3-year Report on European Union Pharmacovigilance Activities

Pharmaceutical Committee

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Health and Food Safety

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EU pharmaceutical legislation

Directive 2001/83/EC	**The core legislation governing the regulation of medicines in EU:** • **Title IX – Pharmacovigilance** • Article 108b – report on performance of pharmacovigilance tasks by Member States
Regulation (EC) No 726/2004	**Sets the procedures for the authorisation and supervision of medicinal products at EU level and establishes the European Medicines Agency:** • **Title II - Chapter 3 – Pharmacovigilance** • Article 29 - report on performance of pharmacovigilance tasks by Member States

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Commission report

- Report from the Commission (COM(2016) 498 final) and accompanying staff working document (SWD(2016 284 final) adopted 8 August 2016
- Includes pharmacovigilance activities of Member States and the European Medicines Agency
- Mainly covering July 2012 – December 2014

EUROPEAN COMMISSION

Brussels, 8.8.2016
COM(2016) 498 final

REPORT FROM THE COMMISSION

Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)

{SWD(2016) 284 final}

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European Union Pharmacovigilance - a network approach

- Member States
- European Medicines Agency (including the Pharmacovigilance Risk Assessment Committee (PRAC)
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Functioning of the system

TRIGGERS OF THE DECISION MAKING PROCEDURE	ACTIONS BASED ON PHARMACOVIGILANCE CONCERNS
• Monitoring adverse drug reactions (ADRs) • Signal of a new adverse event, ADR • Periodic safety update reports (PSUR) • Specific procedure: referrals • Oversight of post-authorisation obligations	• Change of marketing authorisation • Suspension • Withdrawal • Revocation • Non-renewal

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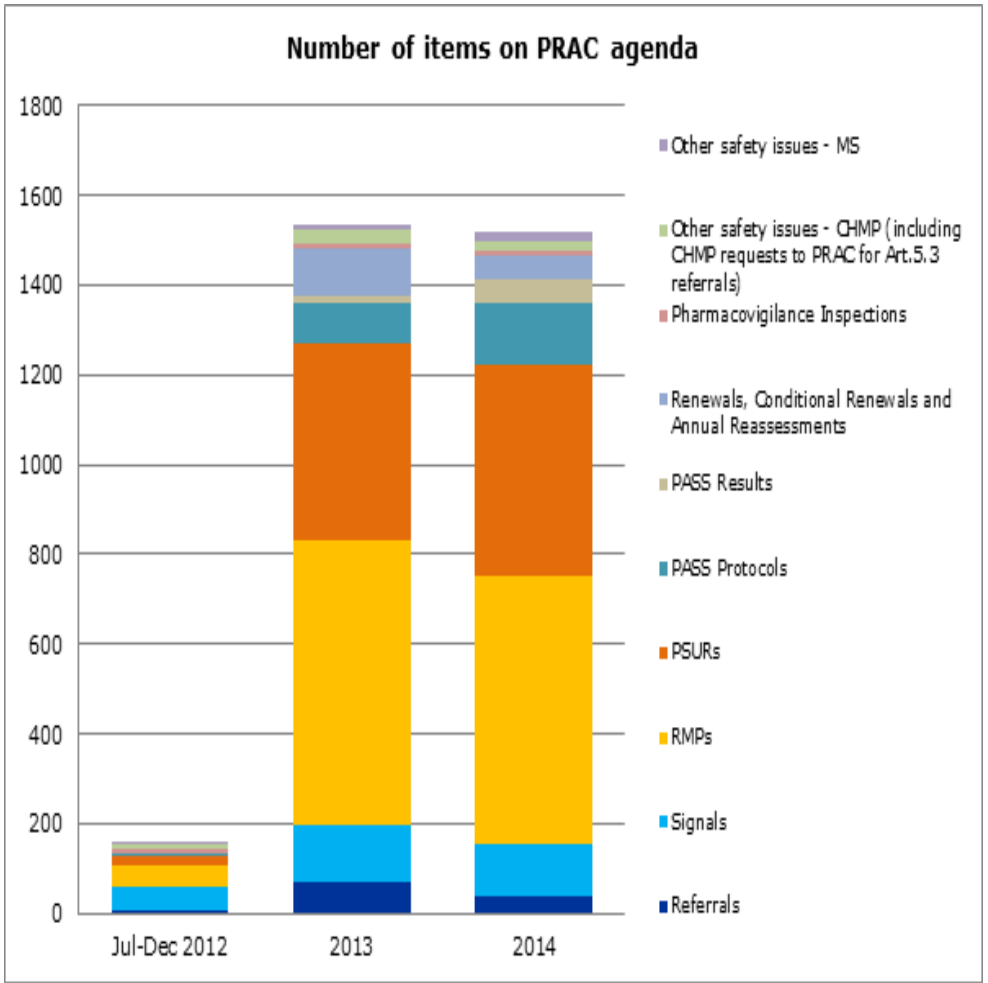
Items on the PRAC agenda



