EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How are medicines evaluated at the EMA – Part II Pharmacovigilance

Nathalie Bere, Patients relations co-ordinator

Pharmacovigilance

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines.

Authorised!

What now?

What does Pharmacovigilance really mean

- Reducing uncertainty regarding **known** risks
- Generating new information regarding **unknown** risks

What we know at the end of the clinical trial programme…

Is the tip of the iceberg

compared to what we don't know! … which is the rest of the iceberg..

How do we monitor the risks?

Patient experiencing Adverse Drug Reaction (ADR)

OR

Healthcare professional

Adverse Drug Reaction (ADR) report

Marketing Authorisation Holder (MAH)

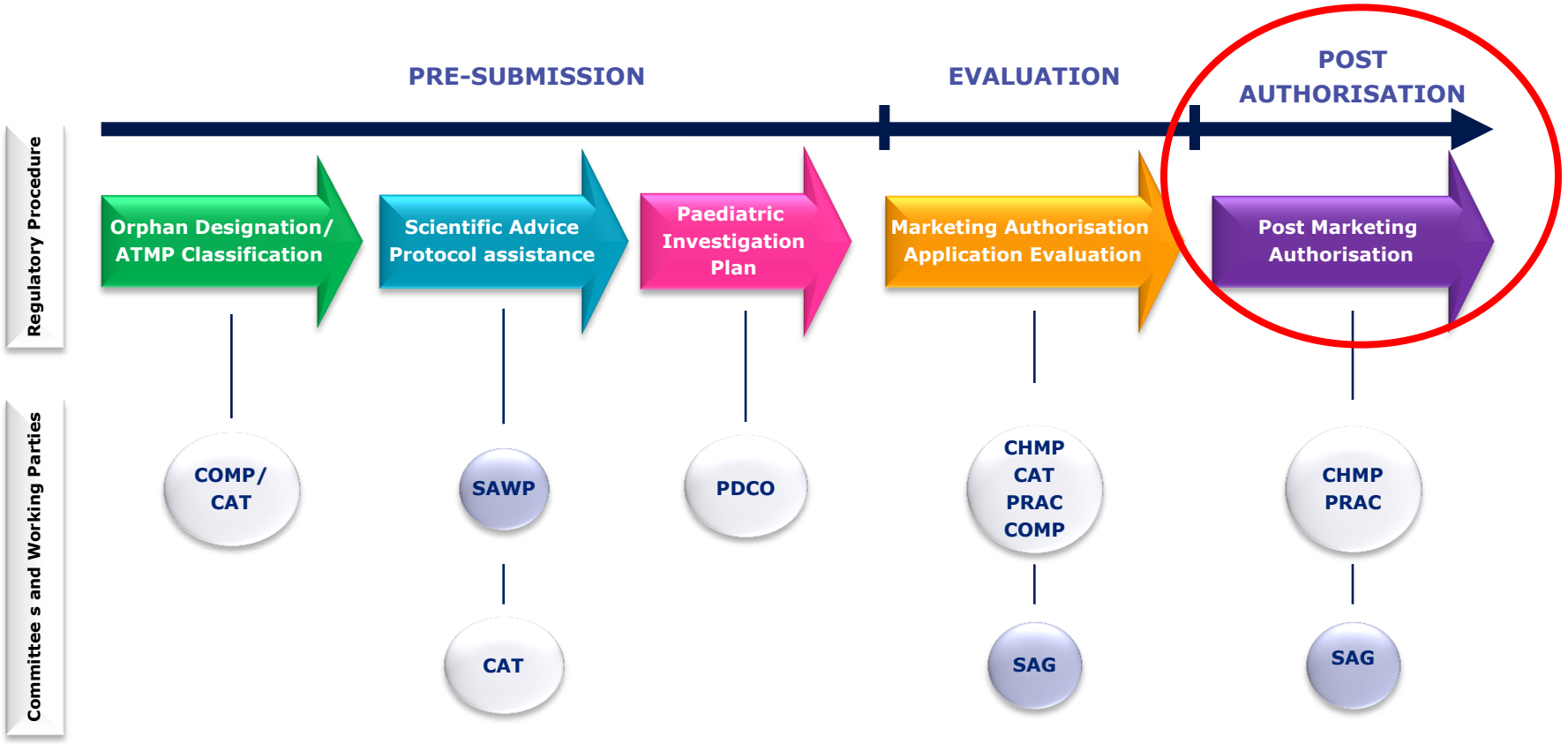
OR

National Competent Authority (NCA)

