EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How are medicines evaluated at the EMA

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Patient interaction / Stakeholders and communication Division

An agency of the European Union

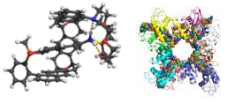
Overview of medicines development

EUROPEAN MEDICINES AGENCY

Non-clinical

Drug discovery

Identification of candidate



Non-clinical testing

Safety and Efficacy tests

Clinical

Phase I

Phase II/III

Regulatory

Submission of marketing authorisation request

Approval after evaluation by authorities

Availability and pricing dependent upon individual country

Post-Marketing

Phase IV

The European System

Centralised Procedure

Mutual Recognition/ Decentralised Procedure

National Procedures

Optimised utilisation of resources
Harmonised scientific opinions
Harmonised information to healthcare professionals & patients

EMA: focal point of the centralised procedure

ONE

Marketing Authorisation application

Evaluation

Authorisation in all EU

Invented name

Product information

(Summary of Product Characteristics (SmPC), Labelling, Package Leaflet (PL))

ALL

EU languages

Which medicines are **mandatory** for evaluation at the EMA?

- Rare diseases
- HIV, cancer, neurodegenerative disorders, diabetes
- Auto-immune diseases, viral diseases
- All biotech products
- Gene therapy
- Monoclonal antibodies

± Other innovative products

The EMA is **not** responsible for pricing or reimbursement

Eligibility "Optional Scope"

New Active Substances

Significant Innovation

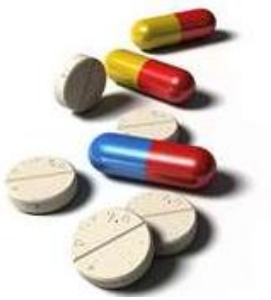
(Therapeutic, and/or Scientific, and/or Technical)

OR

Interest of Patients at Community Level

Medicines outside the mandatory scope can also be evaluated at EMA if they meet certain criteria.

