



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of current patient involvement

Patient involvement in pharmacovigilance processes

Twelfth Pharmacovigilance Stakeholder forum

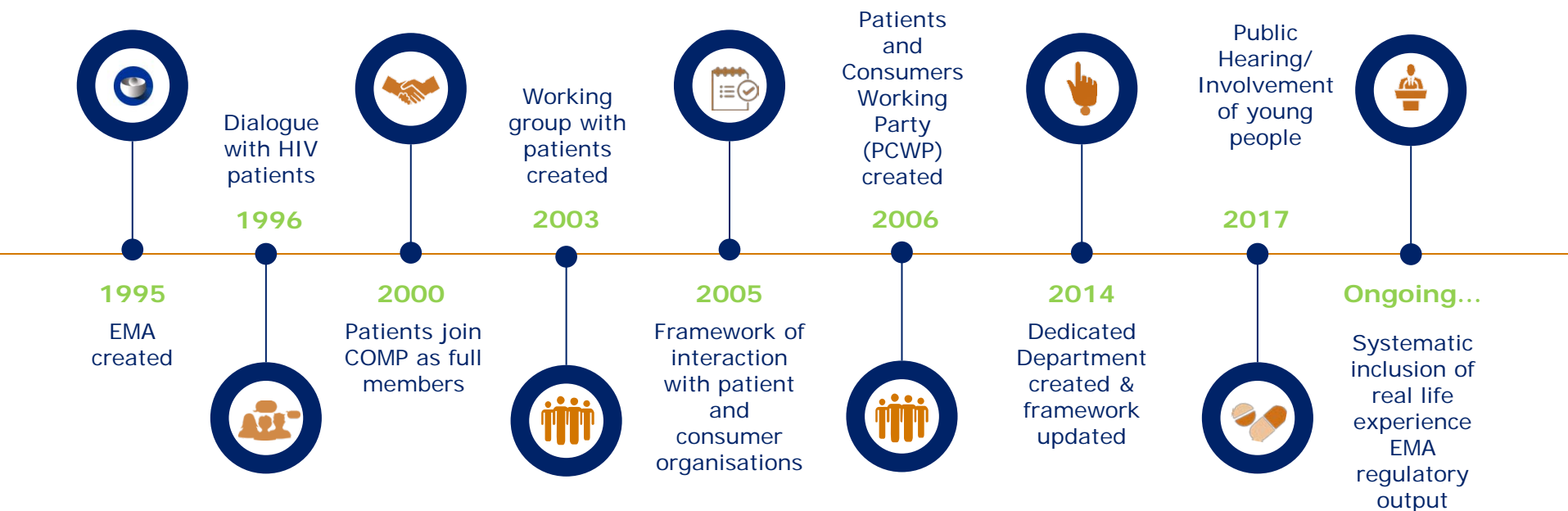
Presented by Maria Mavris on 24 September 2018
Public Engagement Department, European Medicines Agency