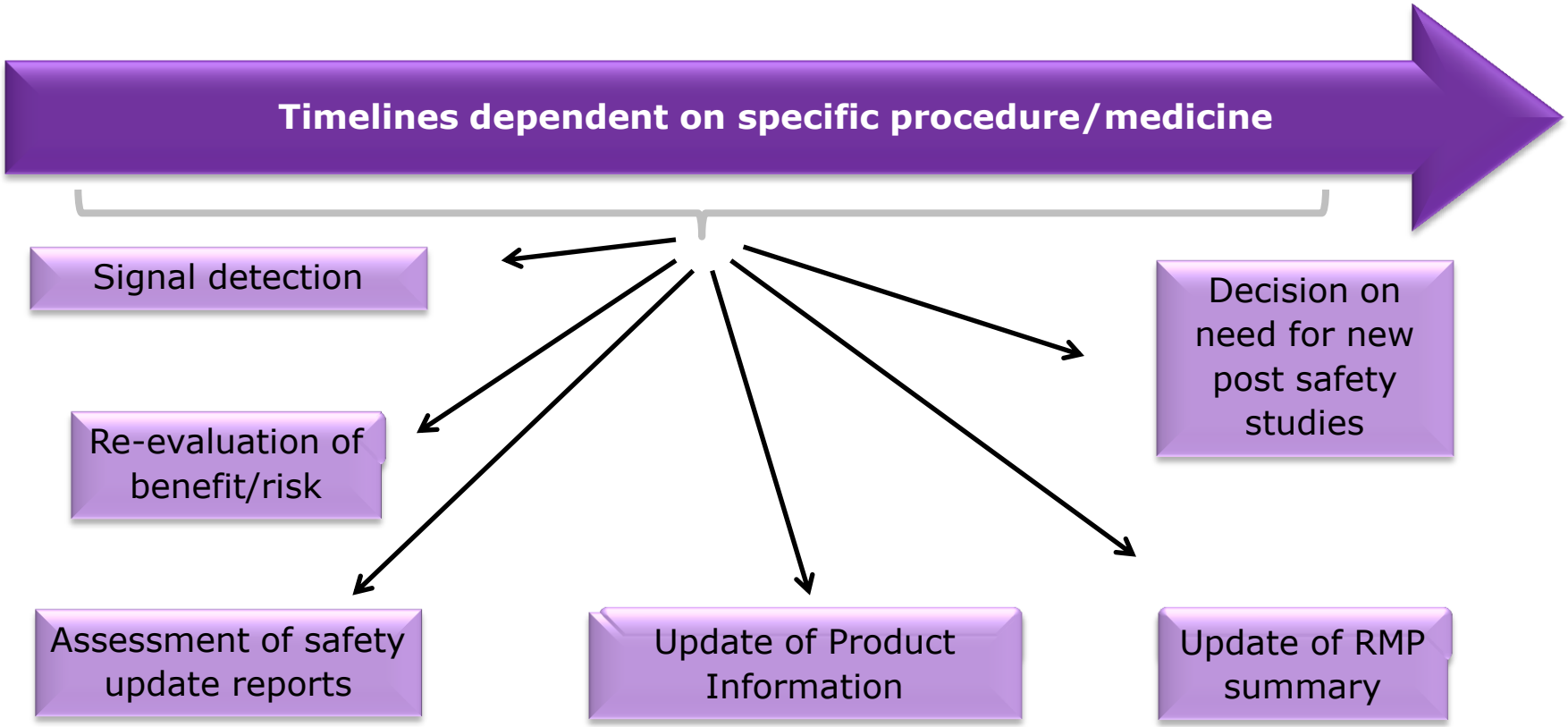
EudraVigilance Human

Safety monitoring

Committees in human Medicines Regulatory process



Pharmacovigilance and Risk Assessment Committee



What safety actions can be taken

- When new information arises that warrants action, regulators have several tools available:
- Update patient information/Summary of Product Characteristics (SmPC)
- Inform patients and/or healthcare professionals (Safety Communications, Direct healthcare professional communication (DHPC), educational material)
- Review of benefit-risk profile of medicine (referral)
- Restrict access to medicine