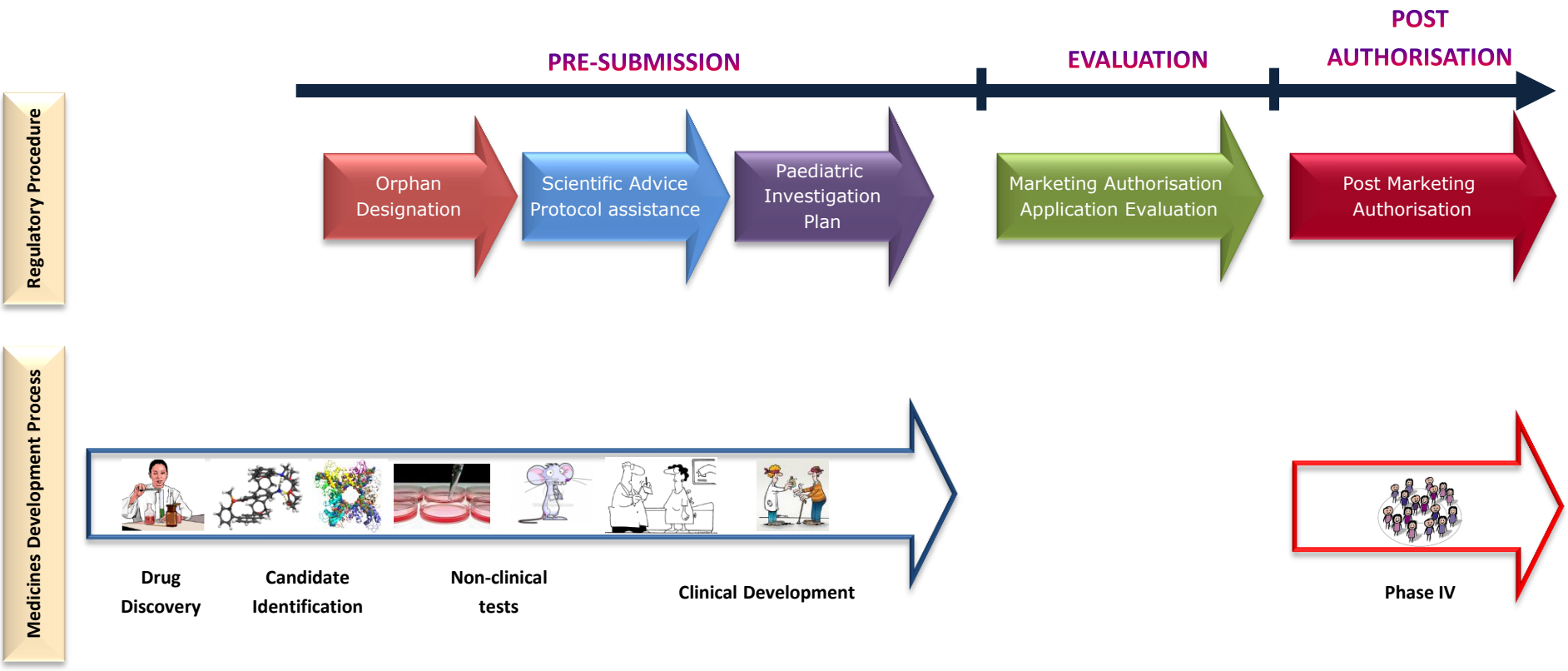
The various roles of the EMA



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**

Medicines Lifecycle: Development and Regulatory



Type of Approvals

Normal:
Comprehensive data

Exceptional Circumstances:

- Comprehensive data not available and cannot be provided
- Must meet criteria (rarity, medical ethics, state of scientific knowledge)

Conditional Approval:

- Comprehensive data not available; to be provided after approval
- Must fulfil scope (orphan drugs, emergency threats, serious and life-threatening diseases)
  Approval valid for 1 year, renewable

EMA-EU Network

28 EEA Member States
+ 4,500 European experts

EU institutions:
Commission - Parliament

Committee for Human Medicinal Products (CHMP)

Management Board

Committee for Veterinary Medicinal Products (CVMP)

Paediatric Committee (PDCO)

EMA Secretariat

Committee for Orphan Medicinal Products (COMP)

Committee for Herbal Medicinal Products (HMPC)

Pharmacovigilance Risk Assessment Committee (PRAC)

Committee for Advanced Therapies (CAT)

