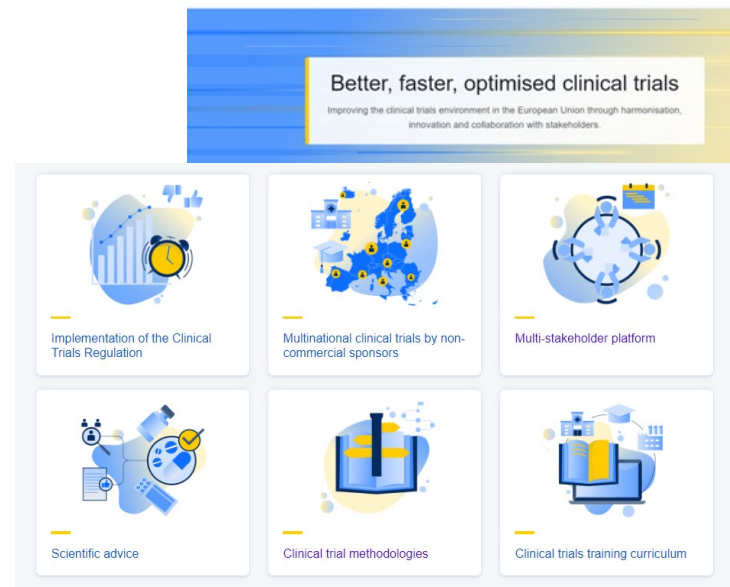
Healthcare professional organisations



ENGAGEMENT: KEY TOPICS IN 2023

Accelerating clinical trials in the EU (ACT EU)

- Public consultation (May) and multistakeholder workshop (Sep) on Clinical trials information system **(CTIS) transparency rules**
- Public consultation (Feb) on **Multistakeholder platform** and kick off workshop (Jun)
- Multistakeholder workshop on ICH E6(R3) Good Clinical Practice (Jul)
- Multistakeholder **methodology** workshop (to be held on 23 Nov)



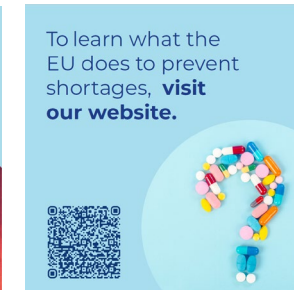
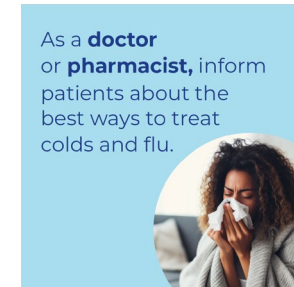
https://accelerating-clinical-trials.europa.eu/index_en



ENGAGEMENT: KEY TOPICS IN 2023

Shortages

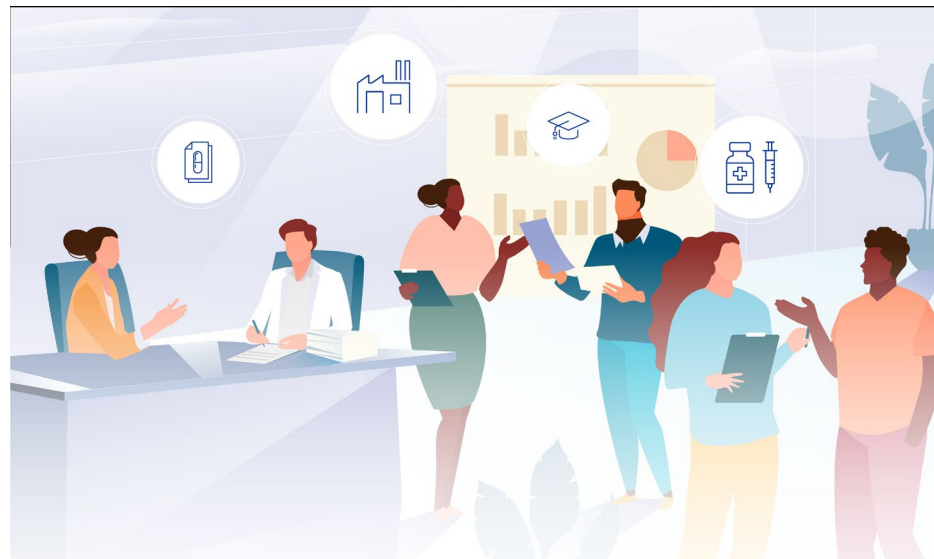
- Patient and healthcare professional representation in the **executive steering groups** on shortages of medicines (MSSG) and medical devices (MDSSG)
- **Multistakeholder workshop** on shortages (Mar)
- Monitoring and managing **shortages of antibiotics** (Jan) and prevention campaign for autumn/winter season (Oct)
- **Set-up of a subgroup** to work on the implementation of the prevention guide for patient and HCP organisations



