Capturing the value of SCOPE to the EU

Flagship Event
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Health and Food Safety

Outline of the presentation

- Characterisitics of Joint Actions
- Pharmacovigilance activities in the EU
- SCOPE Joint Action - impact and sustainability

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Joint Actions

- A specific funding instrument under the EU health programme
- A joint endeavour between the European Commission and the Member States who express interest to be involved

Joint Actions – Particular characteristics

- Joint Actions have a clear EU added value and are co-financed by Member States
- Involve a greater number of partners than other projects
- Focus on implementation (rather than knowledge production)
- Broad dissemination of deliverables among ALL Member States
- Higher expectation of sustainability

SCOPE Joint Action

Objective

- Facilitating collaboration among the Member States for the effective operation of the pharmacovigilance system in the EU

Main aims

- Support Member States to find solutions for organising and running their pharmacovigilance system in the context of the new pharmacovigilance legislation in the EU

- Support the achievement of a consistent approach to the implementation of the pharmacovigilance legislation across the EU

Significant EU added value expected

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European Union Pharmacovigilance – a network approach

- Member States
- European Medicines Agency including the Pharmacovigilance Risk Assessment Committee (PRAC)
- European Commission

Advantages of the network approach

- Transparency and early involvement
- Bringing together multiple experts for the benefit of public health
- Collaborative development of (scientific) guidelines taking account of the state-of-the-art
- Facilitating communication with a variety of stakeholders including academia, patients and industry

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Pharmacovigilance activities:

- pro-active risk management
- monitoring of data on the safety of medicines
- acting to protect public health
- communication on risks

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Report on Pharmacovigilance Activities

- 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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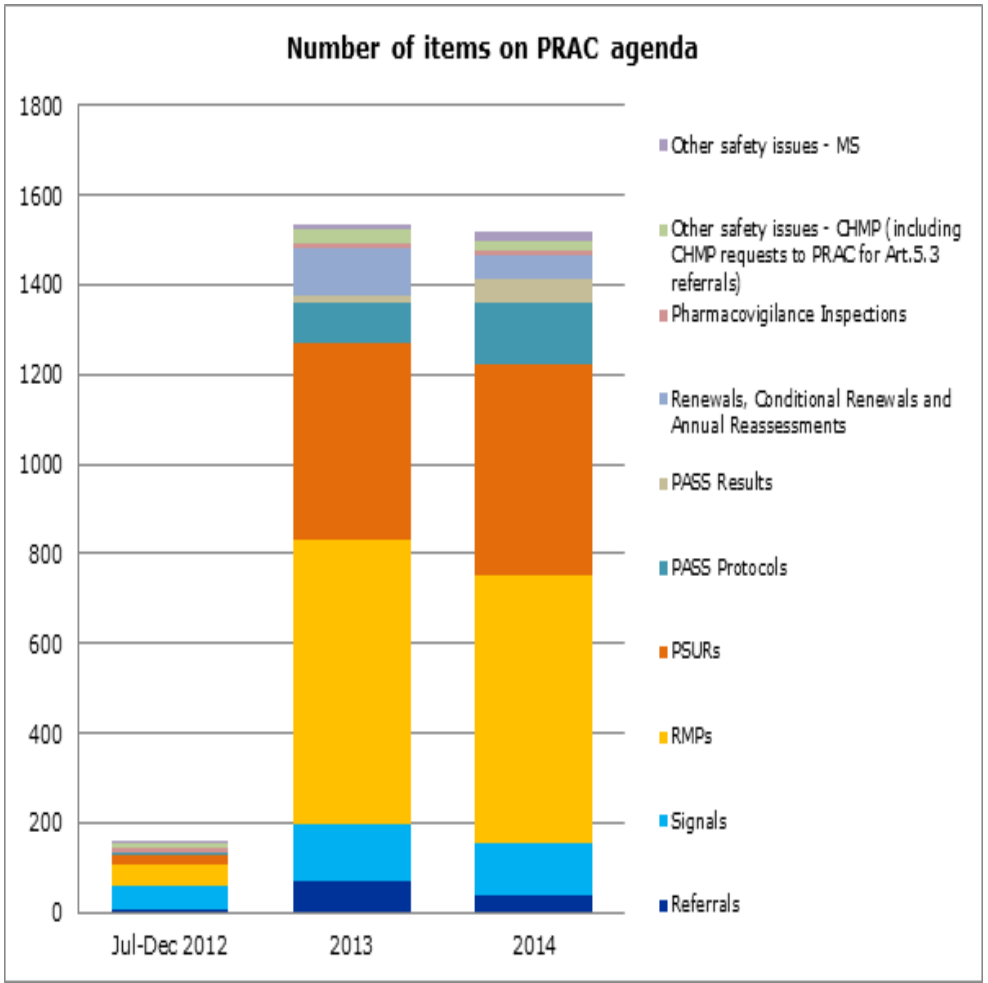
PRAC agenda items