An agency of the European Union



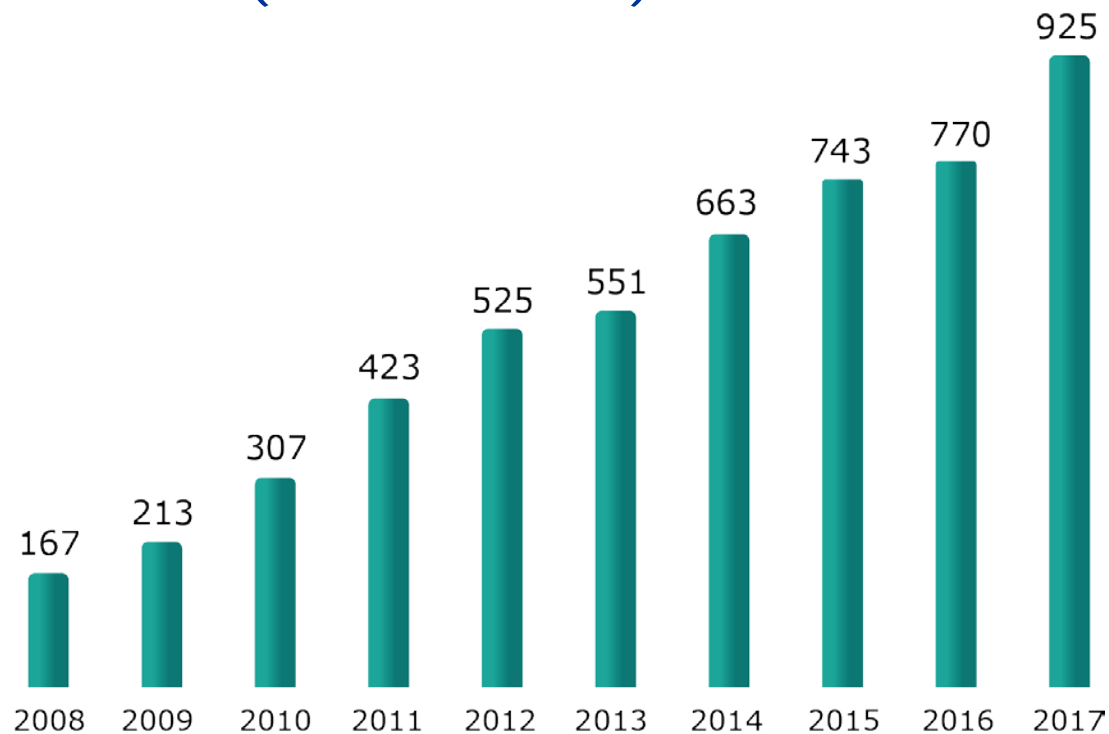


Collaboration with patients: the EMA journey... so far

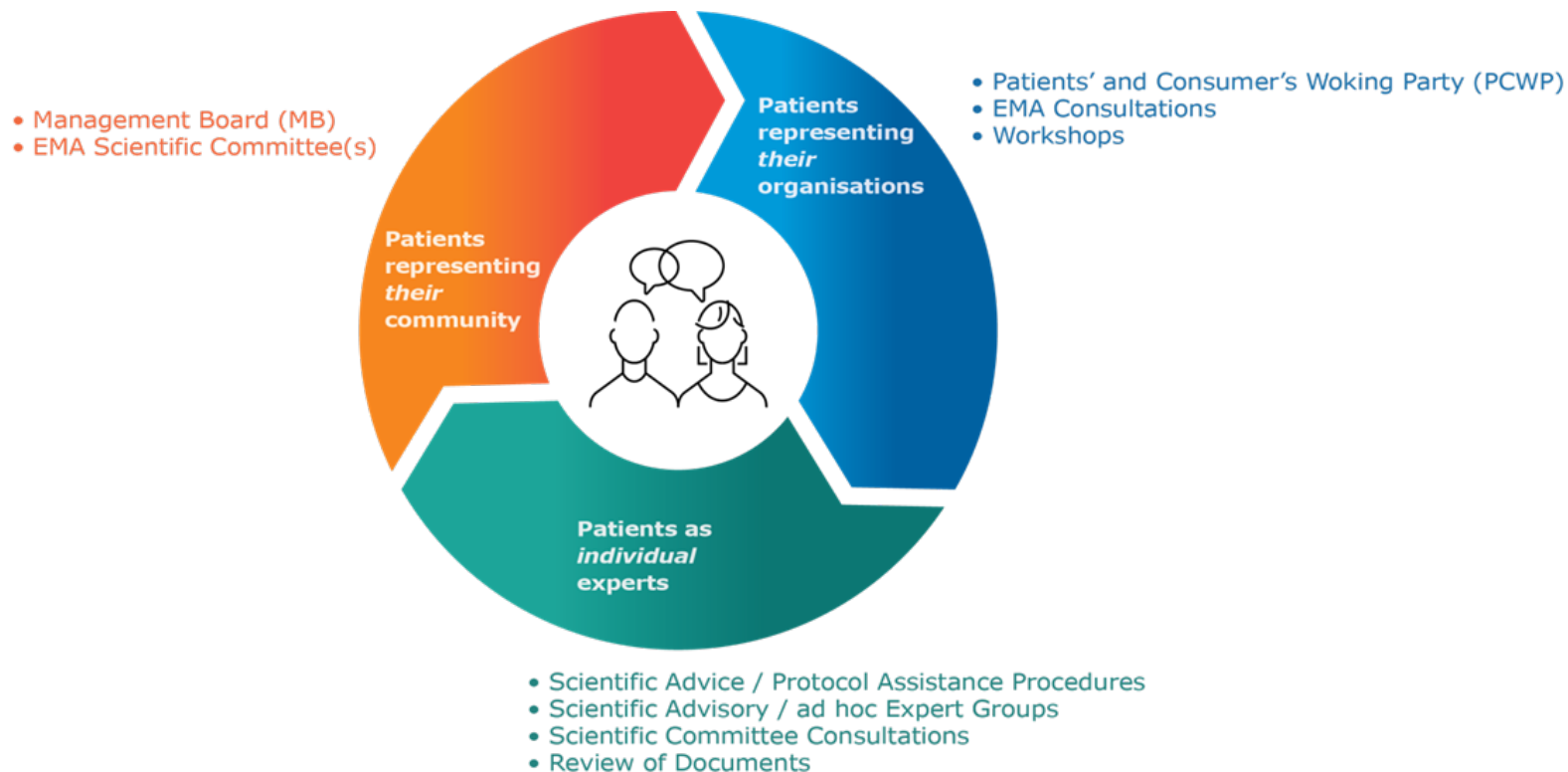




Patient involvement (2008 – 2017)