ENGAGEMENT: KEY TOPICS IN 2023

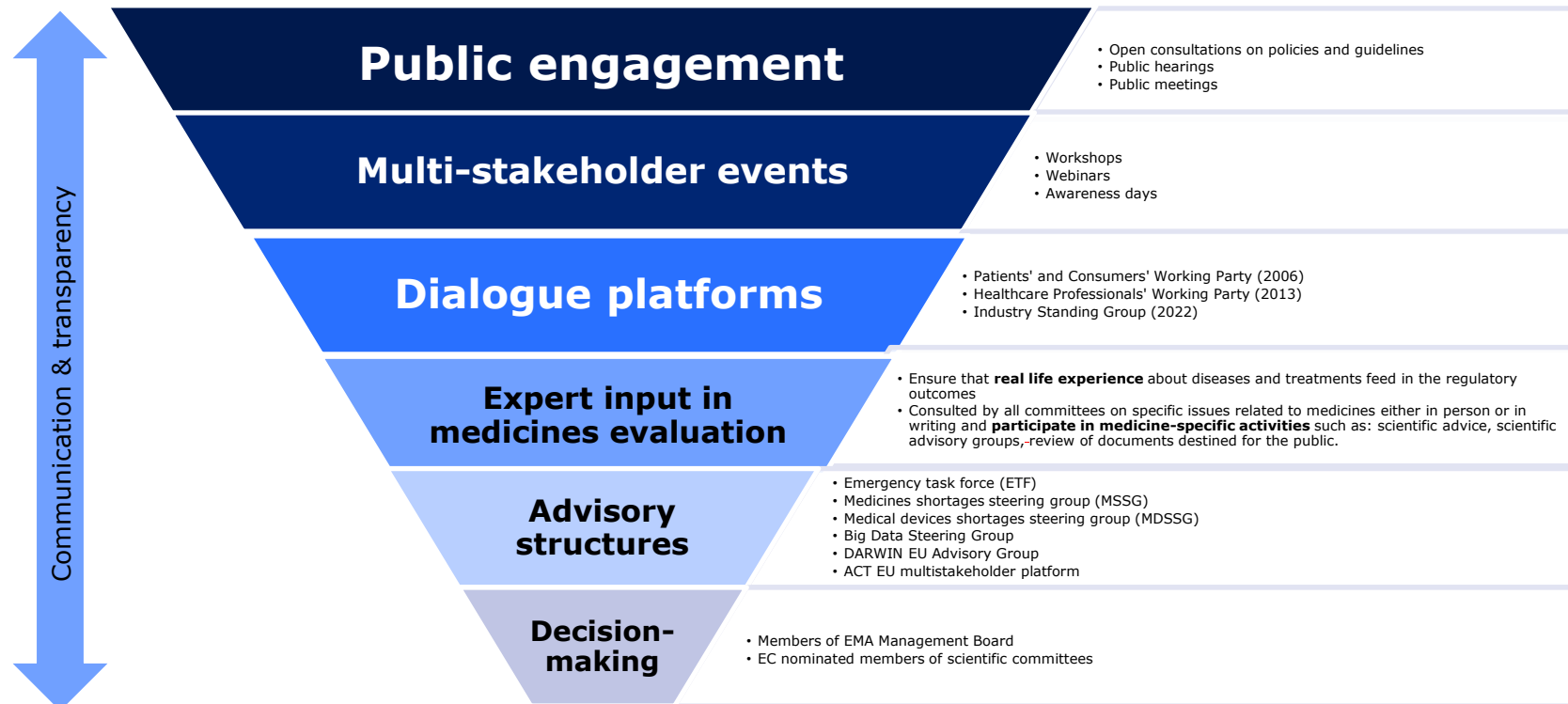
Use of real-world data for medicines approval