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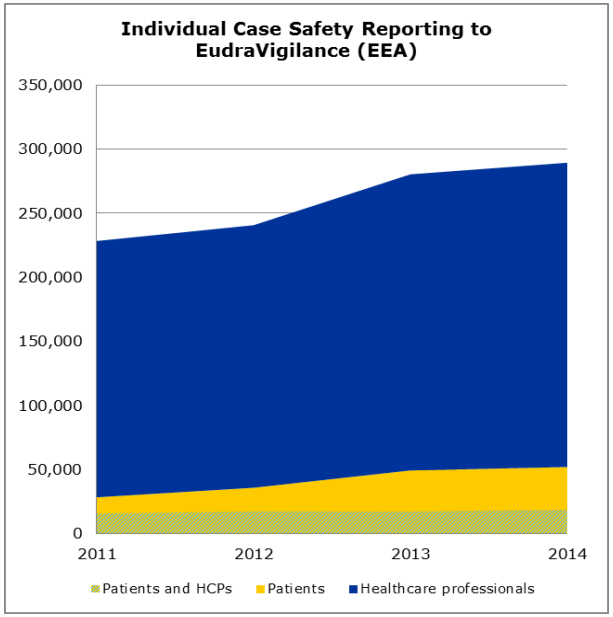
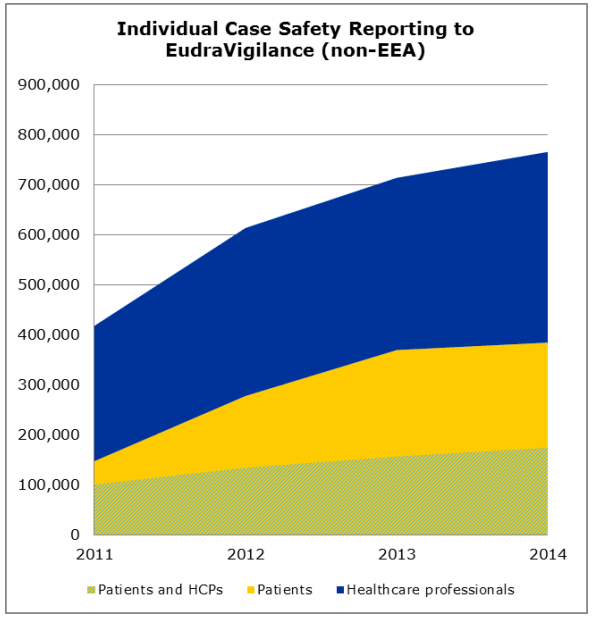
Monitoring adverse drug reactions

- Increasing number of reports
- Patient reporting increased by around 50%





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Signal management

Aim	• Signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action
Process	• Through **signal detection** signals are identified. The data is evaluated during **signal validation** to verify the existence of a new potentially causal association or a new aspect of a known association. **Confirmed signals** are **analysed and prioritisation** by PRAC. Following the scientific evaluation of all the evidence available through the **signal assessment** by PRAC a **recommendation** is made.

Determined if there are new risks identified for a medicine and if changes to the marketing authorisation are required