Three categories of patient representation

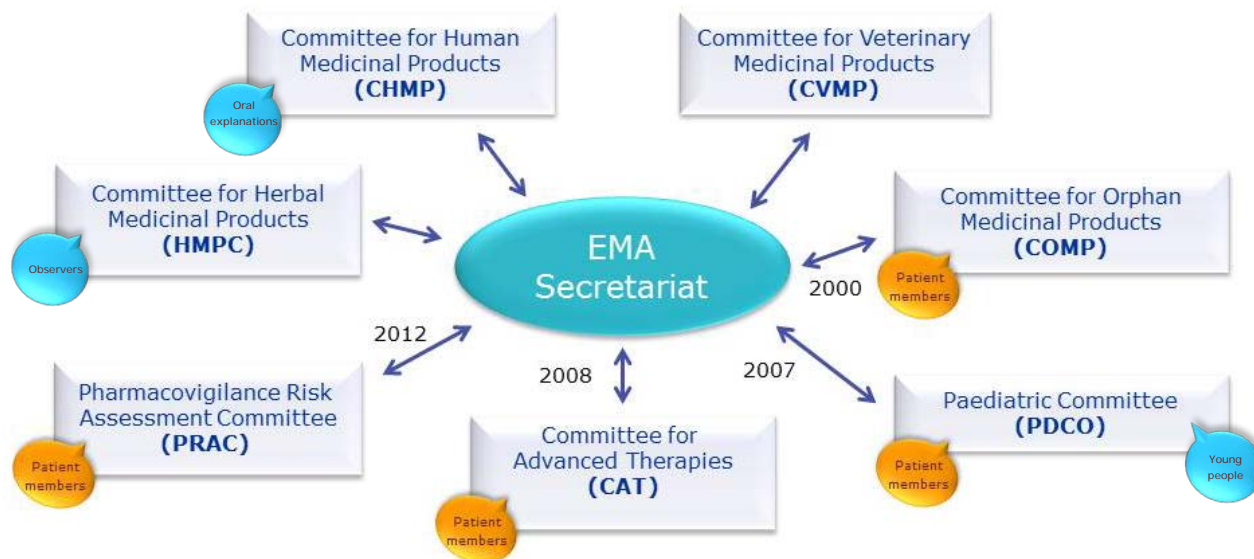




Patients representing their community



Patients and EMA scientific committees





Patients representing their organisation



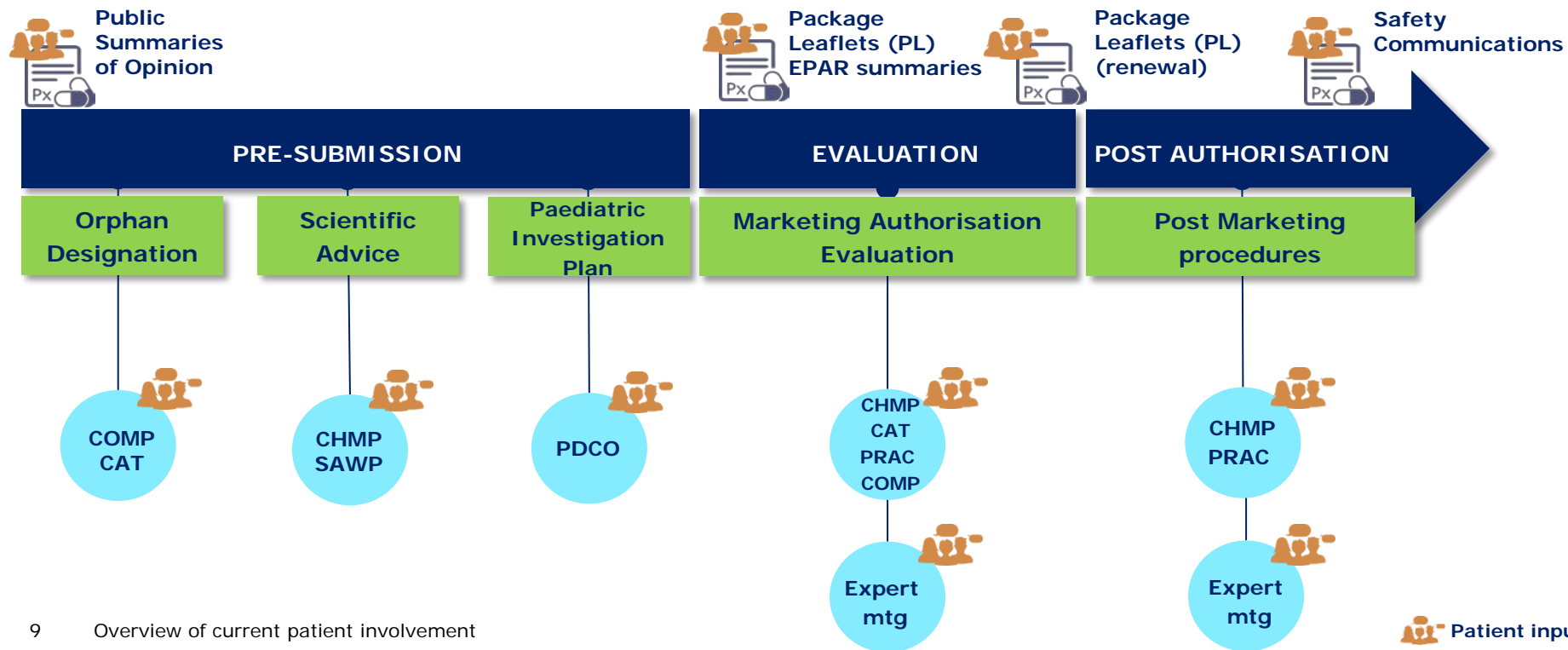
Patients and Consumers Working Party (PCWP)