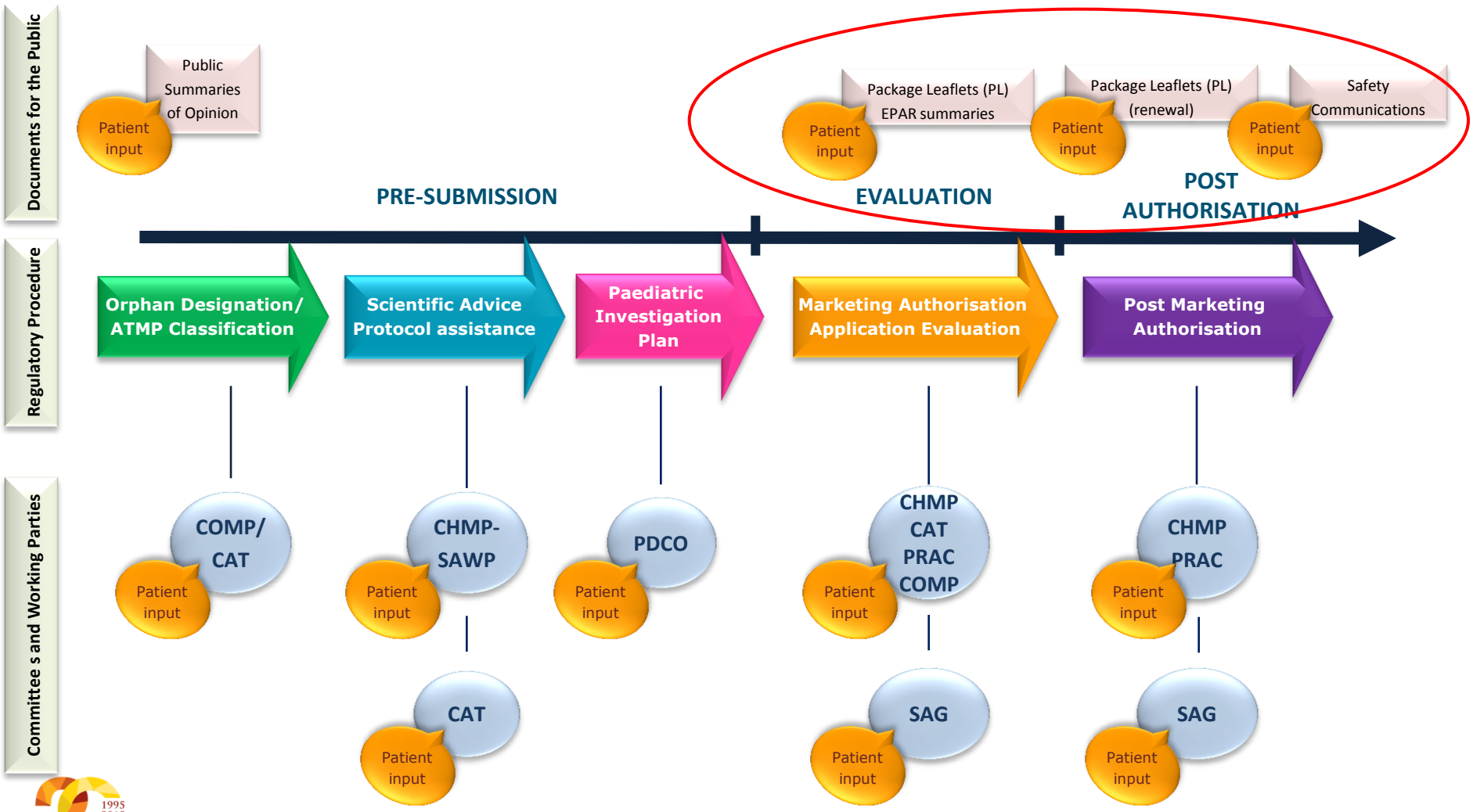
What role do Patients play in Pharmacovigilance

Patients play an essential role in key stages; from reporting to pharmacovigilance decisions;

- Scientific advisory/ad hoc expert group meetings convened by PRAC
- Written consultations on safety issues/ risk minimisation actions
- Review of product information and safety announcements
- 2016: Public hearings

Review of Documents

Patient involvement along the medicine lifecycle at EMA



Which documents do patients review?

