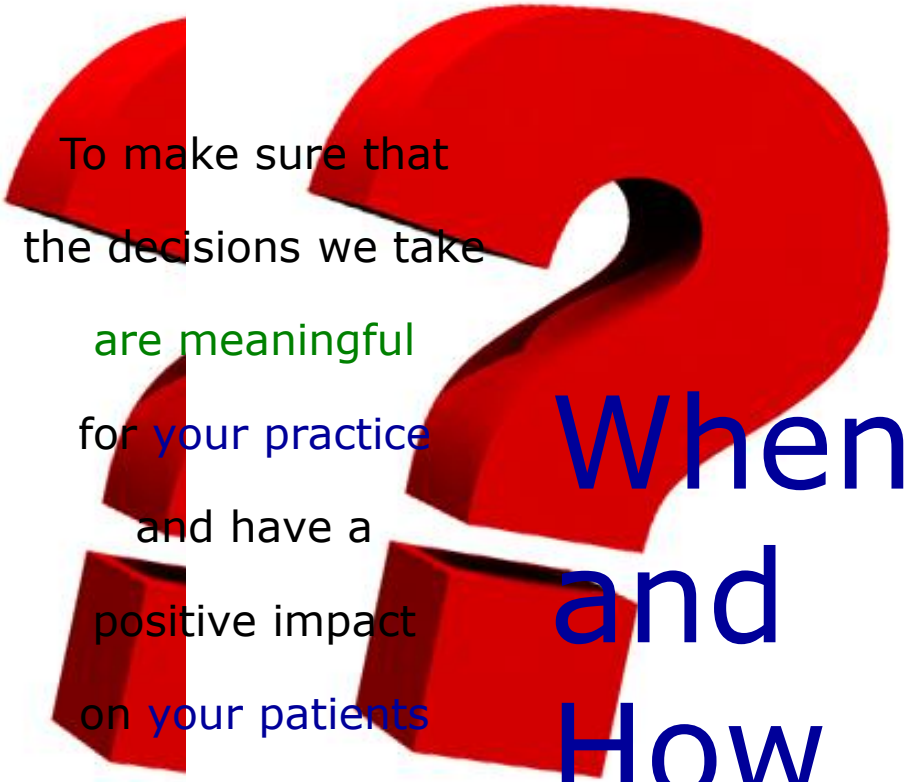
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Bringing real-life experience into the evaluation of medicines

EMA interaction with healthcare professionals

Presented by Ivana Silva on 19 April 2016
Patients and Healthcare Professionals Department / Stakeholders and Communication Division

Why do we need to talk to each other



To make sure that

the decisions we take

are meaningful

for your practice

and have a

positive impact

on your patients

When and How

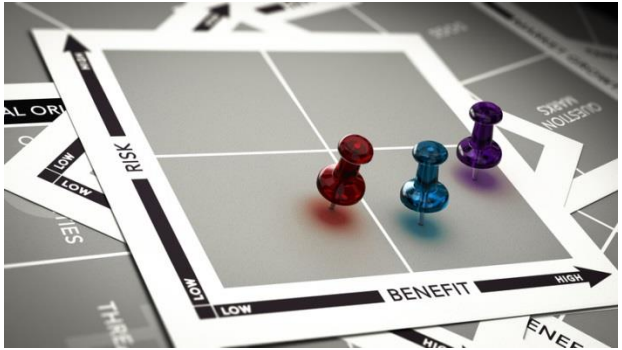
The various roles of the EMA

The Agency is responsible for:

- The **evaluation of marketing authorisation** for **human and veterinary** applications submitted by pharmaceutical companies
- The coordination of European **pharmacovigilance** (supervision of the medicines on the market)
- The provision of **scientific advice** on the development of medicines
- The evaluation of applications for **orphan** designation in EU
- The evaluation of **paediatric investigation** plans (or waivers)
- The evaluation of **arbitration** and **referral** procedures
- The provision of good quality and independent **information** on the medicines it evaluates to patients and healthcare professionals
- The coordination of Member States' **inspections** *(GMP, GCP, GLP)*

Where do the regulatory and clinical contexts come together?