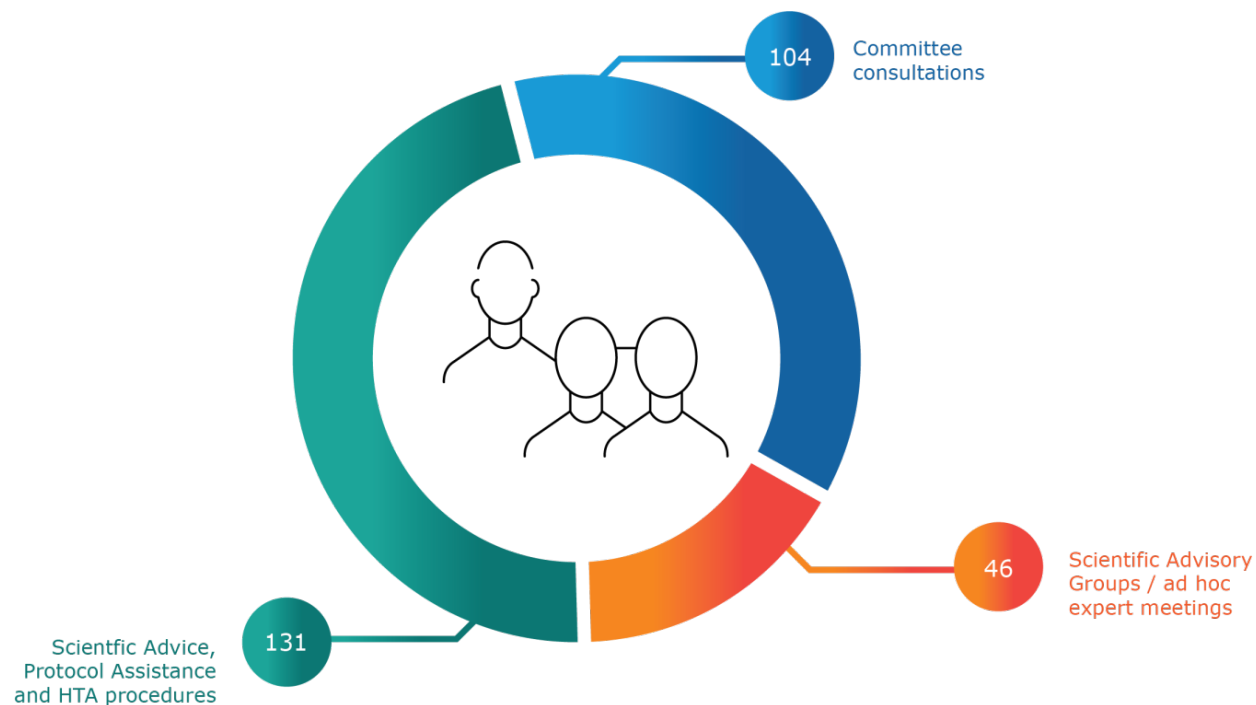
Patients as individual experts

Patient involvement along the medicine lifecycle at EMA



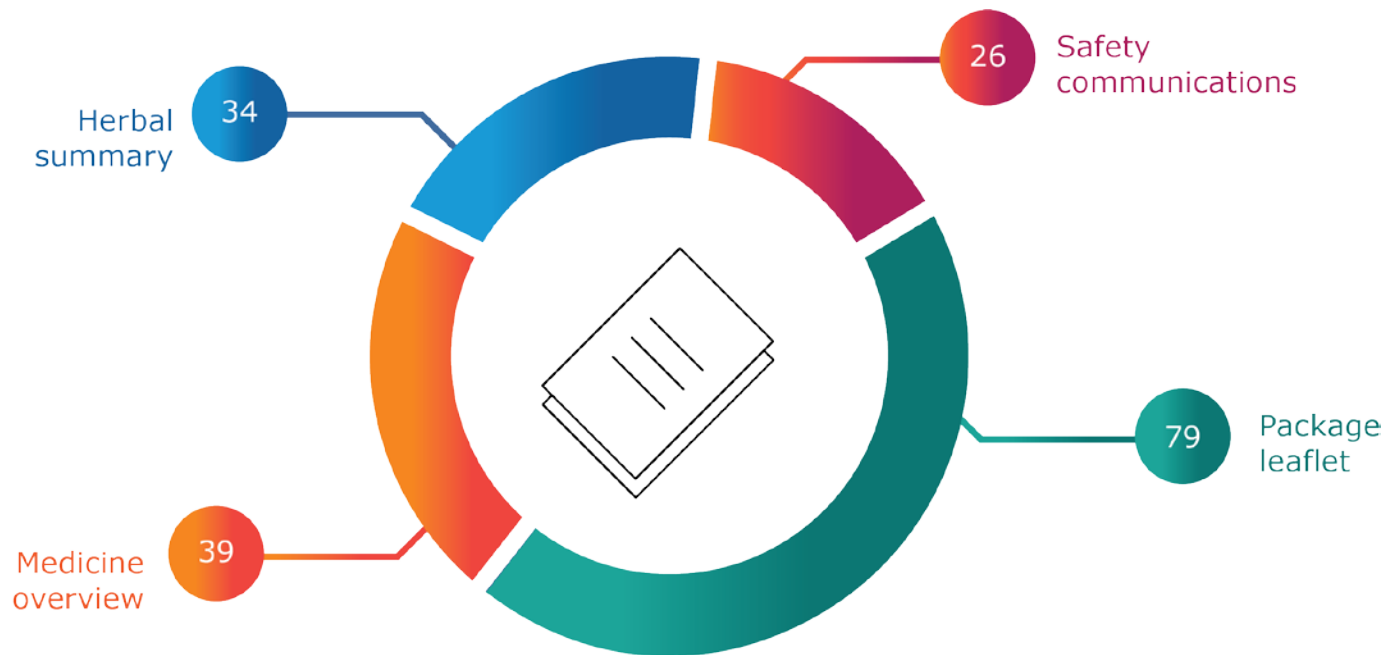


Patients in scientific meetings





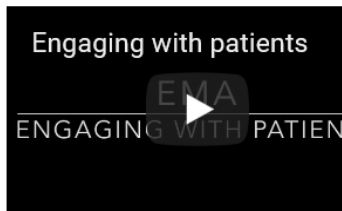
Patients and review of documents



Who do we work with?

- Any organisation representing EU patients or consumers may express an interest to work with the Agency, however they must meet the defined eligibility criteria (application form on the [EMA website](#))
- List of eligible patients & consumers organisations published on the EMA website
- Individuals can also register to be involved

Video: Engaging with patients



[All images hyperlinked](#)