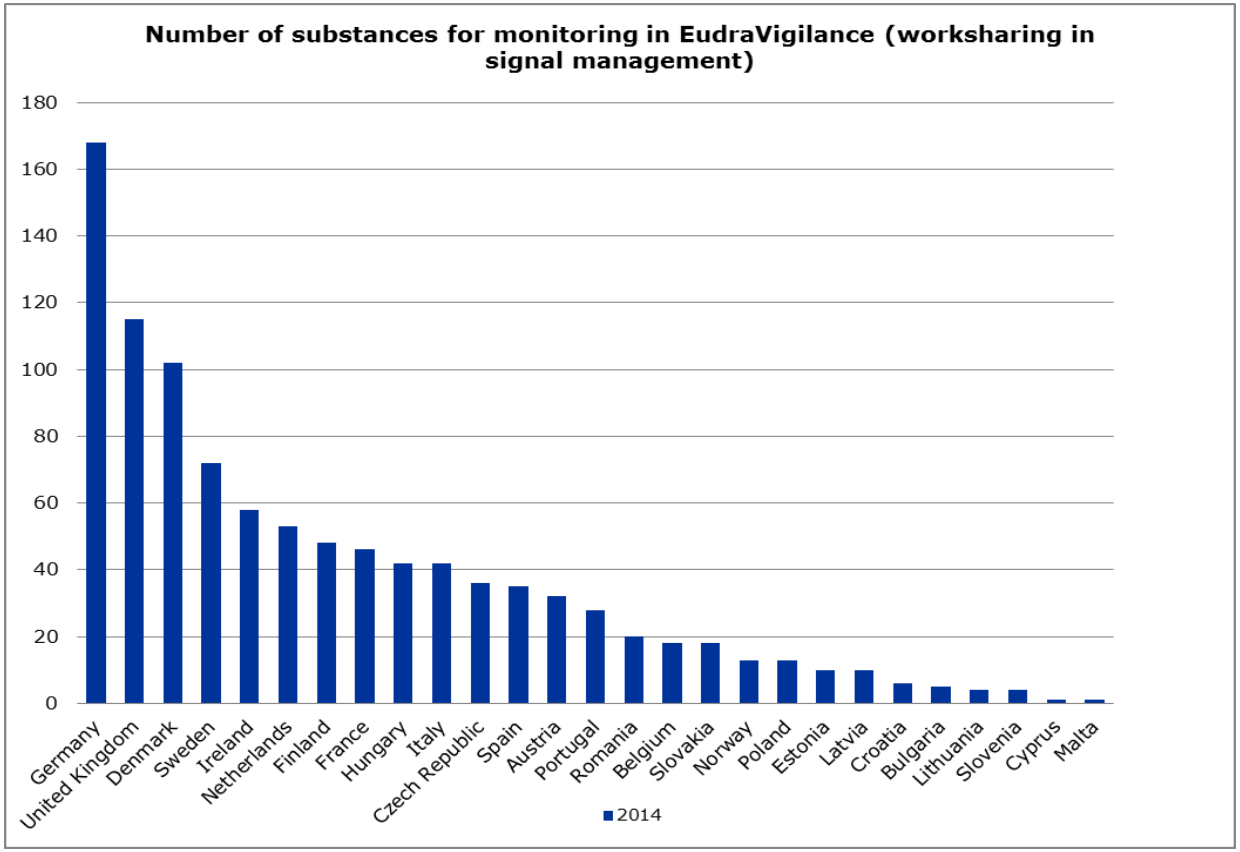


Member State activities

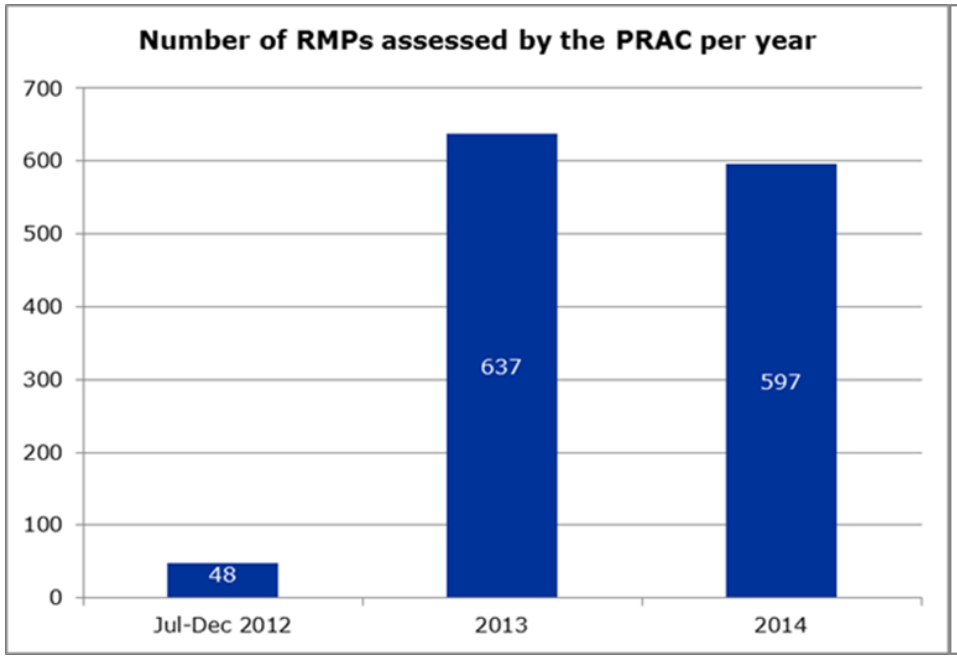
Total between July 2012 – December 2014 in 28 members of the network:

