



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Pharmacovigilance – vision and needs for the future

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EMA perspective

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An agency of the European Union

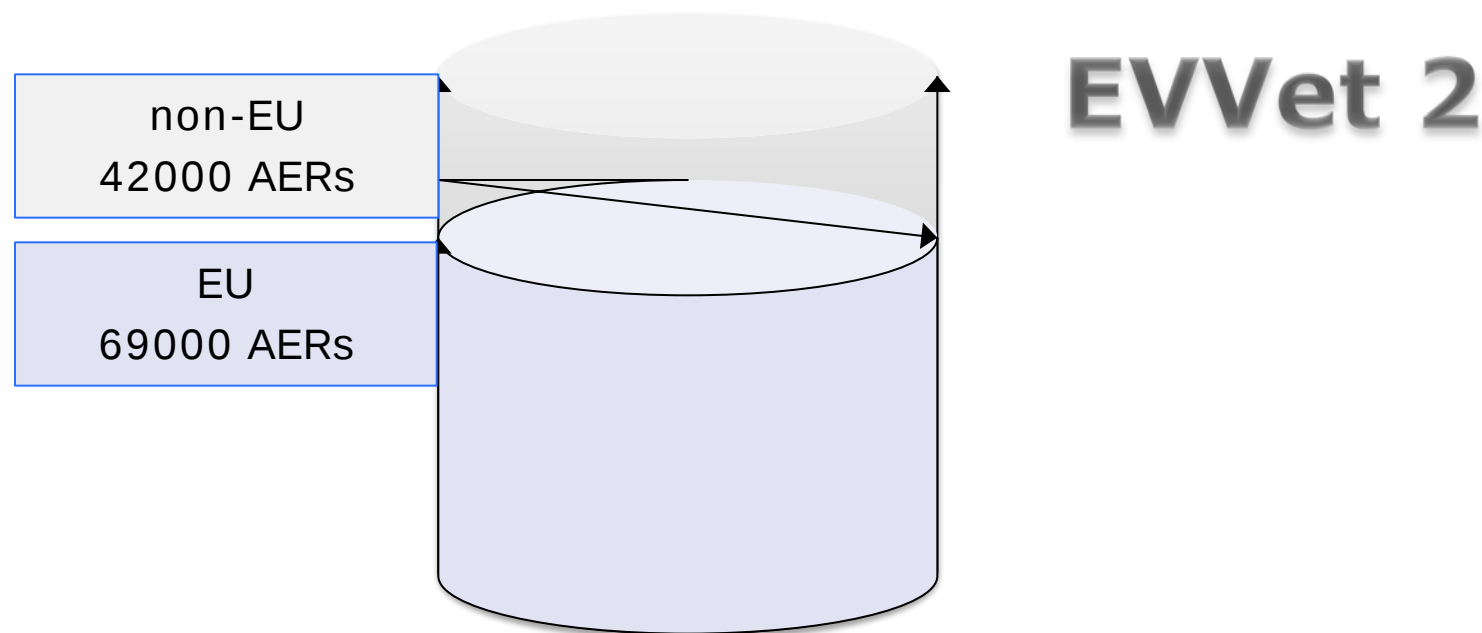






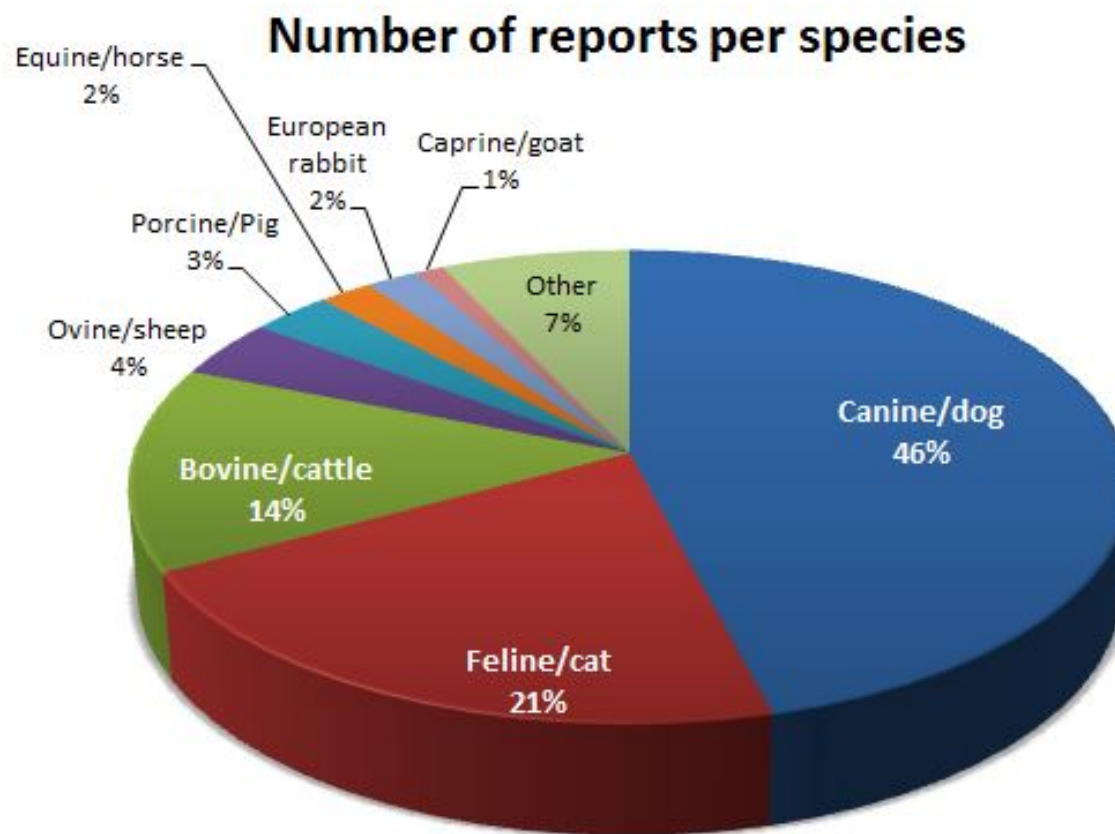
# Current status and key events

- 2005 – mandatory electronic reporting





## Current status





## Current status and key events

PSUR work-sharing initiated in 2008 by HMA-V.

- 25 Member States to participate in 2014
- Voluntary for MAHs
- 85 active substances distributed for 2014



## Current status and key events

- CVMP signal detection procedure for CAPs since Sept 2011
  - Using the Data Warehouse signal detection queries
  - Periodically (3 monthly), 6 monthly, yearly
  - Each analysis results in a report recorded in a database - > 1000 reports
- Draft recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products (consultation end 30/06/2014)
- Pharmacovigilance inspections becoming routine