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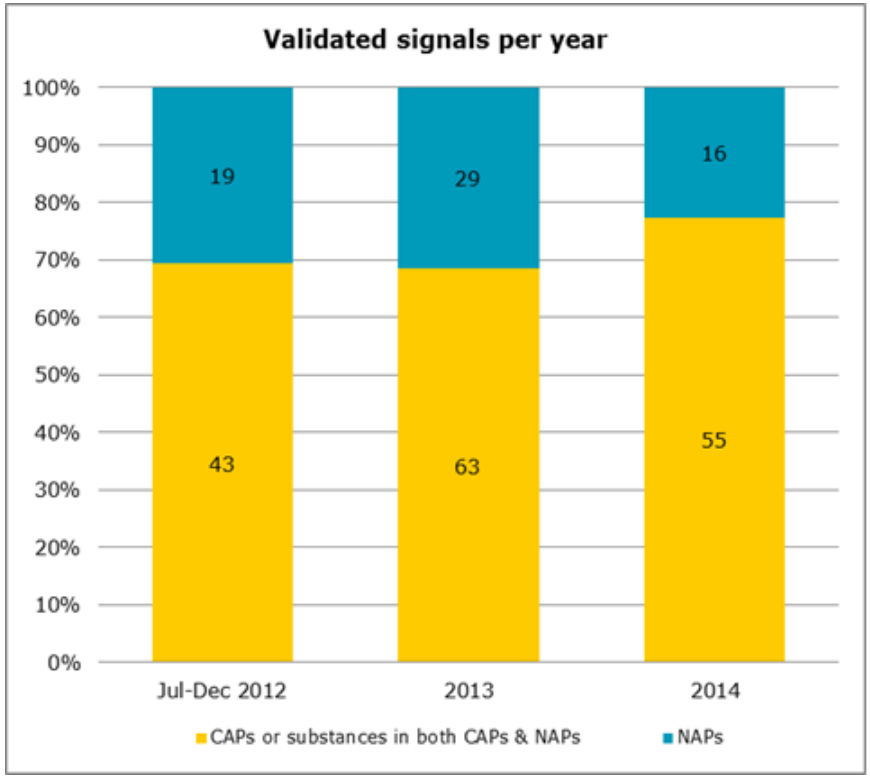
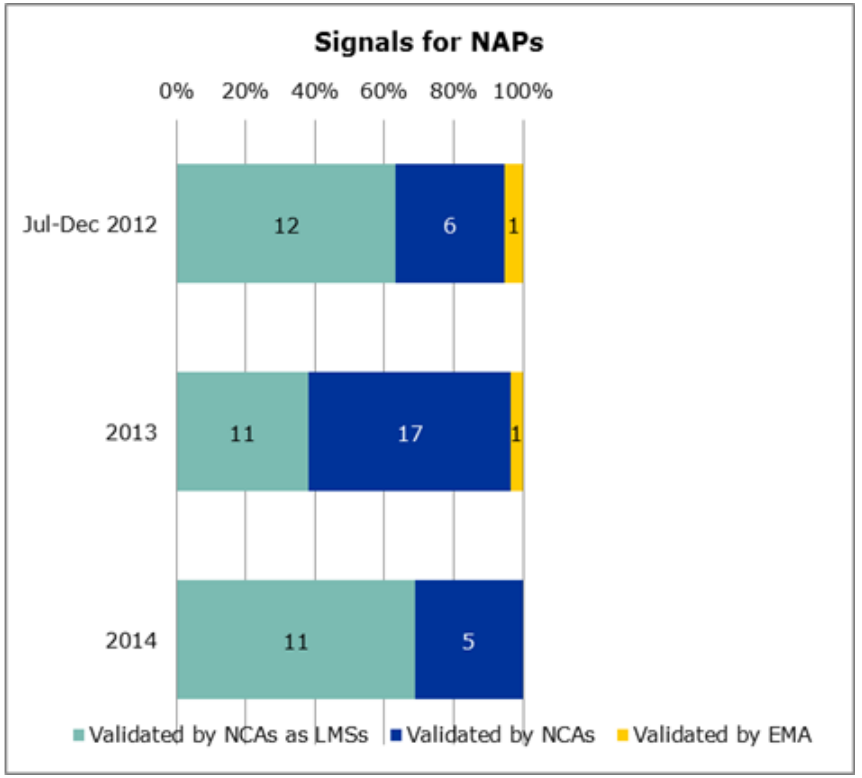
Signals - collaborative validation