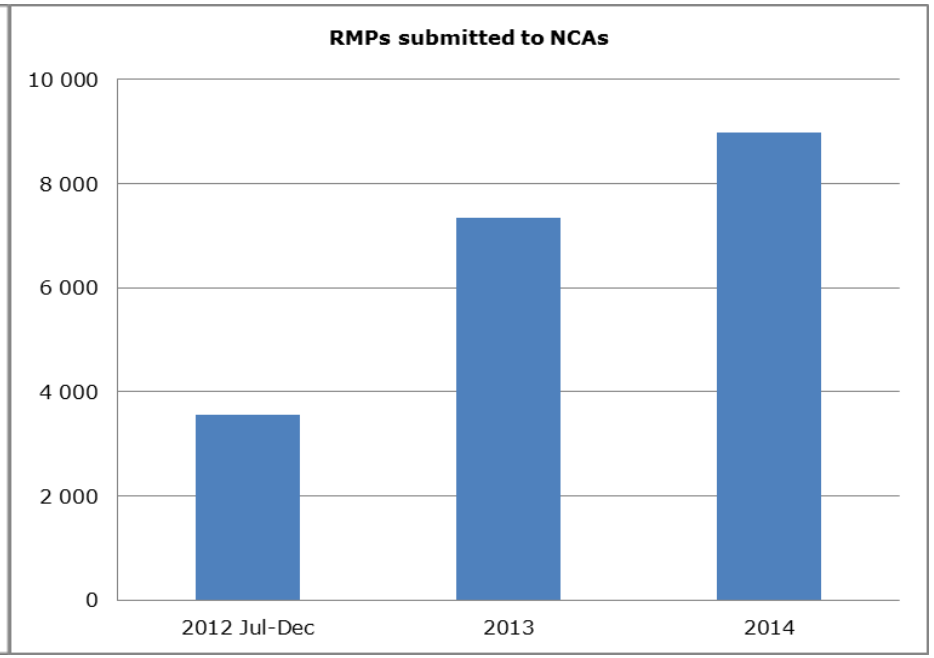
- Risk management plans: 19 901
- Periodic safety update reports: 11 307
- Post authorisation safety studies: 17
- Post authorisation efficacy studies: 1