Benefits/risks balance



Risk management and communication

Medicines information

Approved via EMA (centralised procedure)

Dabigatran	Cangrelor
Rivaroxaban	Canagliflozin
Bivalirudin	Loxapine
Aripiprazole	Paliperidone
Imatinib	Lurasidone
Sunitinib	Olanzapine
Insulin degludec	Duloxetine
Pioglitazone hydrochloride	Orlistat

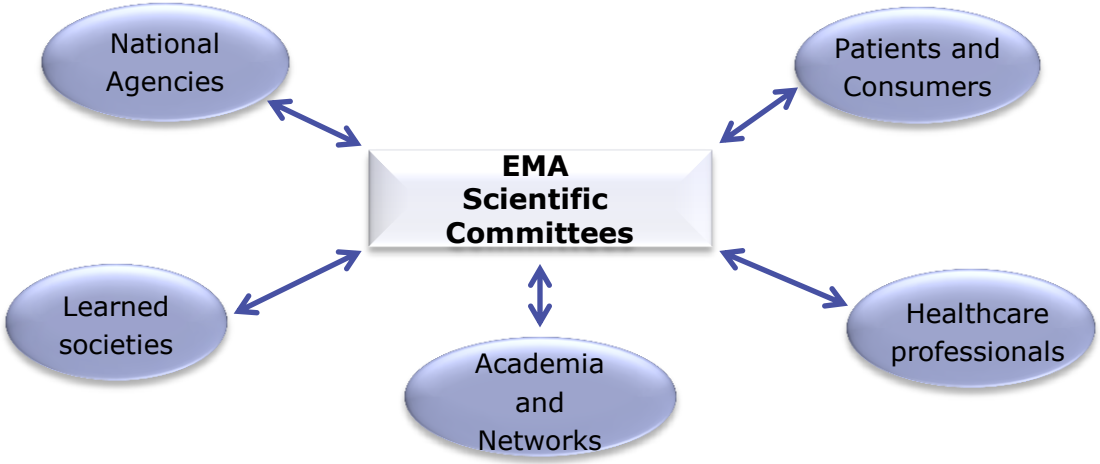
Safety reviews involving nationally authorised medicines (EMA level)

- Valproate
- Codeine
- Domperidone
- Diclofenac
- Tetrazepam

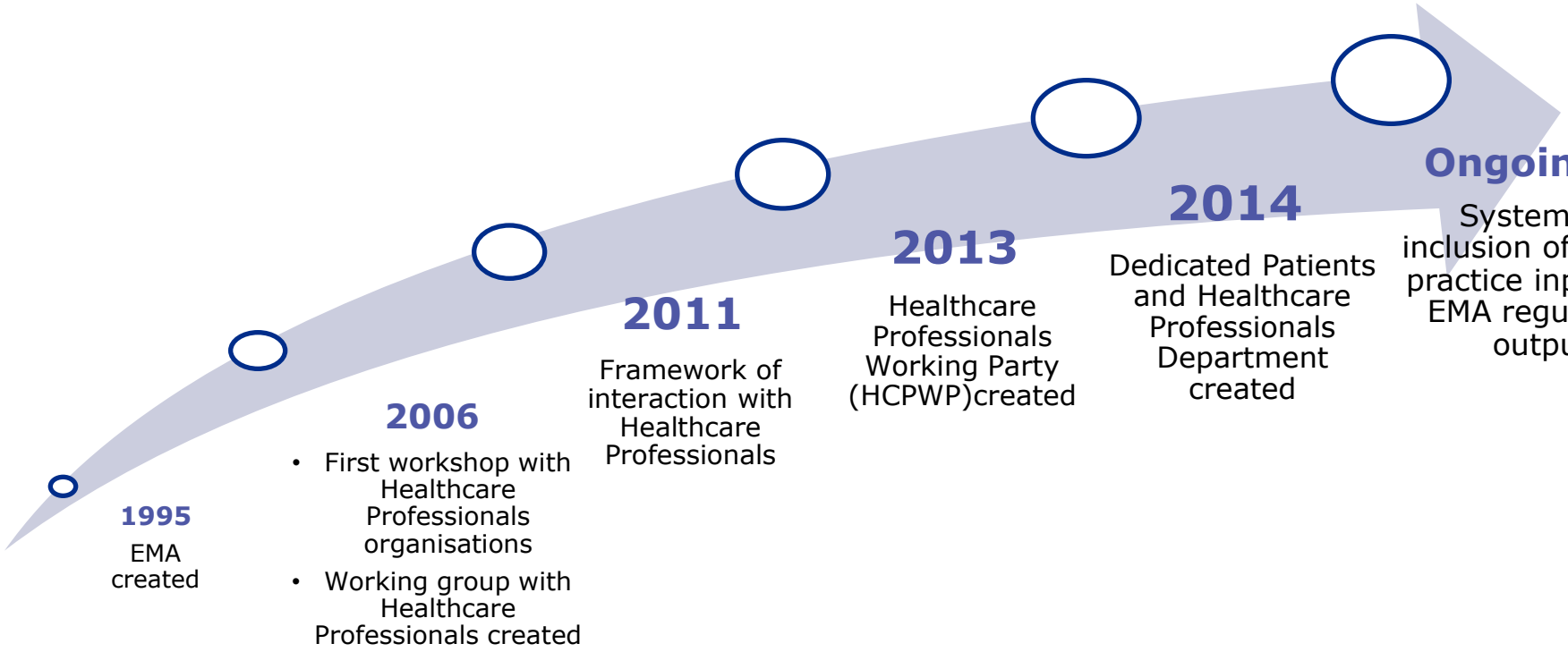
Outcomes of periodic safety update report single assessments