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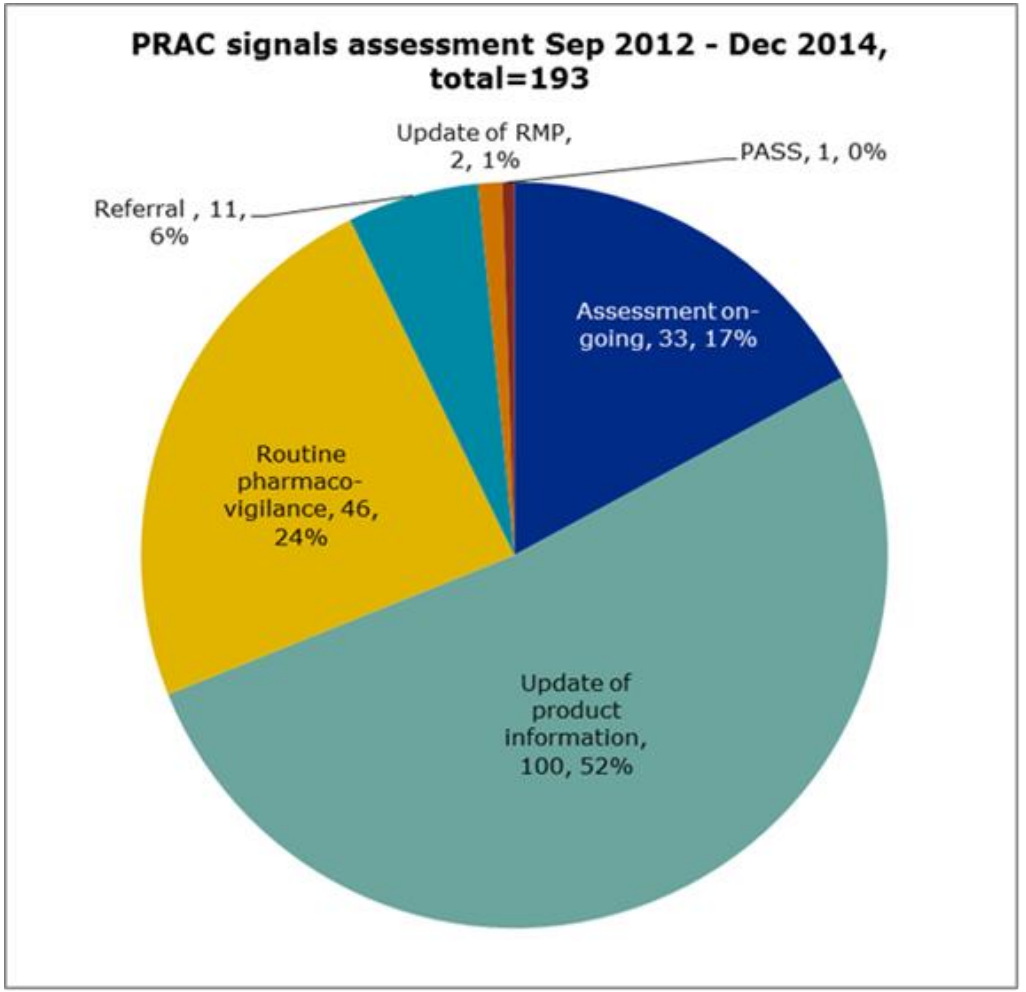
Signal detection
recommendations