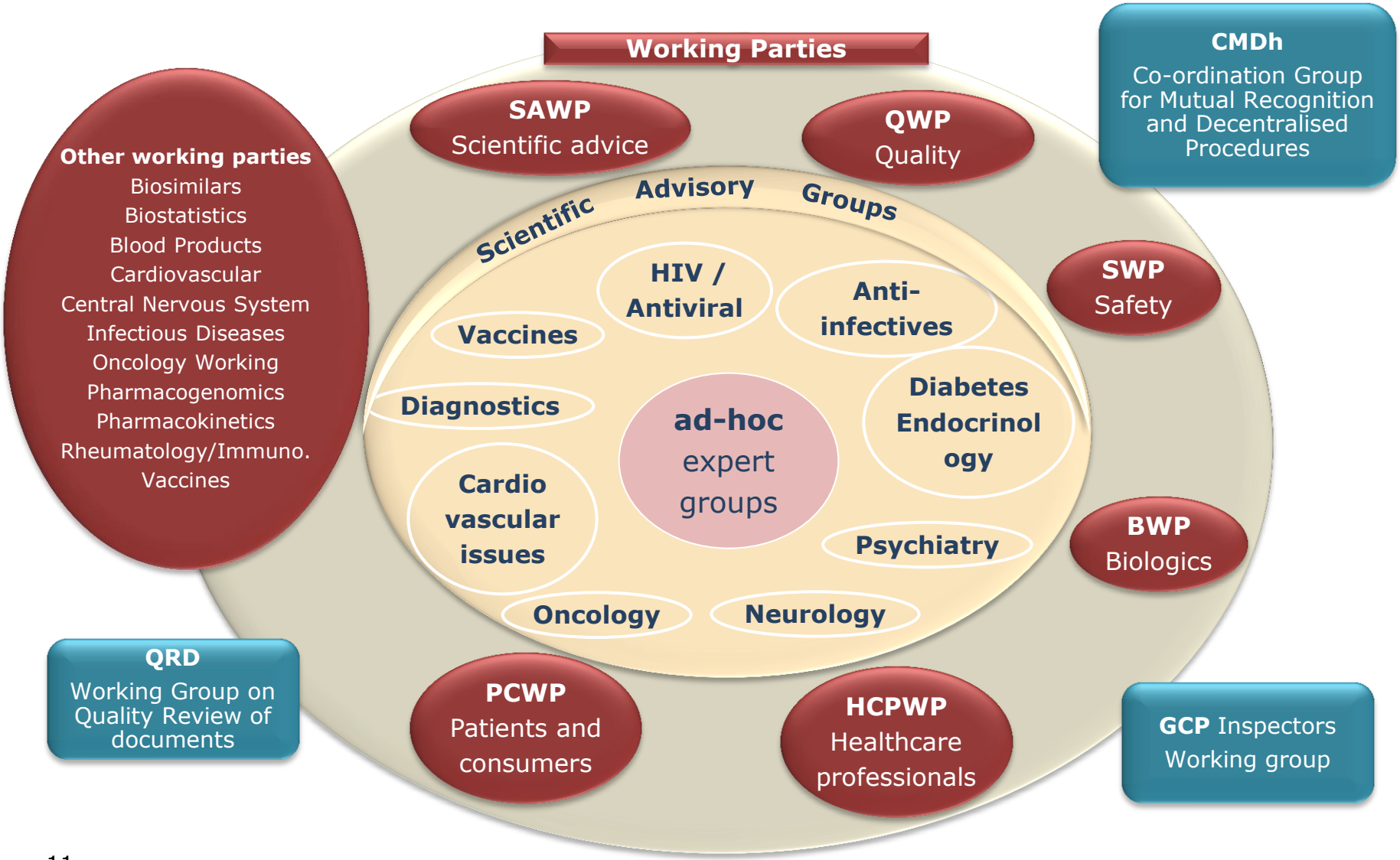
CHMP*

1 scientific expert member nominated by each member state + 1 alternate
5 co-opted members