European Regulatory Network

The European regulatory system for medicines is a unique model in the global regulatory environment.



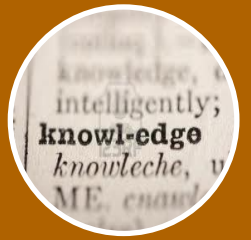
Collaboration of EMA with healthcare professionals



Framework for interaction between the EMA and healthcare professionals

Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**

Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines



Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations

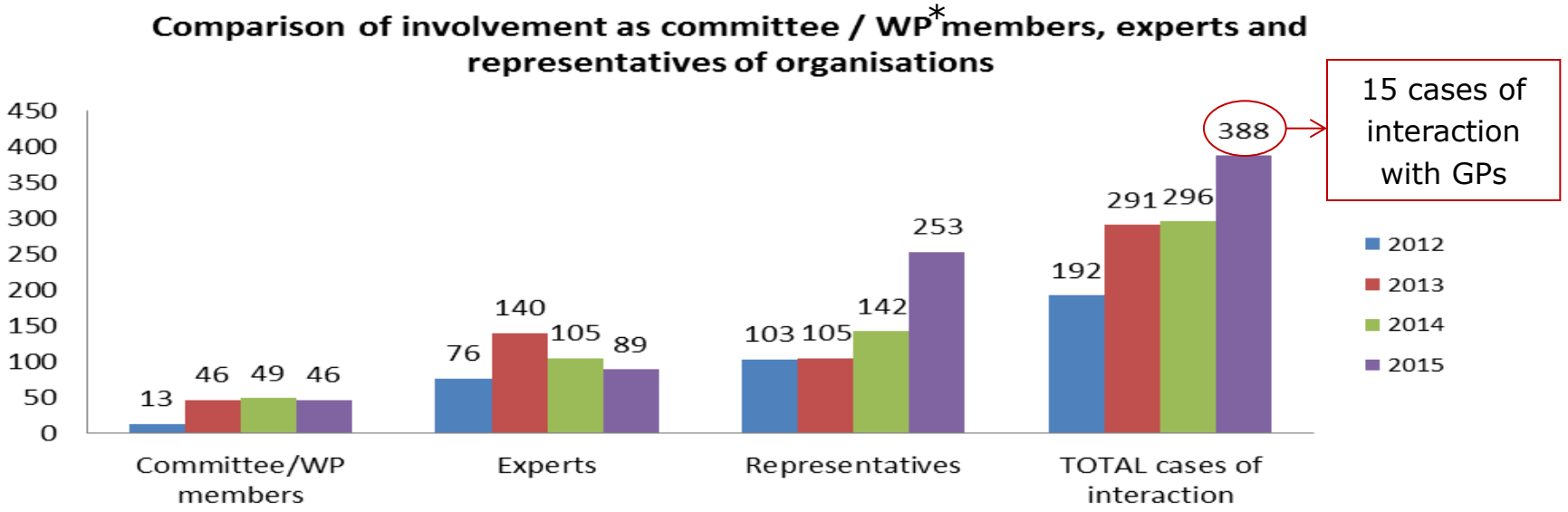
Maintenance of the Network of European healthcare professional organisations (HCPOs)