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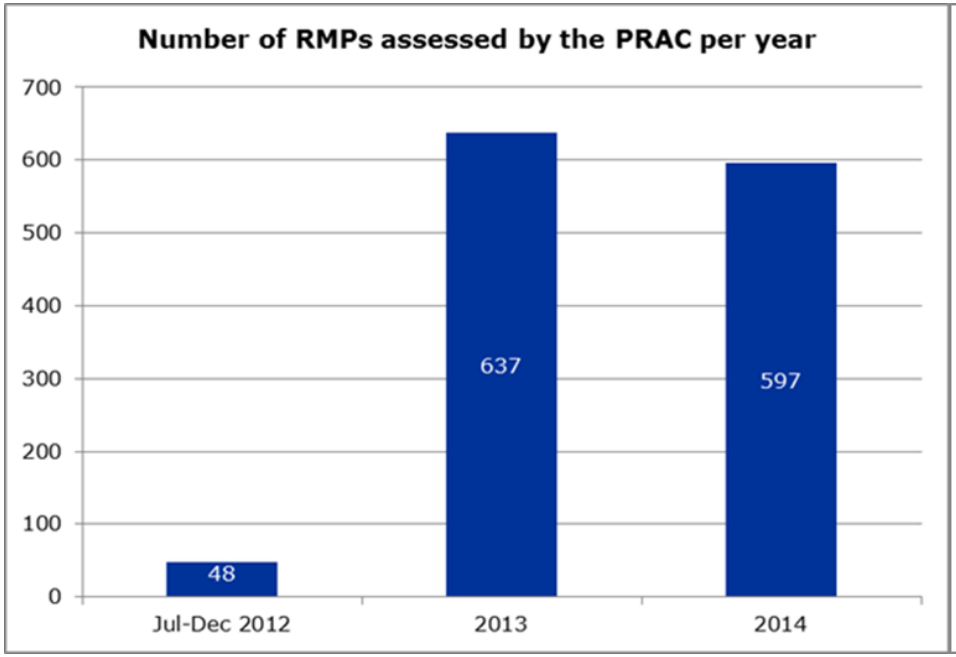
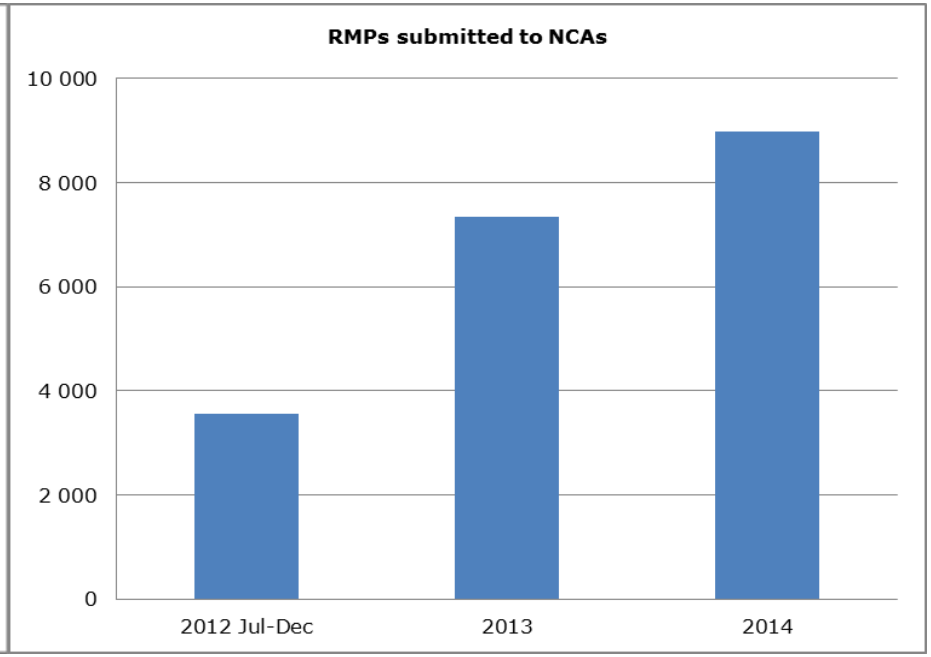
Risk management plans





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Periodic Safety Update Reports

Aim	• Periodic safety update reports (PSURs) are reports providing an evaluation of the benefit-risk balance of a medicine • Marketing authorisation holders must submit PSURs at defined time points following a medicine's authorisation
Scope	• Cumulative data - focus on the new information • Scientific assessment and integrated benefit-risk evaluation • Single PSUR for all products containing the same active substance

Determined if there are new risks identified for a medicine or whether the balance of benefits and risks has changed