Patients in pharmacovigilance activities

Members of PRAC



Albert
van der Zeijden



Marco
Greco

PRAC consultations of patients



Examples

Insulin : new strength box label design
: extraction from pre-filled pens

Dopamine dysregulation syndrome - questionnaire



Review of safety communications

Reporting side effects



Side effects reports



EudraVigilance - European database of suspected adverse drug reaction reports

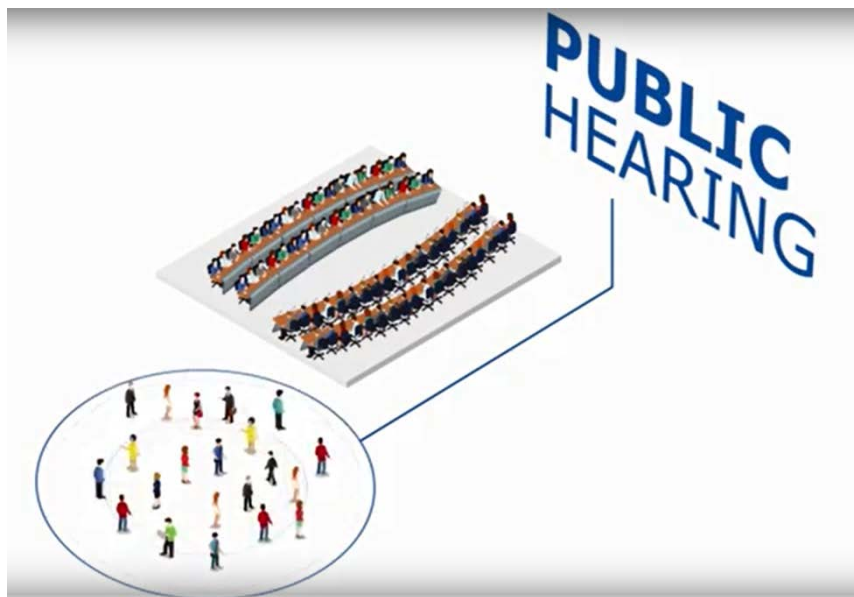


bg Европейска база данни относно съобщенията за подозирани нежелани лекарствени реакции
es Base de datos europea de informes de presuntas reacciones adversas
cs Evropská databáze hlášení podezření na nežádoucí účinky léčivých přípravků
da Europæisk database over indberetninger om formodede bivirkninger
de Europäische Datenbank gemeldeter Verdachtsfälle von Arzneimittelnebenwirkungen
et Ravimite võimalike kõrvaltoimete teatiste Euroopa andmebaas
el Ευρωπαϊκή βάση δεδομένων αναφορών πιθανολογούμενων ανεπιθύμητων ενεργειών φαρμάκων
is Evrópskur gagnagrunnur fyrir tilkynningar á ámeintum alvarlegum aukaverkunum lyfja
en European database of suspected adverse drug reaction reports
fr Base de données européenne des rapports sur les effets indésirables suspectés des médicaments
ga Bunachar sonraí Eorpach na dtuascálacha um fhrithghníomh díobháilach amhrasta in aghaidh druga
hr Evropska baza podataka prijave sumnji na nuspojeve lijekova
it Banca dati europea delle segnalazioni di sospette reazioni avverse ai farmaci
lv Eiropas zīpojumu par iespējamām zāļu blakusparādībām datu bāze
lt Pranešimų apie įtariama nepageidaujama reakcija į vaistus Europos duomenų bazė
hu Feltételezett mellékhatásokról szóló jelentések európai adatbázisa
mt Database Ewropea ta' rapporti dwar reazzjonijiet avversi suspettati għal medikina
nl Europese database van rapporten over vermoedelijke bijwerkingen van geneesmiddelen
no Europeisk database over rapporter om antatte bivirkninger
pl Europejska baza danych zgłoszeń o podejrzanym działaniach niepożądanych leków
pt Base de dados europeia de notificações de reações adversas medicamentosas suspeitas
ro Baza europeană de date privind rapoartele despre reacții adverse suspectate la medicamente
sk Európska databáza hlásení o podozreniach na nežiaduce účinky liekov
sl Evropska podatkovna baza poročil o domnevnih neželenih učinkih zdravil
fi EU:n tietokanta lääkkeiden epäilyistä haittavaikutuksista koskevista ilmoituksista
sv Europeiska databasen för rapporter om misstänkta läkemedelsbiverkningar





Attendance to public hearing



2017: Valproate containing medicines

2018: Quinolones and fluoroquinolones

Importance of engaging with patients in EMA

- Engagement with patients:
 - Brings the everyday aspects of living with a disease into the scientific discussions and helps bridge the gap between clinical trial data and real world data
 - Improves transparency and trust
 - Increases understanding and dissemination of EMA outcomes
 - Adds to quality of regulatory outcome
- ALL perspectives are crucial and have ultimately resulted in more meaningful decisions for all concerned.





Any questions?



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Send a question via our website www.ema.europa.eu/contact