- 29 eligible organisations by Dec 2015
- Transition into revised eligibility criteria

Healthcare Professionals Working Party (HCPWP)

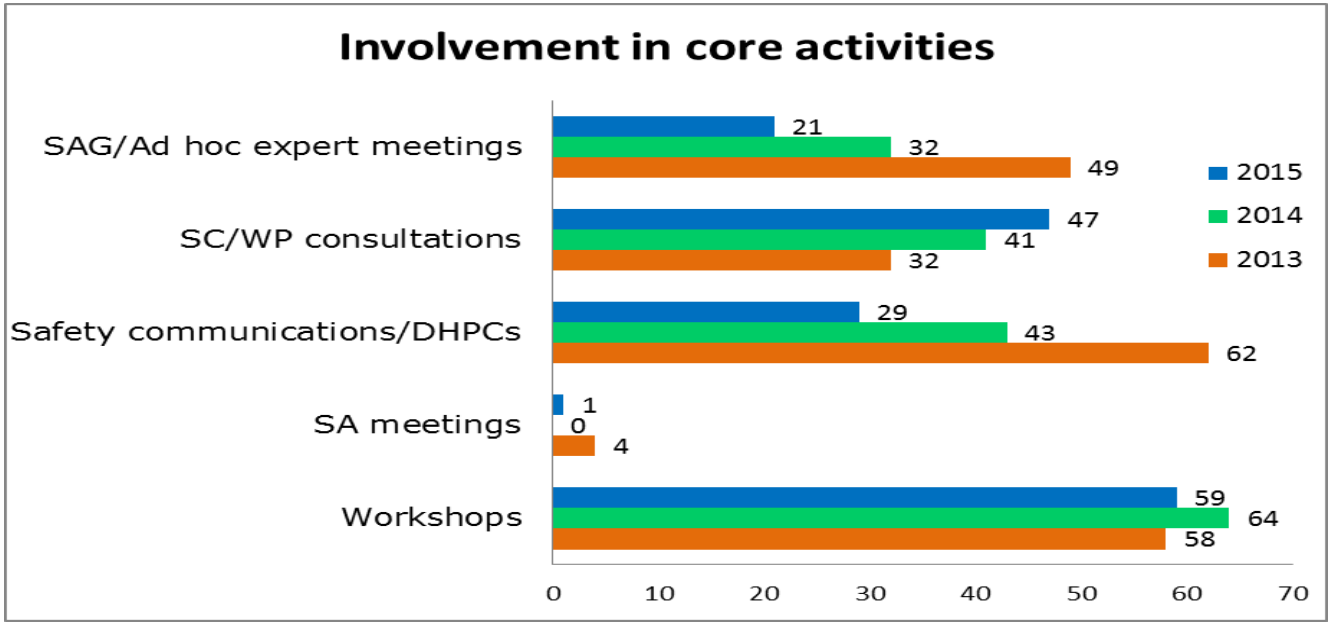
Platform for dialogue and exchange on relevant issues concerning medicines;
The HCPWP provides recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to healthcare professionals