1. **The Package leaflet (PL)** is supplied to the patient in the package in which the medicine is contained, and provides information related to the use of the medicine

2. **The European Public Assessment Report (EPAR) summary** is a lay-language document, which provides a summary of the grounds on which the EMA/CHMP based its recommendation for the medicine to receive a marketing authorisation

3. **Safety communications** are documents specifically addressed to the public on authorised medicines that convey an important (emerging) message relating to the medicine (e.g. withdrawal or suspension for safety reasons, new contraindication or warning, or there is a product defect).

Why and how are patients involved?

- To ensure information is clear and understandable
- To raise any questions on unclear/missing information
- To improve the information aimed at patients for safer use of medicines
- Documents are sent to patient organisations representing the therapeutic area in question
- Documents are exchanged by e-mail (via a secure system called Eudralink) with comments made preferably using track changes mode or comment boxes.

Package Leaflet (PL)

- PL is part of the "product information" that is approved at the time of marketing authorisation
- Initially prepared by applicant when requesting a marketing authorisation
- All new and renewal PLs are sent for review to relevant patients with 10 days to comment
- Patients review in parallel to other scientific/linguistic reviewers
- Committee adopts the PL as part of its opinion
- Final PL published with Commission Decision
- After approval of the medicine, the PL is regulary updated

European Public Assessment Report (EPAR) summary

- At the time of marketing authorisation, the Agency publishes a European Public Assessment Report (EPAR) for the medicine which reflects the scientific conclusions reached by the CHMP
- It contains an EPAR summary written in a manner that is understandable to the public
- Drafted by the EMA immediately after the CHMP opinion and sent for review to the EMA project managers, CHMP rapporteurs, patients and the applicant
- All new EPAR summaries are sent for review to relevant patients with 10 days to comment
- The EPAR summary is finalised within about one month, adopted by the CHMP and then translated into all official EU languages before publication.
- EMA implements patient comments where possible

Safety communications (SC)

- SCs concern authorised medicines and tend to relate to major safety issues, often within 'referral' procedures
- Preparation of SCs implies short timelines with multiple stages of review and input from internal and external experts with limited predictability
- Once finalised SCs are published on the Agency website
- All SCs are sent to patients for review, if feasible within timelines (usually 24 hrs)
- Once aware of an upcoming safety concern EMA will contact organisation(s) requesting availability to review the communication
- Draft document is forwarded to the expert(s), usually with 12-24 hours deadline, in some urgent cases only 3-4 hours may be available for consultation.

Input from patients, completes the picture…..

Acronyms

- ADR : Adverse Reaction
- AR : Assessment Report
- CHMP : Committee for Medicinal Products for Human Use
- LoQ : List of Questions
- LoOIs : List of Outstanding Issues
- MAH : Marketing Authorisation Holder
- PRAC : Pharmacovigilance Risk Assessment Committee
- PSUR : Periodic Safety Update Report
- RMP : Risk Management Plan
- SAG : Scientific Advisory Group
- COMP: Committee for Orphan Medicinal Products;
- CHMP: Committee for Human Medicinal Products;
- CAT: Committee for Advanced Therapies;
- PDCO: Paediatric Committee;
- SAWP: Scientific Advice Working Party;
- SAG: Scientific Advisory Group;
- PRAC: Pharmacovigilance and Risk Assessment Committee;
- EPAR: European Public Assessment Report;
- ATMP: Advanced Therapy Medicinal Product
- SmPC : Summary of Product Characteristics

Contact

Nathalie Bere

Patient relations
Stakeholder and Communication Division
nathalie.bere@ema.europa.eu
www.ema.europa.eu
PCWPsecretariat@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 8452 **Facsimile** +44 (0)20 3660 5550
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**