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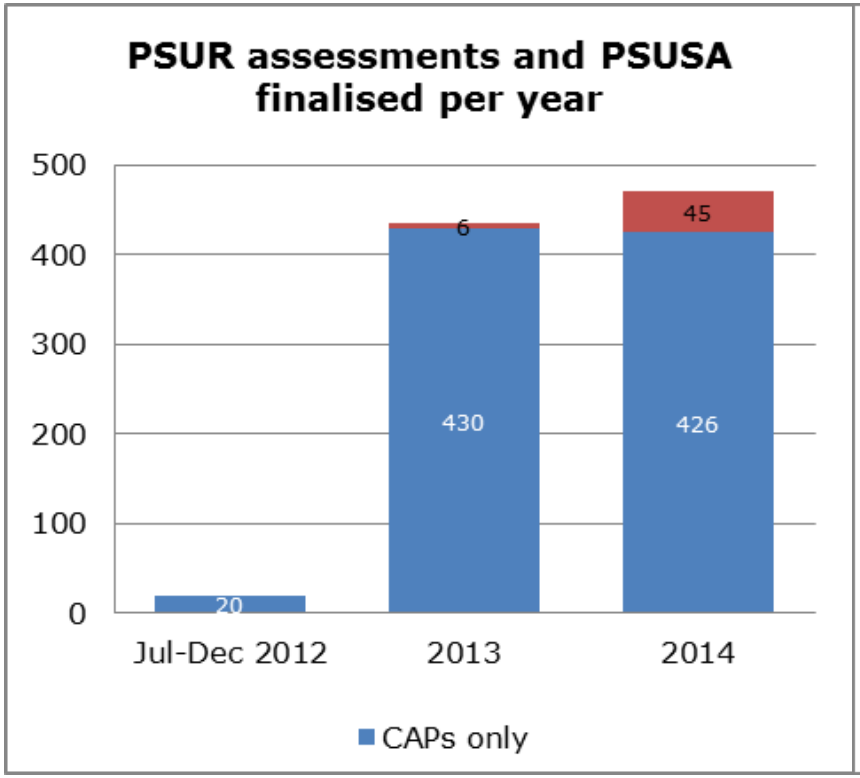
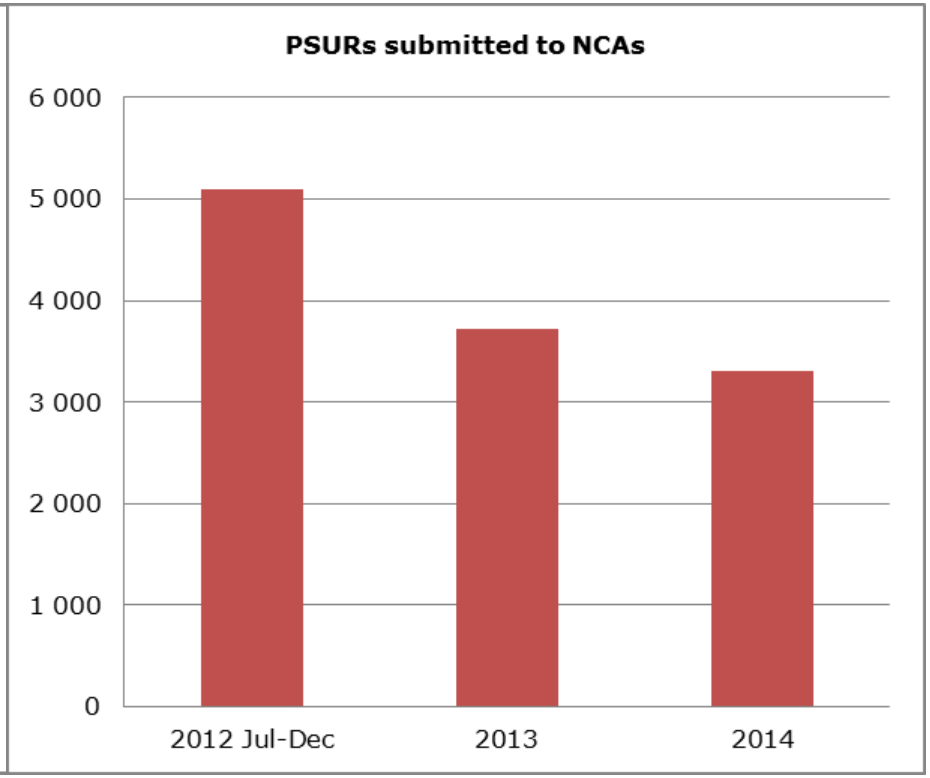
PSUR assessments





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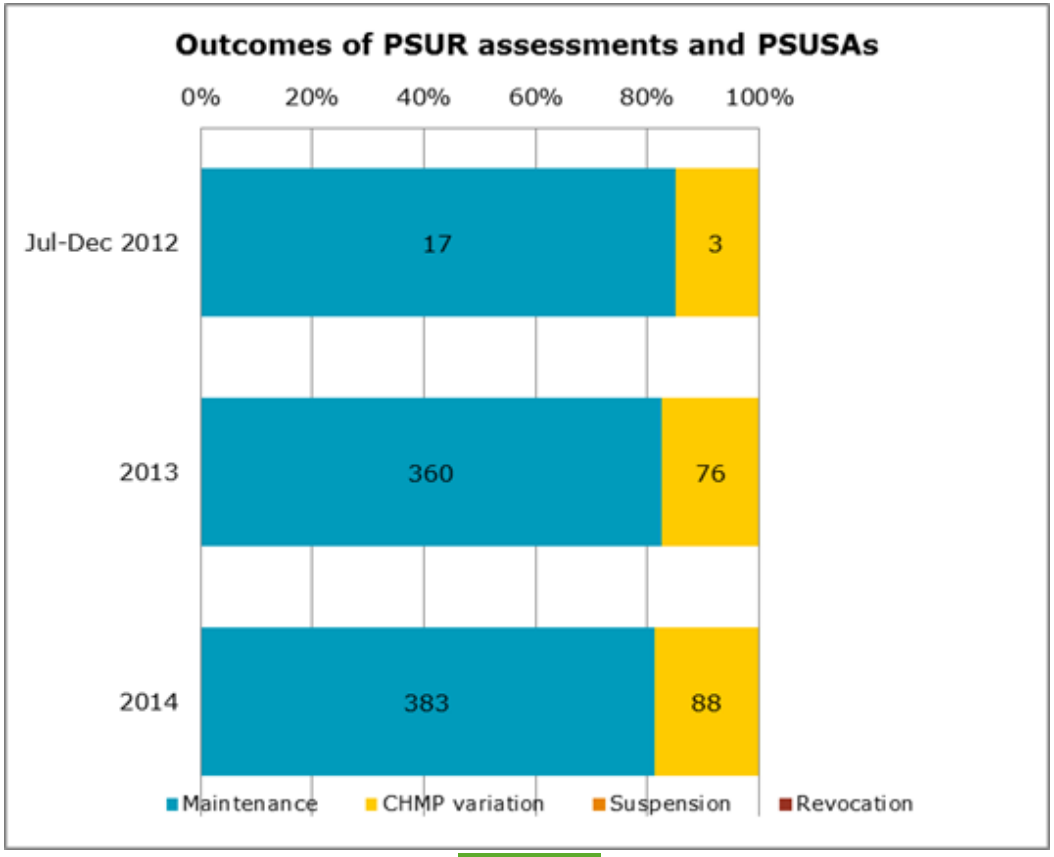
PRAC PSUR assessments outcomes