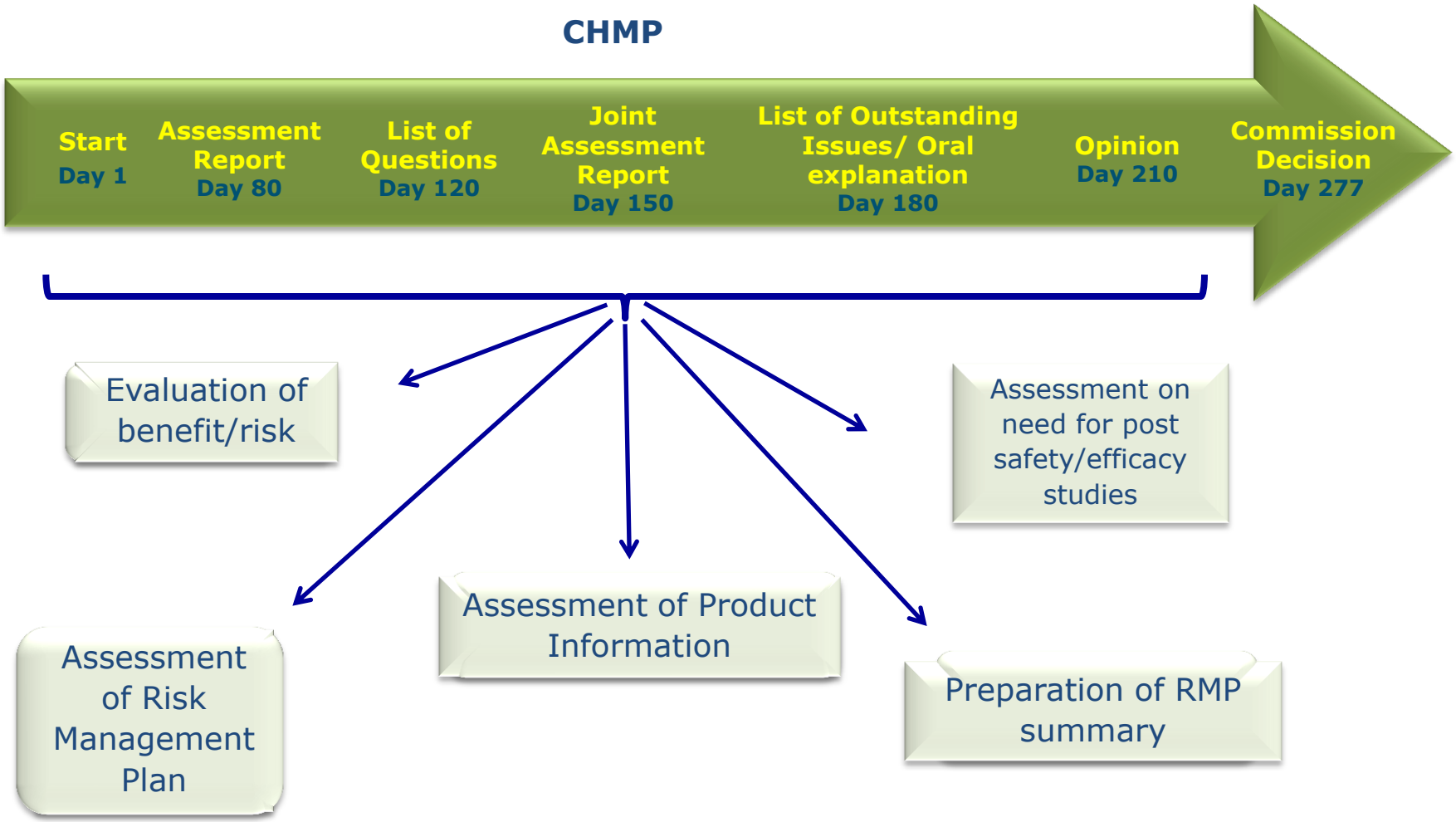
Chair: Tomas Salmonson

*Committee for Human Medicinal Products

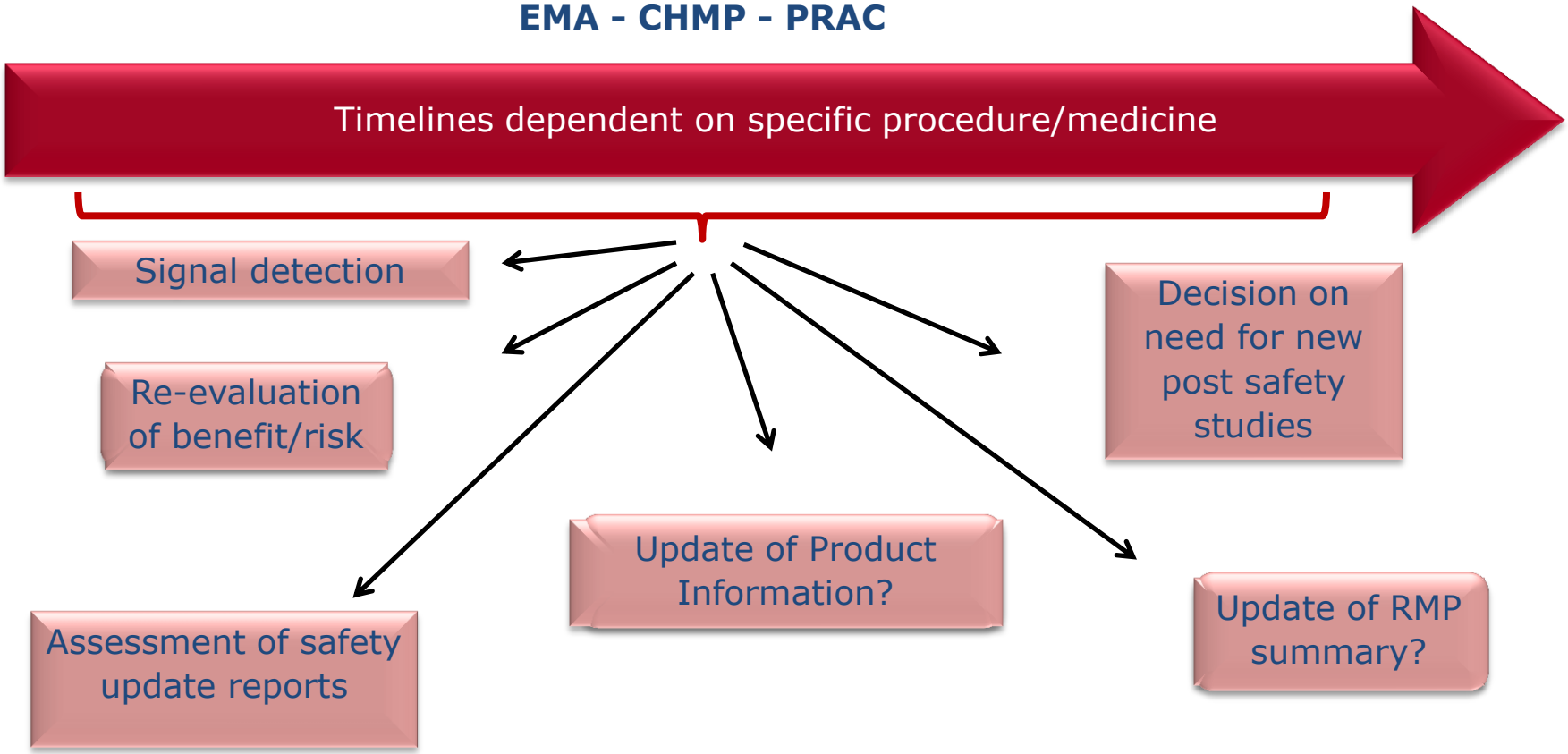
Working Parties and other Groups



EVALUATION OVERVIEW

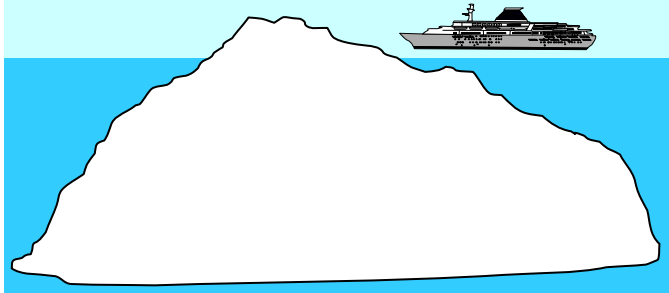


POST-AUTHORISATION OVERVIEW



Pharmacovigilance and Risk Management

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

