EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# How patients contribute to the safety monitoring of medicines

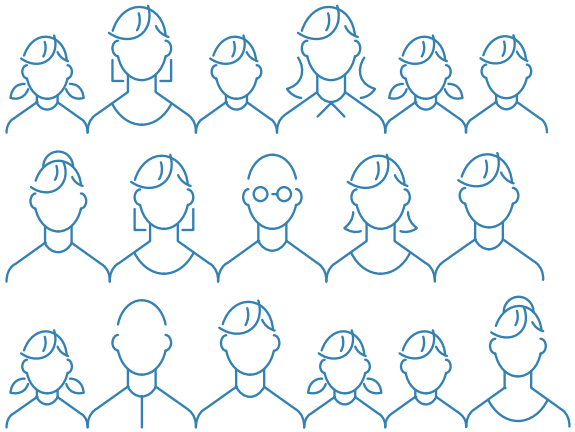
Multi-stakeholder workshop on patient experience data in medicines development and regulatory decision-making

Presented by Sabine Straus on 21 September 2022
PRAC Chair and Medicines Evaluation Board (NL)

An agency of the European Union

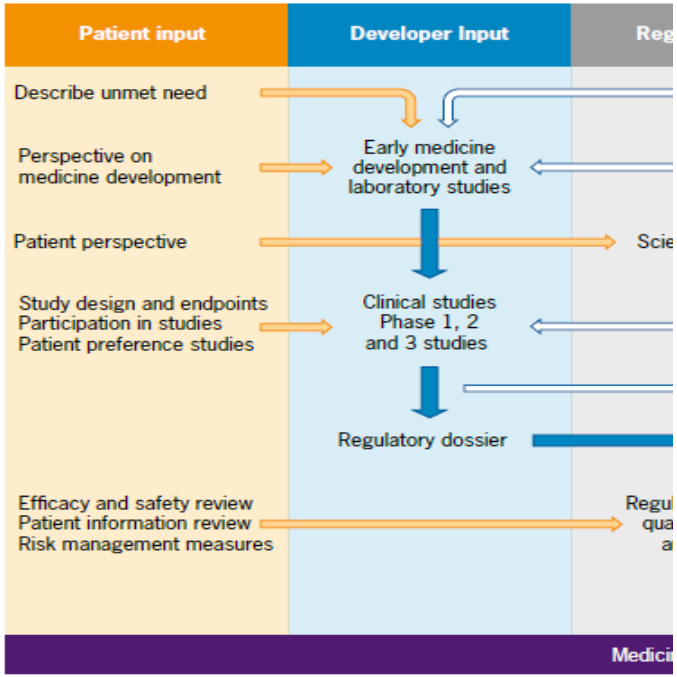
# Outline

- Patient engagement in safety monitoring and risk minimisation
- Patient experience in safety monitoring and risk minimisation
- Added value of patient experience – examples:
  - Public hearings
  - ADR monitoring and Real World Data
  - PRISMA
- Conclusions