Signal detection – sharing the work

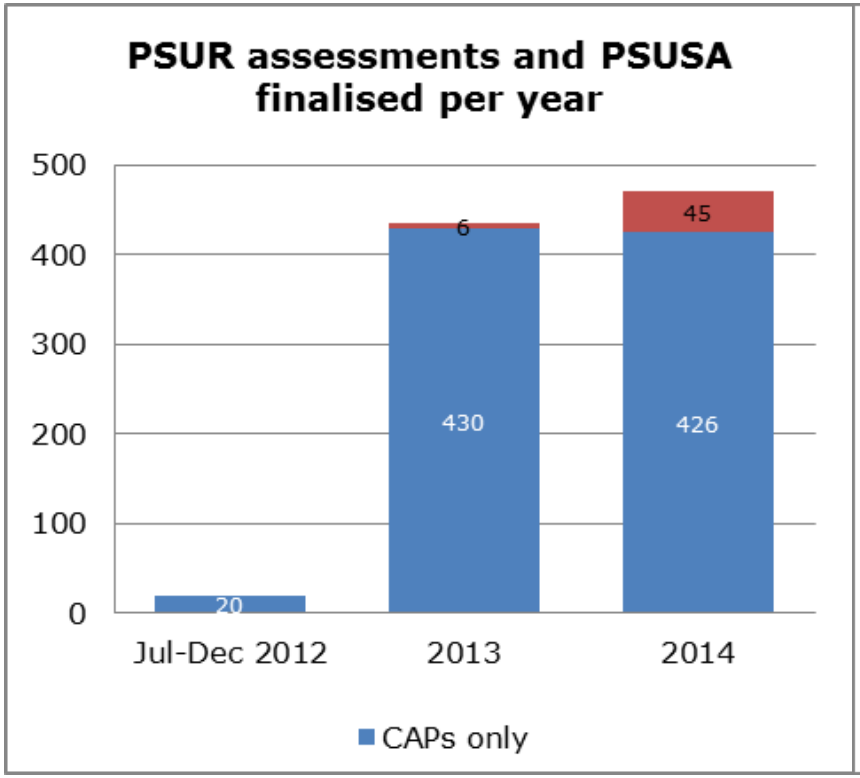


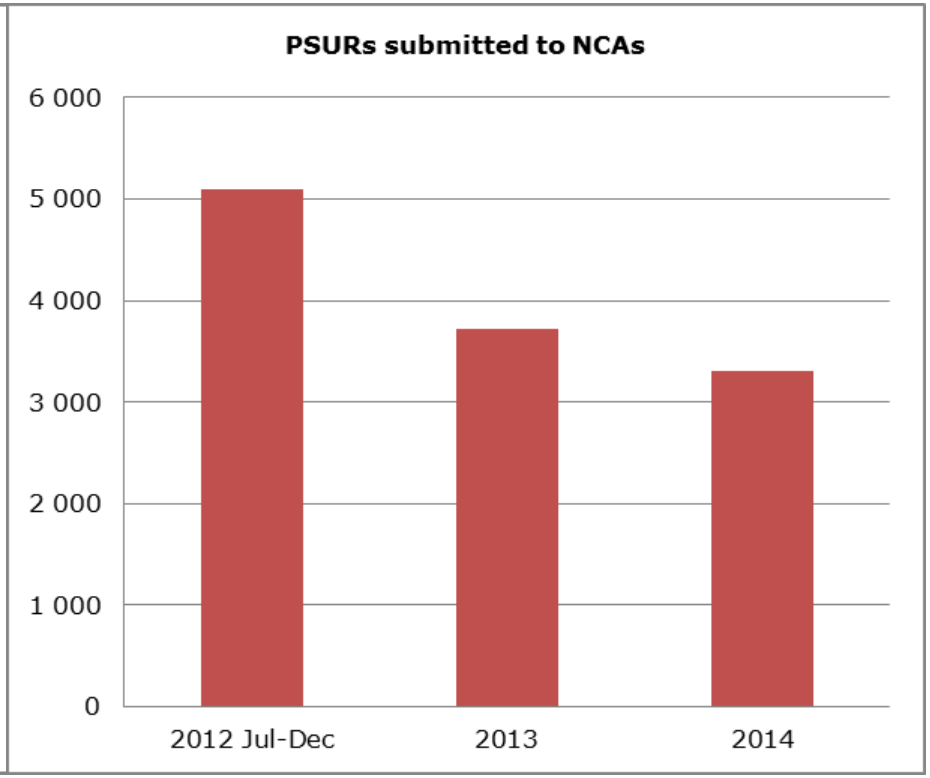
Risk management plans





PSUR assessments





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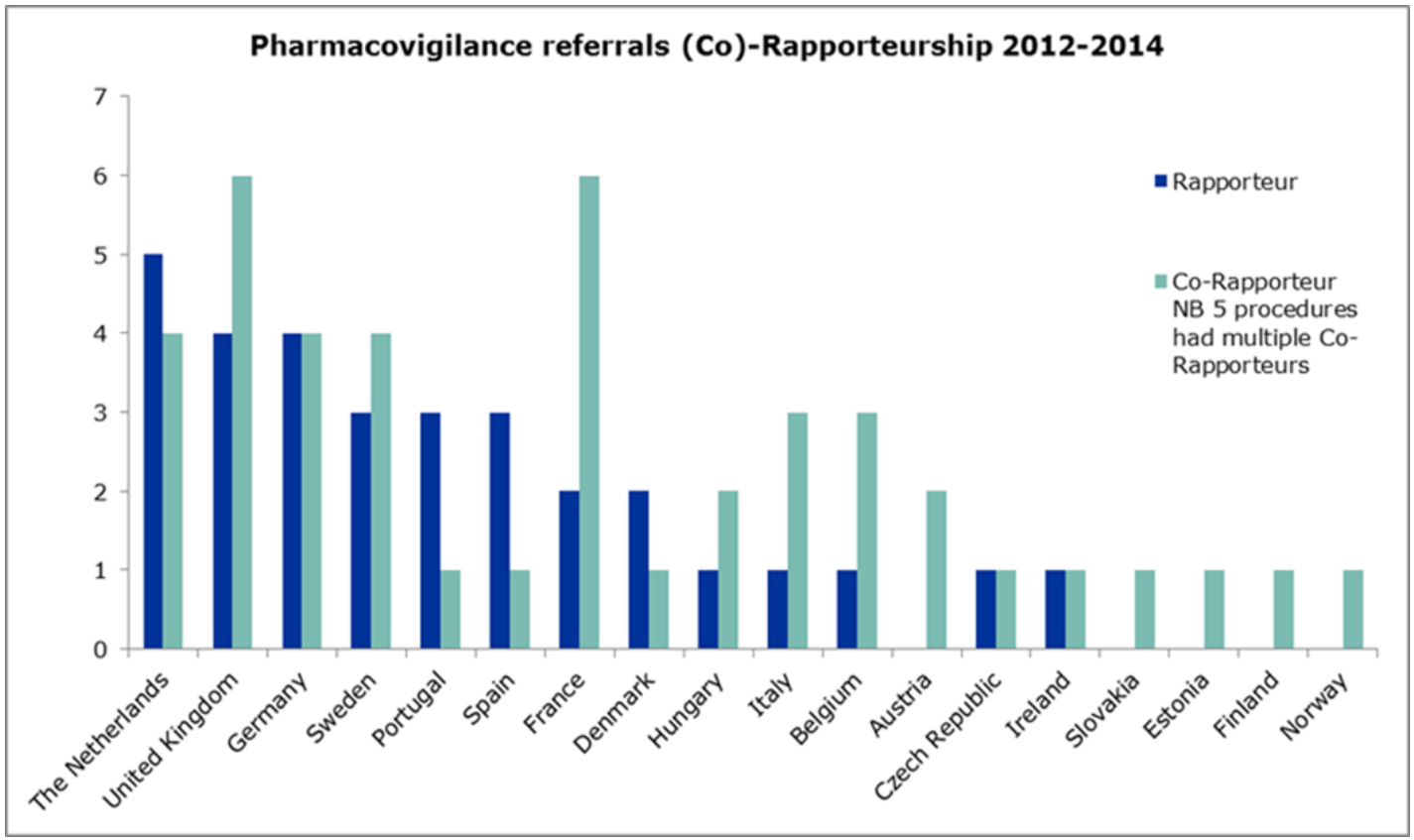
PRAC Referrals - collaborative effort

July 2012 – December 2014: 31 pharmacovigilance referrals



Challenges for MS and PRAC

- Different authorisation procedures
  - central, national, MRP/DCP
- The number of pharmacovigilance procedures and activities
  - RMPs, signals, PSURs, referrals, communication, audits
- Timelines for the assessment procedures
- Identification and promotion of best practices across the network – improving quality, building capacity
- Continuing development of best practice with experience

SCOPE Building Competency

Sustainability and impact are interlinked

- *KEY CHALLENGE* - ensuring uptake and use of the deliverables
- The action will impact pharmacovigilance practice ONLY if the tools are ACTUALLY USED by you
- Embedding deliverables into EU system
  - *Potential for added impact by raising awareness on the EU pharmacovigilance system*

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The biggest challenges lie ahead

- Ensuring adequacy and appropriateness of the training material
- Other stakeholder involvement

  e.g. whole network, healthcare professionals, industry, patients
- Ensuring synergy with other activities in the network
- Identification of the ways and the means to sustain the training component

Goal - effective operation of the PhV system in the EU

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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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