# PHARMACOVIGILANCE: THE PATIENT ROLE

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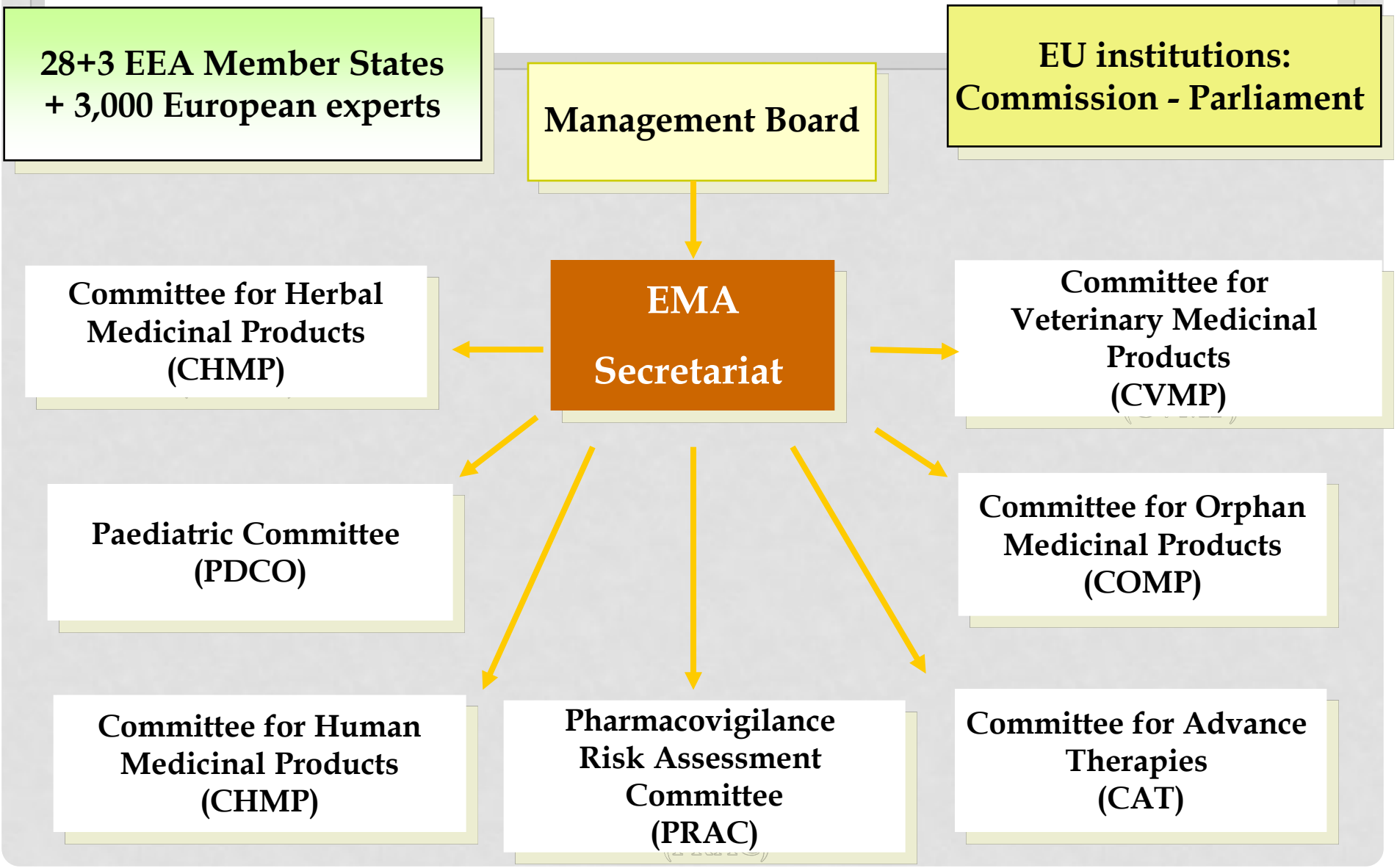
# EUROPEAN MEDICINE AGENCY

The European Medicines Agency has been engaging in dialogue with European patients and consumers since it was founded in 1995.

As users of the medicines that the Agency evaluates, **patients and consumers are key stakeholders** in the Agency's work and have specific knowledge and expertise to offer.

The Agency is committed to maintaining a strong working relationship with these groups

# HOW IS THE EMA ORGANISED?



# PATIENTS AND CONSUMERS INVOLVEMENT IN EMA

- members of its committees + Management Board
- part of the scientific advisory groups;
- responding to specific requests from the Agency
- reviewing information on medicines prepared by the Agency;
- being involved in the preparation of guidelines;
- regularly taking part in Agency conferences and workshops.

# PHARMACOVIGILANCE

- Committee for Medicinal Products for Human Use (ChMP)
- Pharmacovigilance Risk Assessment Committe (PRAC)

# THE PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE

**Mandate of the PRAC**

All aspects of the risk management of the use of medicinal products including:

- the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having *due regard to the therapeutic effect of the medicinal product*
- the design and evaluation of *post-authorisation safety studies* and pharmacovigilance audit

# PRAC: PATIENT INPUT

There are three levels of possible interaction:

- **Personal: Reporting** i.e Reporting of Adverse Drug Reaction
- **Writing to EMA or PRAC** about an already ongoing procedure
- **Consultation**
  - On specific requests from the Agency
  - For information review (prepared by the Agency)
  - Being involved in the preparation of guidelines
- **Representativeness of patients and patients' organizations**
  - 1 representative
  - 1 alternate

Both appointed by the European Commission after a consultation with the EU Parliament

**Both are PATIENTS**

# PATIENT ROLE IN PRAC

**Patient advocacy**: ensure that patient needs as a whole are taken into account in the deliberations of the Committee.

**Public safety**: communication on individual medicinal products should for example consider specific patient requirements.

**… in concrete**

- full members
- vote as all the other members
- offer a different point of view: a perspective shift
- take into deep consideration patients' needs (also small cohort)
- make sure that the outcomes are clear and understandable as well as the related material (e.g. patients' cards)

# PATIENTS IN PRAC vs PATIENT COMMUNITY

In PRAC

Patient representative(s) share the same level of information all the other delegates have;

The patient community captures:

- The outcomes of any procedure
- A strong commitment from EMA
- The behavior of companies

**Process is fast and socially shared**

# WHAT PATIENT ORGANISATIONS CAN DO

- Keeping themselves in the loop
- Cope with the incredibile change of environment
- Structure themeselves
- Make large use of the existing resources
  - EMA Formative Events
  - Second and third level organizations are usually structured for facing the new challenges
- Create strategic alliances (e.g. HCProfessionals)

# CONCLUSION

- IN PHARMACOVIGILANCE
- Patients = end-users of products: **a unique position**
- Patient reports add value to pharmacovigilance:
  - Quality equal to HCP report
  - Patients can specify the circumstances
  - They often give much more detailed and nuanced descriptions
  - Patients report some different types of reactions
  - Often report earlier
  - Perceive impact and severity of reactions differently
- Patients at EMA (2013 data)
  - Review of information for the public: 110 package leaflets, 48 European public assessment reports, 39 safety communications
  - 33 patients participated in Scientific Advisory Groups /ad-hoc meetings
  - 28 patients participated in scientific advice / protocol assistance


For more information:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000537.jsp

# THANK YOU!