Involvement in core activities



*WP – working parties

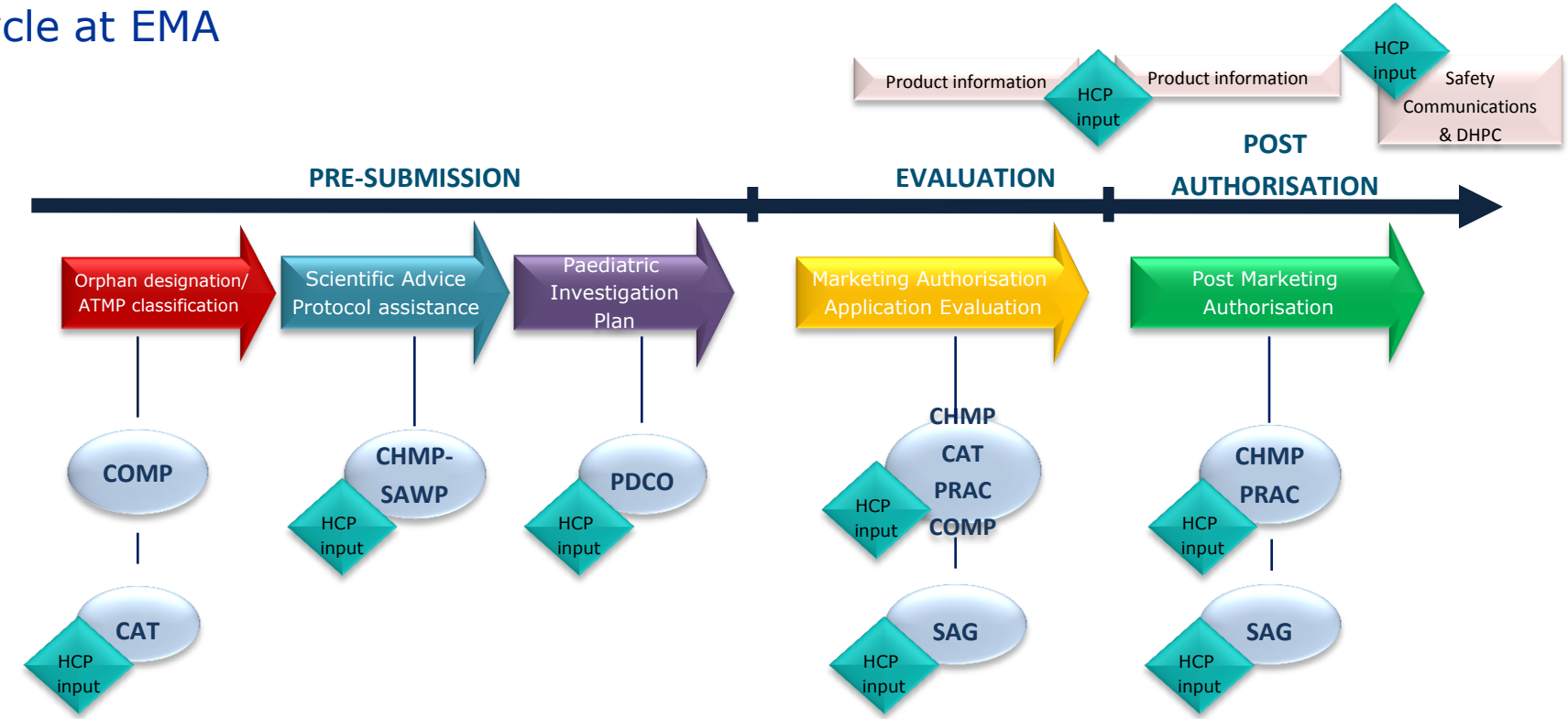
Sustained involvement in core activities



- SAG – Scientific Advisory Group
- SC – Scientific Committee
- WP – Working Party
- DHPC – Direct healthcare professional communication
- SA – Scientific Advice

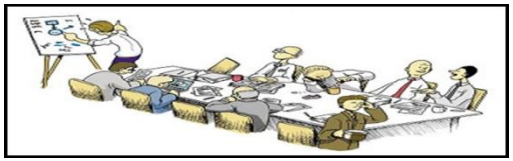
- Input and participation continues to be spread-out by various core activities
- Cases of interaction with previous years differ, due to the nature of the Agency's activities

Opportunities for Healthcare Professional involvement along the medicine lifecycle at EMA

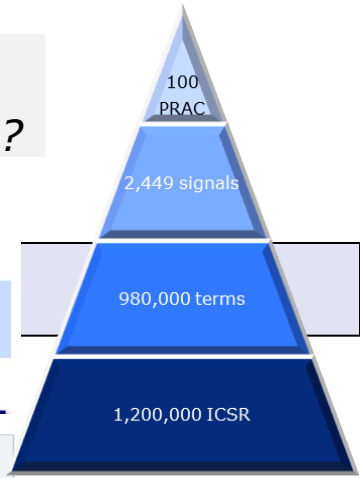


Safety monitoring

Research & Development – Risk management Plan – Periodic Safety Update – Spontaneous report



Real-life data
e-health records?