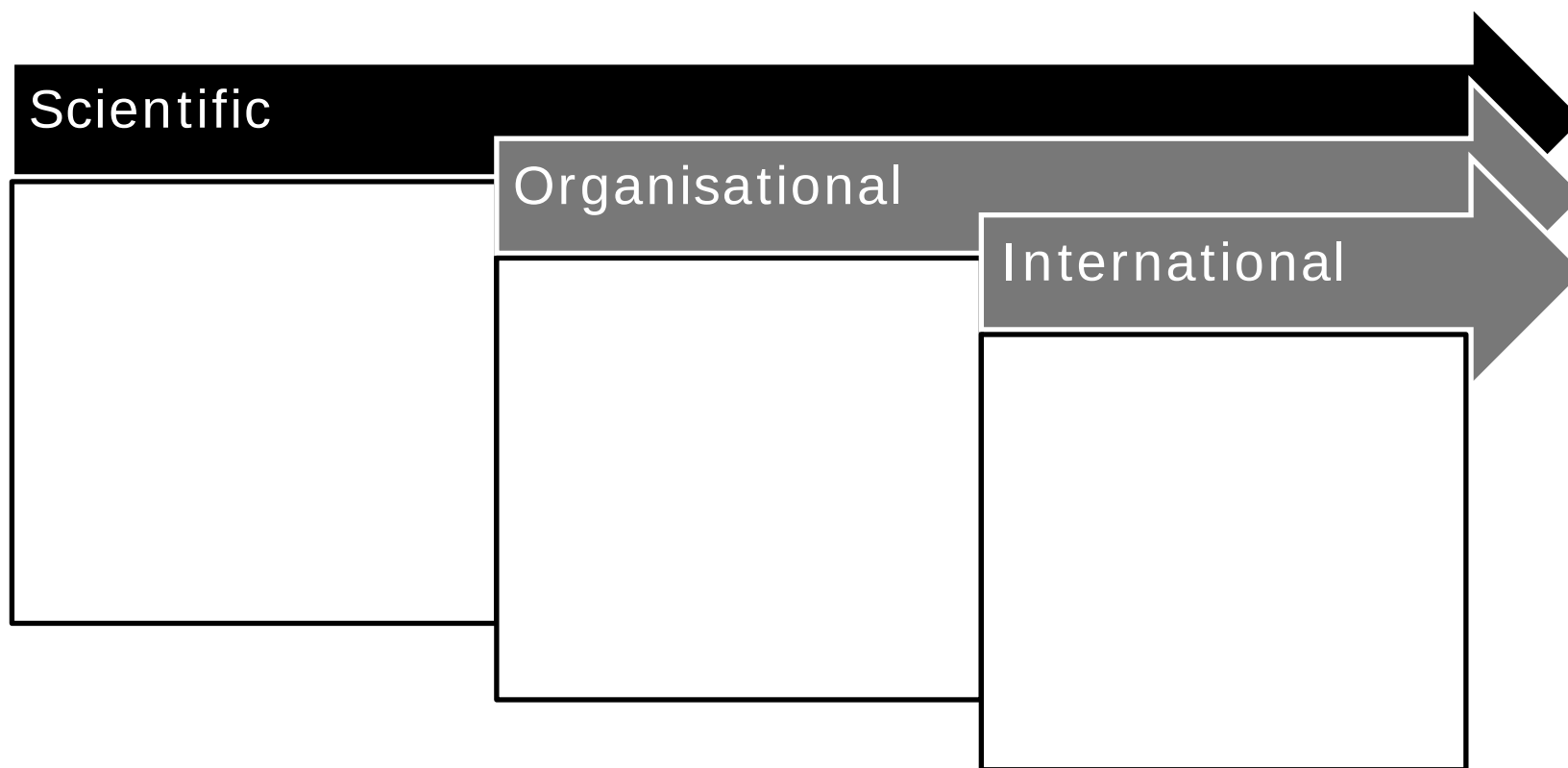


## Current status and key events

- CVMP comments on Commission's consultation on the review of the legislation (July 2010):
  - Levels of surveillance depending on available knowledge and risk
  - Systematic assessment of Data by MAH with periodic communication to competent authorities.
  - Competent authorities to supervise the process with surveillance level responsibility at active substance level or class type level
  - Same surveillance approach for all products regardless of authorisation route / common use of EU database and tools
  - Pharmacovigilance system master file