- Patient and healthcare professional representation in the **Big Data Steering Group** (BDSG) and **DARWIN EU® Advisory Board**
- **Big Data Stakeholder forum** (to be held on 4 Dec)
- Reflection paper on **Patient Experience Data** under development following multi-stakeholder workshop in 2022





How do we engage our stakeholders in our work?





Engagement: PCWP and HCPWP meetings

March

- EMA Working Party reorganisation
- Medical devices
- Clinical trials (ACT EU; ICH)
- Biosimilars and interchangeability
- EMA policy on multilingualism

June

- Pharmacovigilance
- Clinical trials Darwin EU
- Electronic product information (ePI)
- Medicine shortages
- Nitrosamines
- HCPWP 10th anniversary
- Satisfaction survey

September

- EMA working groups
- Crisis preparedness
- Big data
- Medicine shortages
- Patient information
- Clinical trials (ACT EU; ICH)
- EMA communications

November

- Availability and accessibility of medicines
- EMA data related initiatives and digitalisation
- Regulatory science and innovation
- Communications

Webinars: Transparency rules for the EU Clinical Trials Information System CTIS
Revision of the pharmaceutical legislation
CHMP early contact of patient and HCP organisations



Engagement in medicines' evaluation

Scientific advice

Fewer in person meetings with companies – most responses in writing

Scientific Advisory Groups

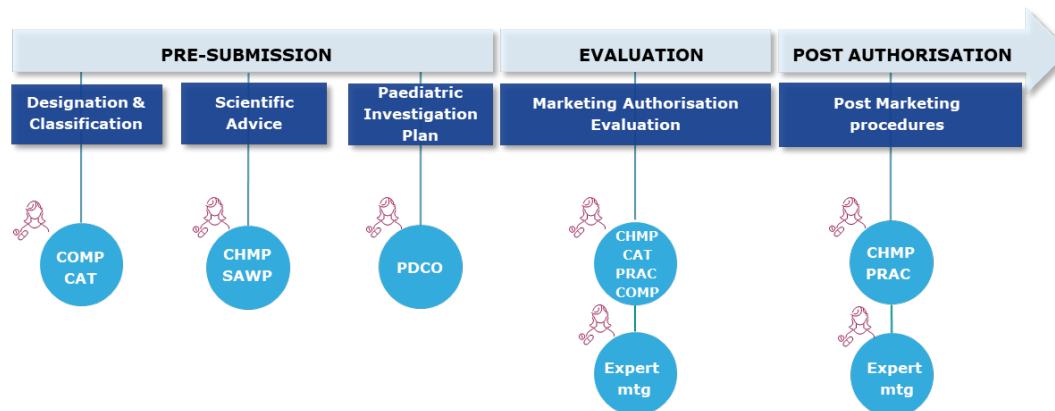
Regular inclusion of patients and HCP in SAG and *ad hoc* expert meetings

Committee consultations

- Early dialogue with CHMP
- PRAC stakeholder meetings (valproate in Feb and Nov; fluoroquinolones in Jun)
- Committee oral explanations

Review of documents

Systematic review of documents



How to support members of advisory structures

Advisory structures

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

- Patients and healthcare professionals involved in groups provide valuable perspectives
- Need for support and input for their participation
- Opportunity for all eligible organisations to indicate areas of interest and experience
- Mapping exercise to be circulated and to be kept open



Support and mutual exchange

- Communications colleagues from your organisations invited to participate in EMA communications activities
- Request from BDSG member George Paliouras (representing patients) who is speaking at the Big Data Stakeholder Forum (4 December). Anyone interested/available to join a call with him on his presentation.





Any questions?

Further information

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