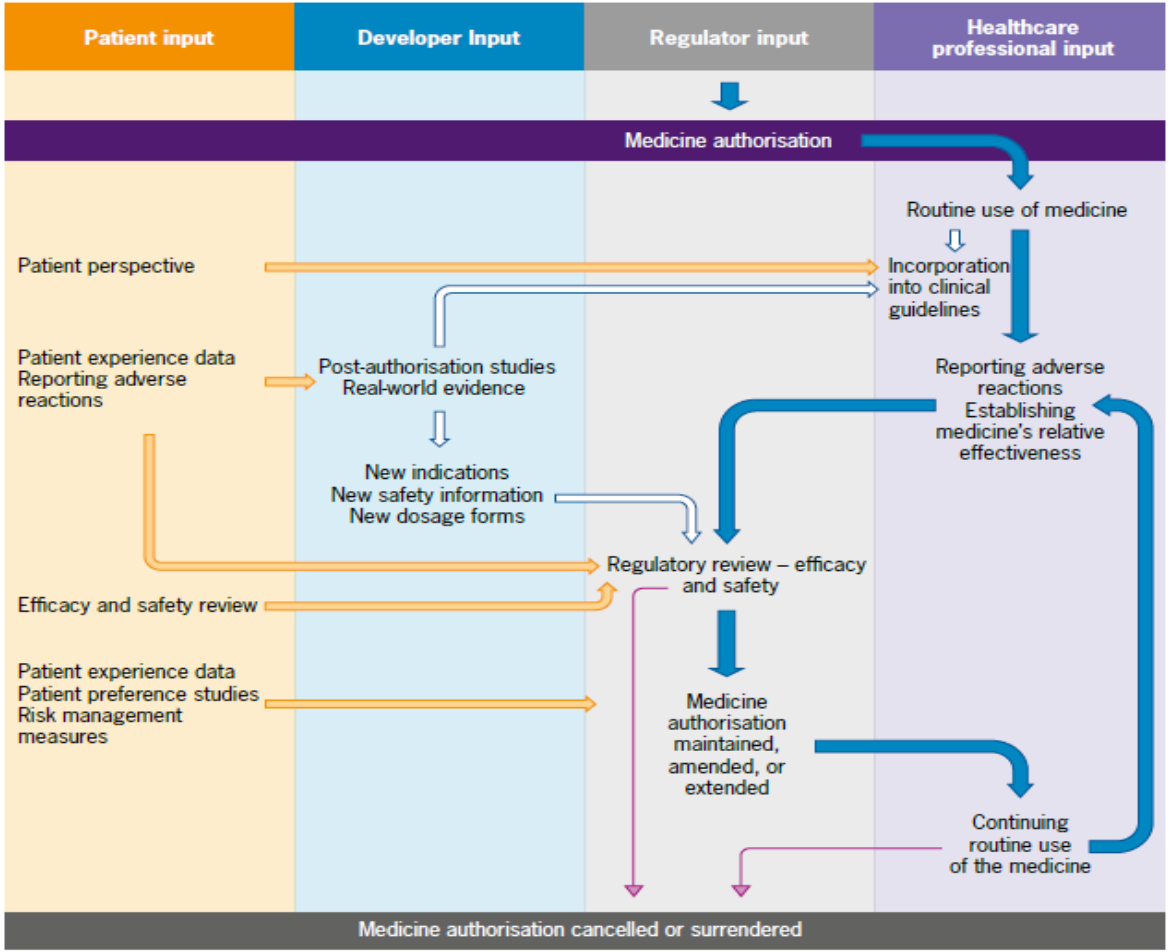
## Figure 1a: Patient involvement during a medicine

Source: CIOMS Working Group XI




## Figure 1b: Patient involvement during a medicine lifecycle – post-authorisation

Source: CIOMS Working Group XI



# Patient engagement in safety monitoring and risk minimisation


Direct reporting


- **Safety committee** (PRAC) = patients are members
- Ad-hoc **expert group meetings** convened by PRAC = patients are participants
- PRAC **written consultation** with patients (f2f /questionnaires/surveys)
- **Stakeholder meetings** (e.g. methotrexate)
- **Public hearings**
- EMA workshops & public consultations on **development /update of regulatory guidance**
- Review of **risk minimisation measures** and **safety communications**

# Patient experience in safety monitoring and risk minimisation

Patient experience data is key for characterizing the safety of medicines throughout their lifecycle

✓ Early medicines' development:

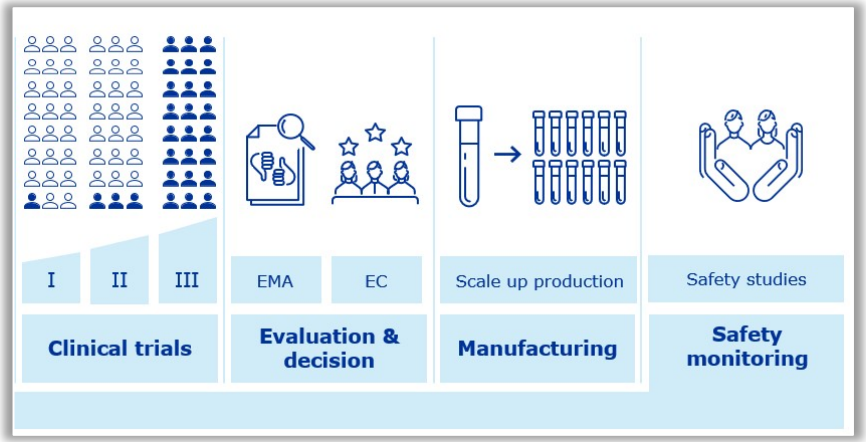
- Design of clinical trials
- Patient preferences on acceptability of ADRs
- Input to product information