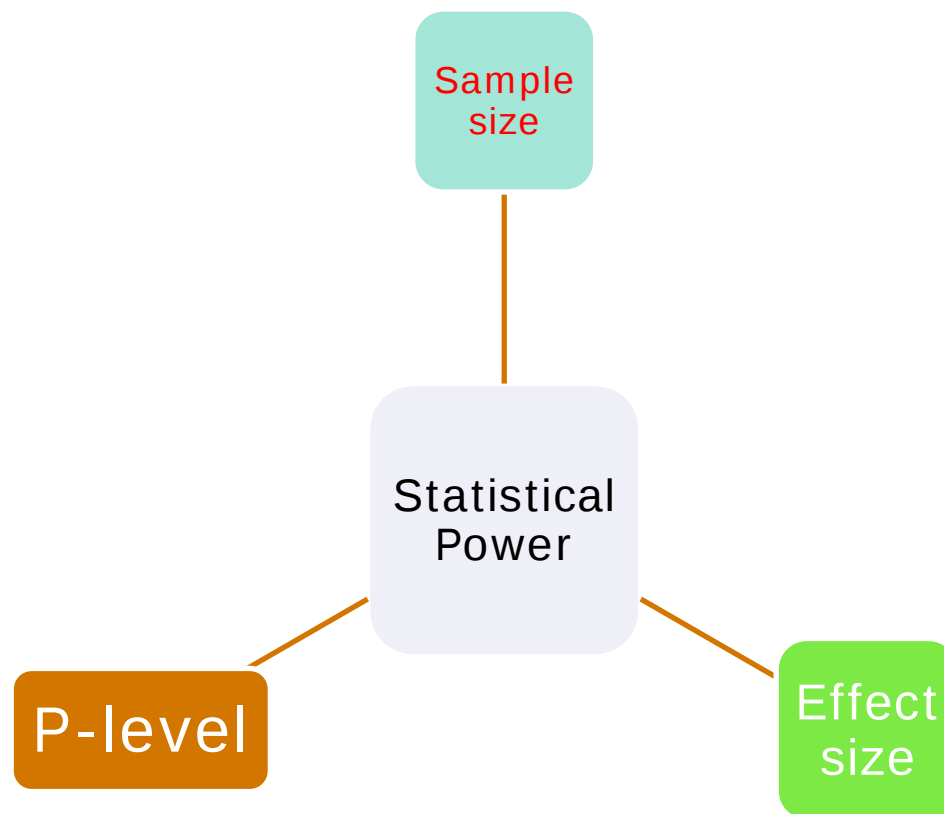


# Opportunities



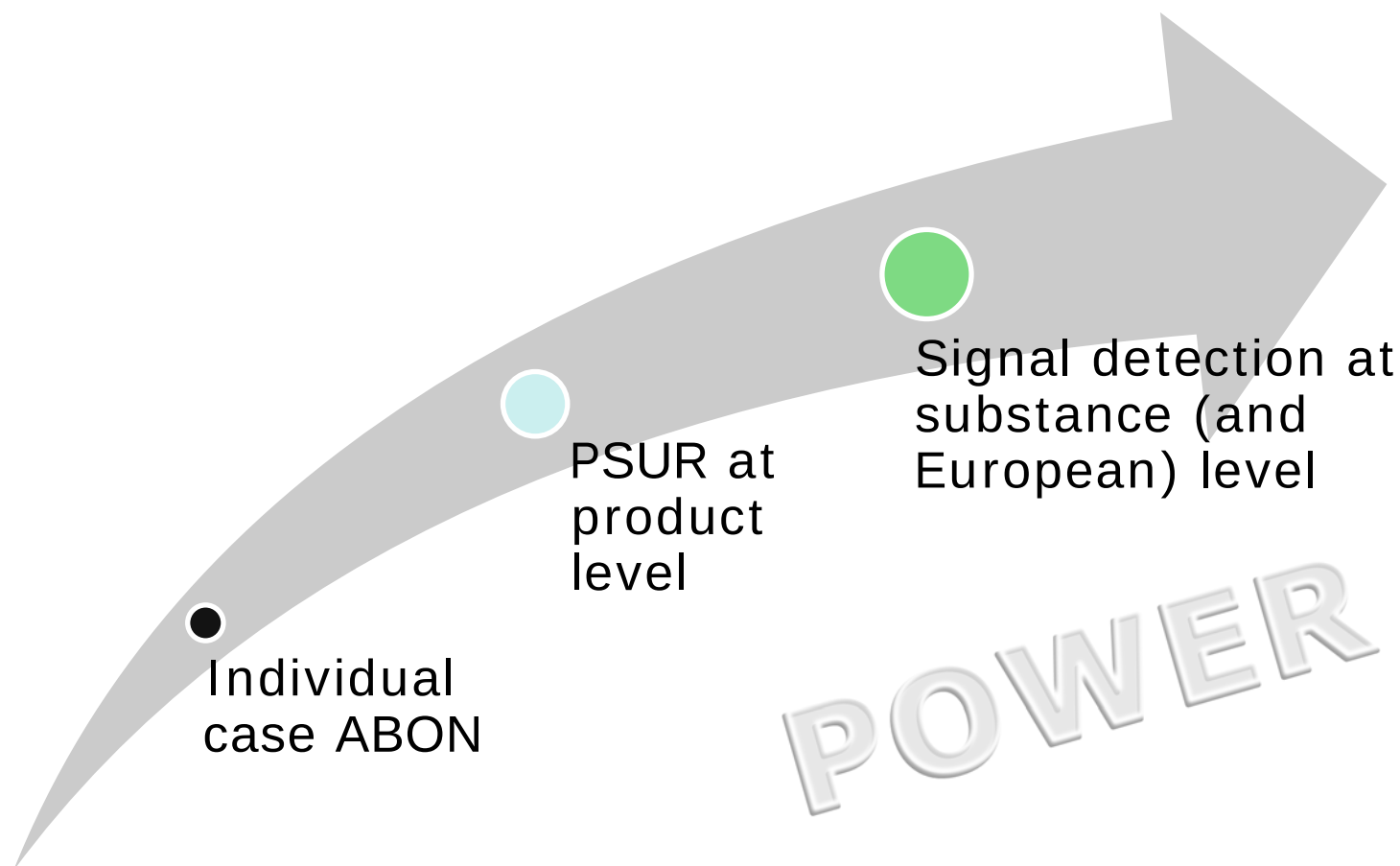


# Opportunities - scientific





## Opportunities - scientific

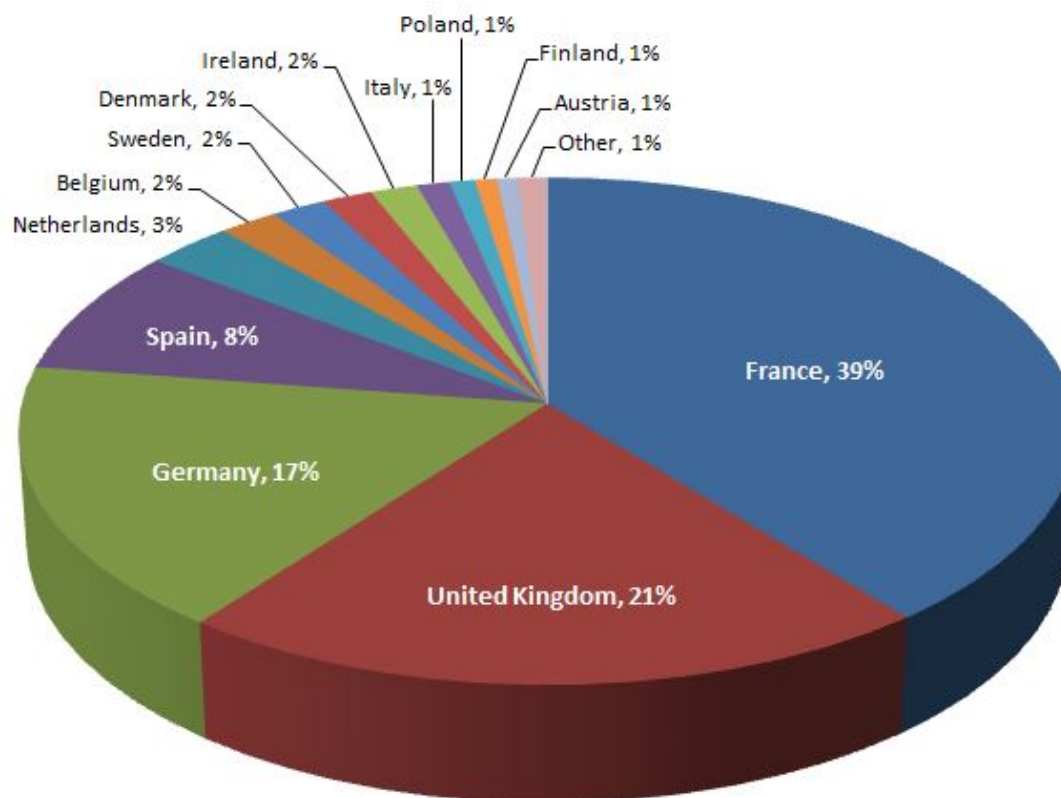




# Opportunities - scientific

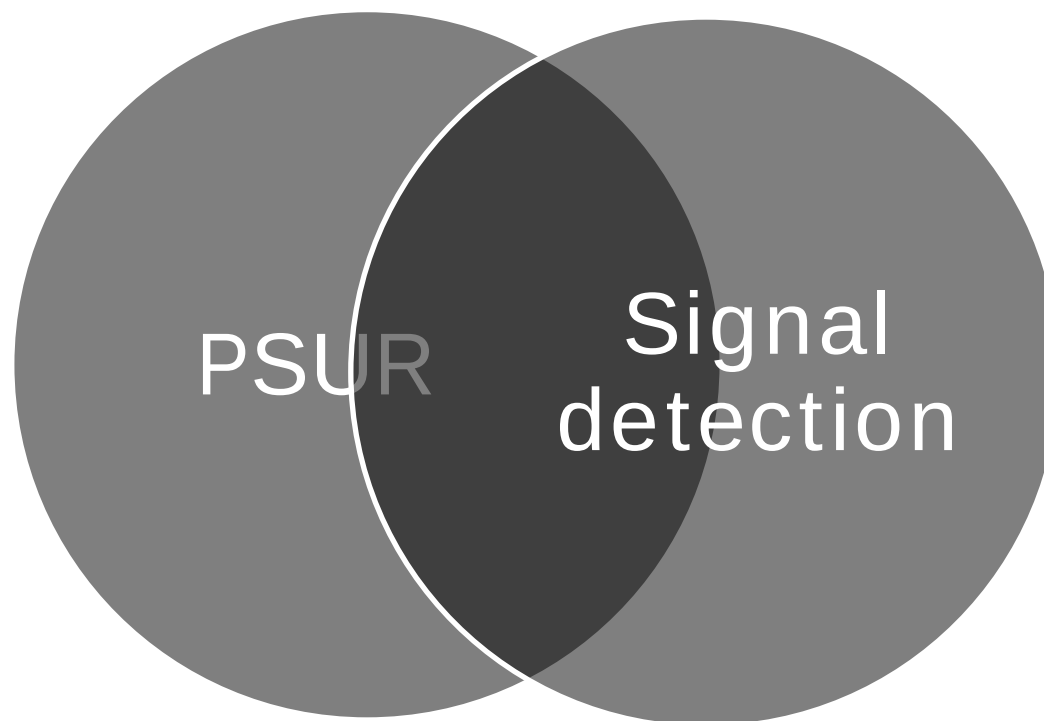
Chart Area