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Referral procedures

Aim	• Resolves issues such as concerns over the **safety** or **benefit-risk balance** of a medicine or a class of medicines • EMA conducts a **scientific assessment** on behalf of the EU and makes a **recommendation** for a harmonised position across the EU
Safety-related referrals	• **Based on evidence from pharmacovigilance** – assessment and recommendation by PRAC, then: • **Centrally authorised or centrally and nationally authorised medicines:** ➢ Assessed by the Committee for Medicinal Products for Human Use (CHMP) • **Only nationally authorised medicines** ➢ Assessed by the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)
Procedure	• **Can be started by the European Commission or any Member State** • For most referrals, the **European Commission issues a decision to all Member States** reflecting the measures to take to implement the Agency's recommendation

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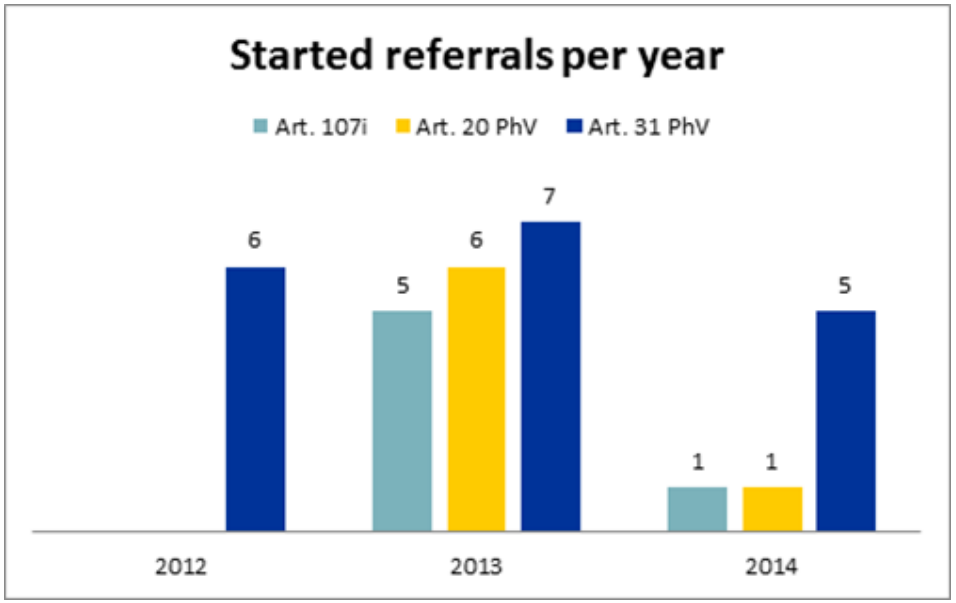
Pharmacovigilance referrals



July 2012 – December 2014

- 6 Art. 107i - urgent safety referrals for nationally authorised medicines
- 7 Art. 20 - related to centrally authorised medicines only
- 18 Art. 31 - related to nationally or nationally and centrally authorised medicines