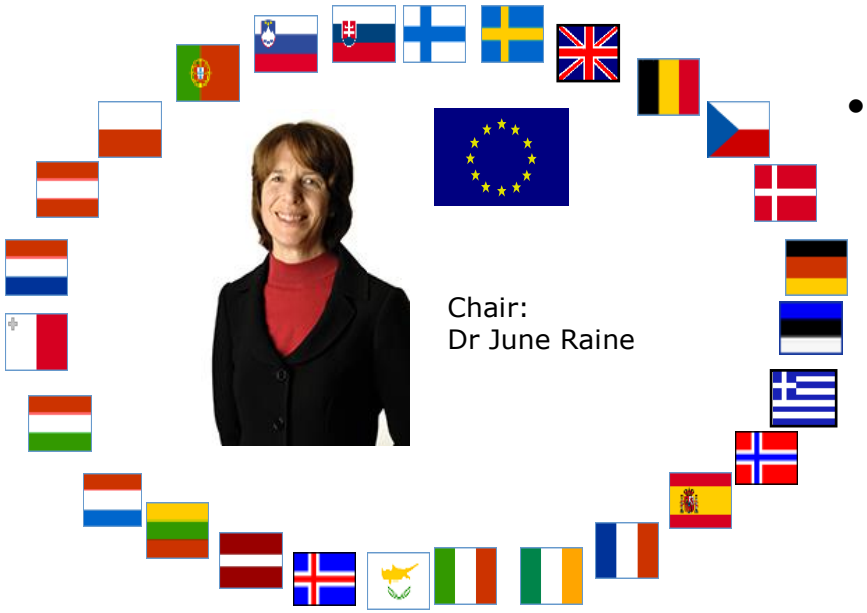


What we don't know!

- What happens when the medicinal product is used in normal practice?
- What is its adverse event profile?

Pharmacovigilance Risk Assessment Committee (PRAC)

Assesses aspects of risk management (detection, assessment, minimisation and communication of risk of adverse reactions)



- 1 member (+ 1 alternate) per Member State
  - plus Norway & Iceland
  - 6 experts nominated by EC
  - 1 member (+ 1 alternate) healthcare professionals
  - 1 member (+ 1 alternate) patients organisations

Pharmacovigilance and Risk Management;

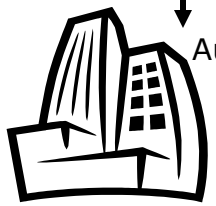
Data Collection and Management

Patient with Adverse Drug Reaction (ADR)