✓ Safety monitoring (pharmacovigilance activities)

- Registries / Patient Reported Outcomes

✓ Risk minimization measures:

- Patient preferences on tolerability
- Compliance with risk management measures
- Prevention of medication errors

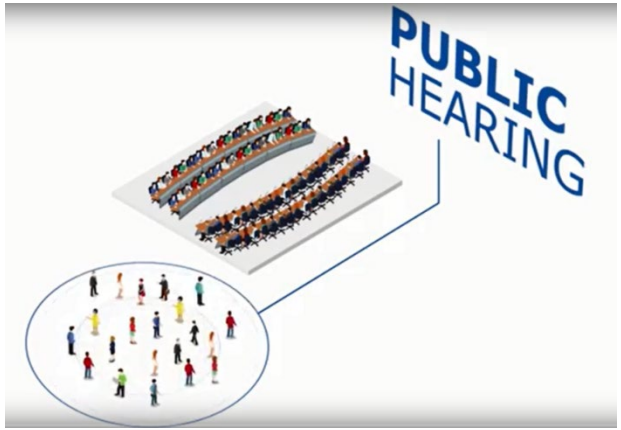


# Added value of patient experience (I)

## Public hearings at PRAC

2017: Valproate containing medicines

2018: Quinolones and fluoroquinolones




## Stakeholder meetings with PRAC

### With patients and healthcare professionals

- **Valproate**;

Written consultation – public hearing – stakeholder meeting – written consultation

- **Retinoids**;

Written consultation – stakeholder meeting

- **Methotrexate**

Written consultation with HCP – medication errors – different doses depending on condition being treated

# Added value of patient experience (II)

## Adverse Drug Reaction (ADR) reporting

- Many ADRs are only identified after authorization
- Around one-third of newly identified safety issues are added to the section warnings and precautions after marketing
- Patients play a key role in ADR reporting

## Real World Data (RWD)

- ADR reporting "is" Real World Data
- Post-market pharmacovigilance pivotal to maintaining long-term patient safety
- RWD useful in vulnerable patient populations that are often excluded from CTs (e.g. older people, pregnancy)
- Social media as opportunity for pharmacovigilance: identify behavioral patterns, environment, drug use, drug-drug interactions, and ADRs.

# Added value of patient engagement (III)

## PRAC Risk Minimisation Alliance (PRISMA)

- Pilot working group on enhancing PRAC's engagement with patients and healthcare professionals:
  - PRAC members/alternates+ patients/HCPs PRAC representatives
  - two representatives from the EMA's GP Forum
  - PRAC rapporteurs
  - EMA
- Monthly online meetings (60 min) to discuss options risk minimisation measures (RMM) and how they can be implemented from a patient and healthcare perspective, as informal input for PRAC decisions in regulatory action
- Pilot running from July 2022 until 2023, with views to making it operative afterwards

# Conclusions

- Patient experience data critical for:
  - Safety monitoring during clinical trials and post-marketing ADR reporting
  - Acceptability and preferences of risk minimization measures
- PRAC: patient experience is included in benefit-risk decision making
- Patients have an important part to play in gathering, analysing and using real-world data
- EMA/PRAC looking to expand use of real-world evidence, patient reported outcomes, patient preferences and patient experience data, for safety monitoring
- The combination of various data sources and expertise will result in safer and more effective pharmacotherapy for everyone
- The voice of the patient critical during the whole life cycle of a medicine

# Any questions?

## Further information

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