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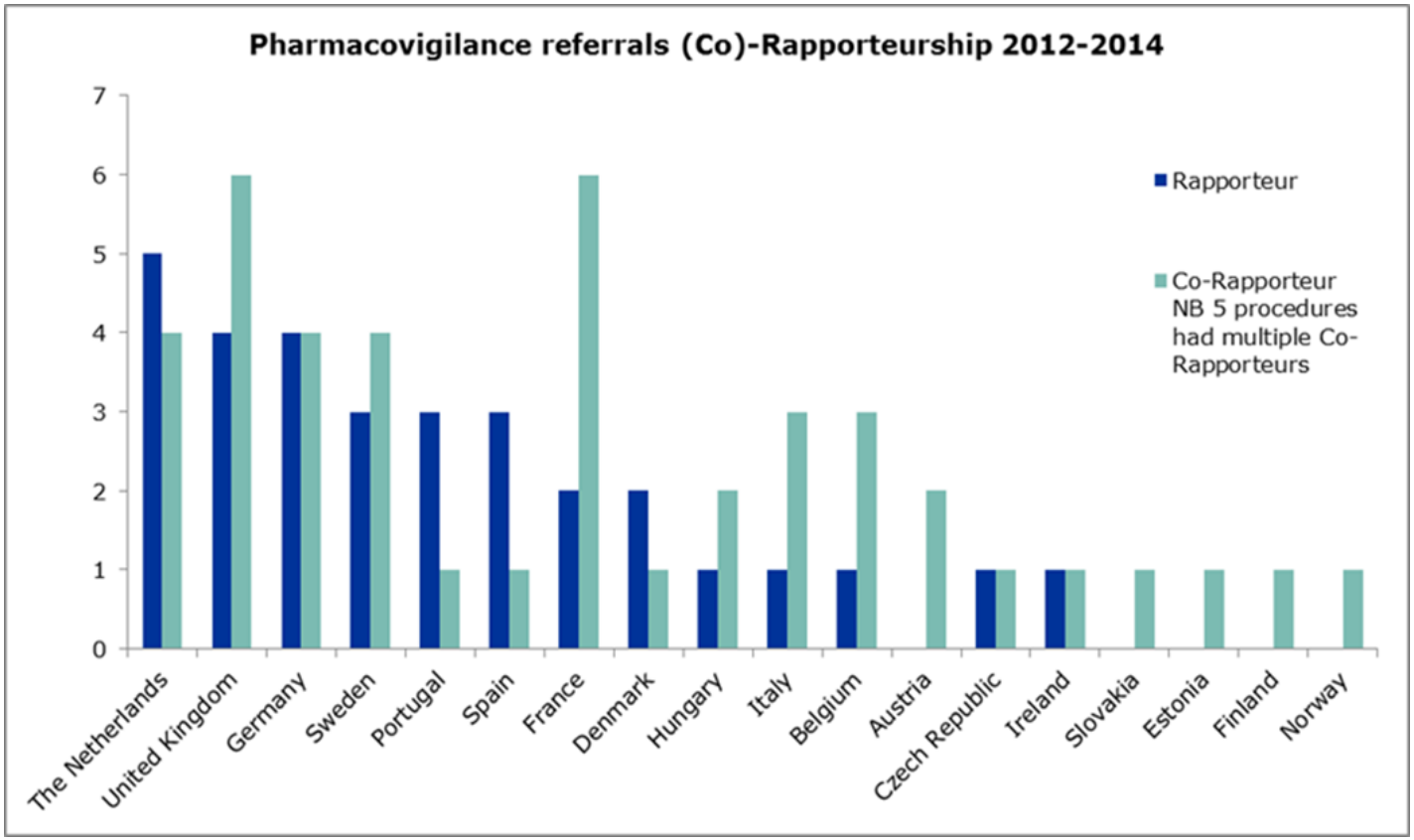
Referrals - collaborative effort



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Referrals outcomes

- 24 variations of marketing authorisation (MA)
- 6 suspensions of indication or MA
- 4 revocations of indication or MA

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Communications and information

- Information related to the PRAC – agendas, minutes
- Public safety communications – e.g. concerning referrals
- European database of suspected ADRs
- European Network of Centres in Pharmacoepidemiology and Pharmacovigilance
  e.g. outcomes of imposed PASS
- Risk management plan summaries

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Systems and services

- Database of medicinal products authorised in the EU (Article 57 database)
- EudraVigilance enhancements
- Literature monitoring service
- PSUR repository

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Future deliverables

- Continuing process improvements and complete implementation of systems and services
  (e.g. EudraVigilance, extension of literature monitoring, dedicated European medicines web portal)

- Continue training network

- Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action

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Thank you for your attention

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Public Health information:

http://ec.europa.eu/health/index_en.htm

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