Healthcare professional

ADR report

OR

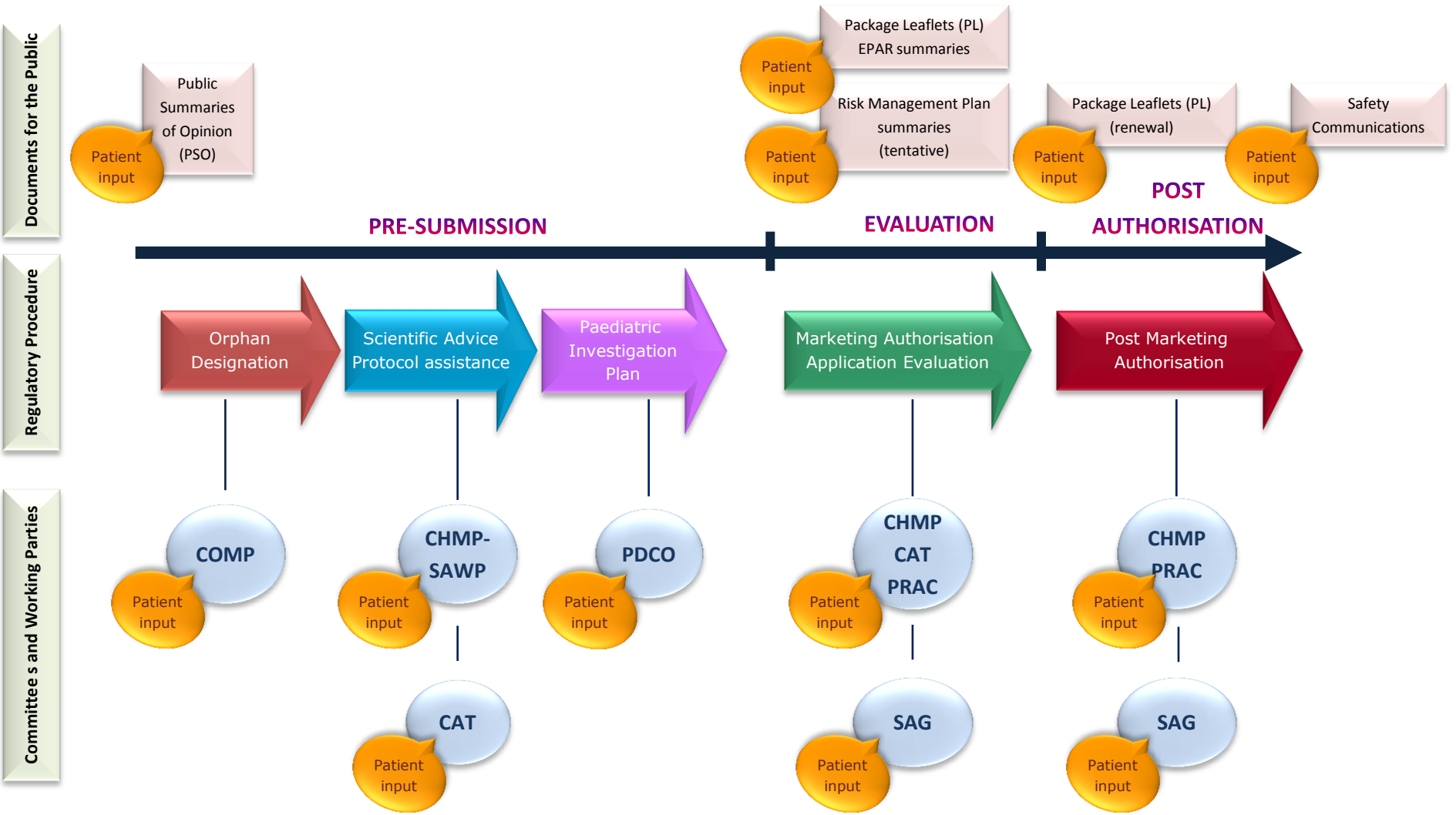


Marketing Authorisation Holder (MAH)

National Competent Authority (NCA)

EudraVigilance Human

Safety monitoring


Documents for the Public
Regulatory Procedure
Committee s and Working Parties
Public Summaries of Opinion (PSO)
Patient input
Package Leaflets (PL) EPAR summaries
Patient input
Risk Management Plan summaries (tentative)
Patient input
Package Leaflets (PL) (renewal)
Patient input
Safety Communications
Patient input
PRE-SUBMISSION
EVALUATION
POST AUTHORISATION
Orphan Designation
Scientific Advice Protocol assistance
Paediatric Investigation Plan
Marketing Authorisation Application Evaluation
Post Marketing Authorisation
COMP
Patient input
CHMP-SAWP
Patient input
CAT
Patient input
PDCO
Patient input
CHMP CAT PRAC
Patient input
SAG
Patient input
CHMP PRAC
Patient input
SAG
Patient input

Acronyms

- ADR = Adverse Reaction
- AR = Assessment Report
- CHMP = Committee for Medicinal Products for Human Use
- CD = Commission Decision
- D1, etc = Day 1 (procedural timeline)
- GCP – Good Clinical Practice
- GLP = Good Laboratory Practice
- GMP = Good Manufacturing Practice
- LoQ = List of Questions
- LoOIs = List of Outstanding Issues
- MAH = Marketing Authorisation Holder
- MS = Member State
- OE = Oral explanation
- PASS = Post Authorisation Safety Study
- PI = product information
- PRAC = Pharmacovigilance Risk Assessment Committee
- PSUR = Periodic Safety Update Report
- RMP = Risk Management Plan
- SAG = Scientific Advisory Group
- SmPC = Summary of Product Characteristics