Non-clinical and clinical safety investigations

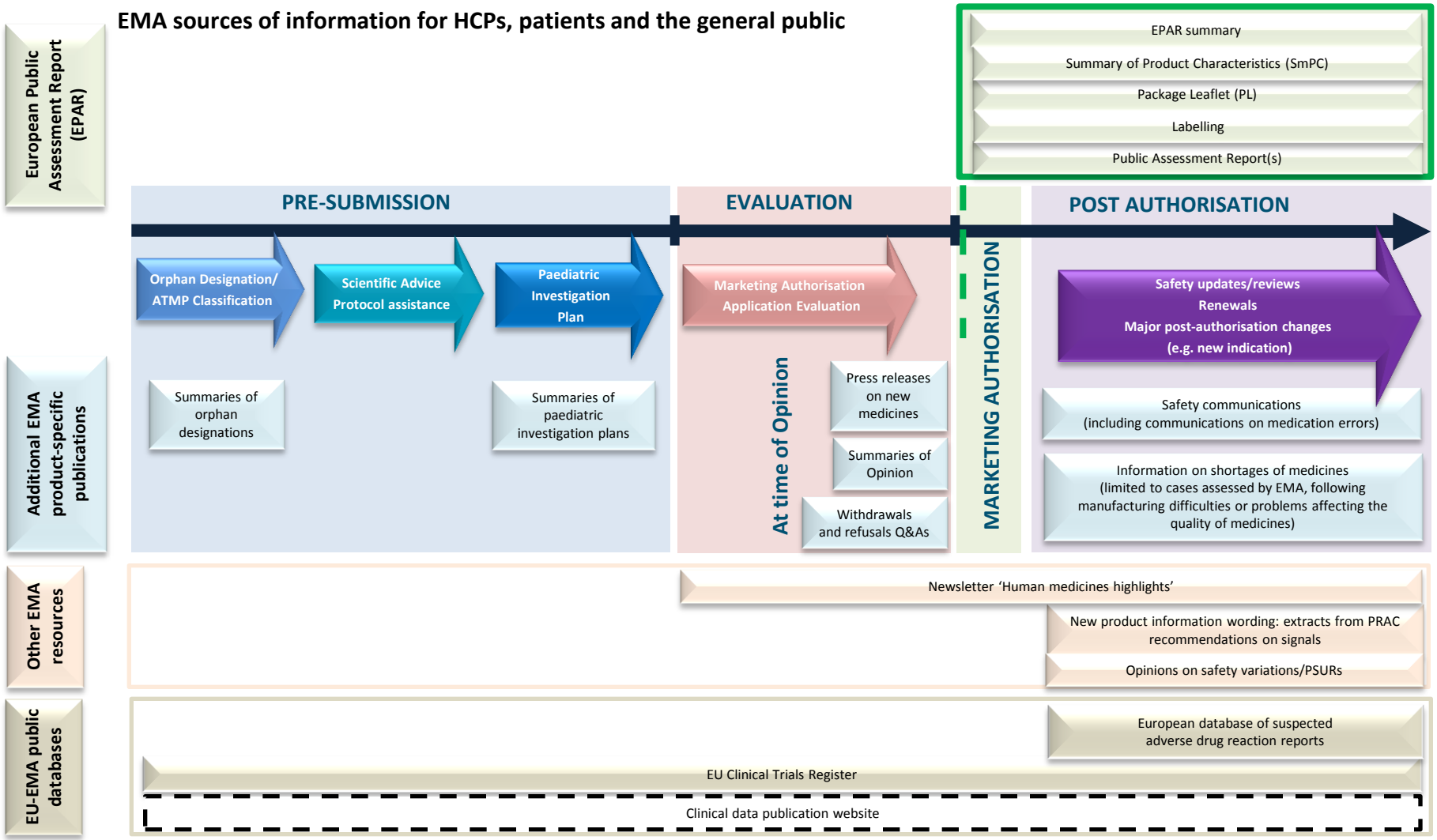
Clinical trials safety data

e.g. post-authorisation safety study or collection of data in subpopulation or drug interaction

How to report a side-effect

Scientific literature

EMA sources of information for HCPs, patients and the general public



Where do the regulatory and clinical contexts come together?

Benefits/risks balance

Risk management and communication

Medicines information

Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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