**Proportional number of cases per Member State**



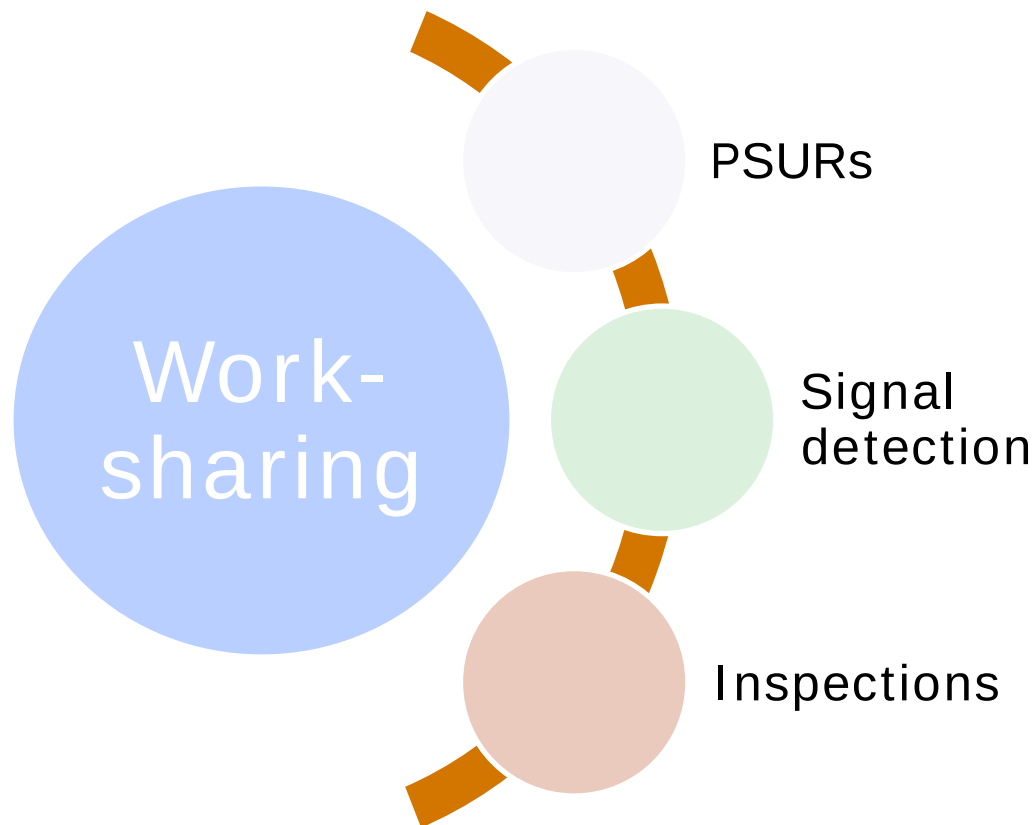


## Avoid duplication





## Opportunities - organisational





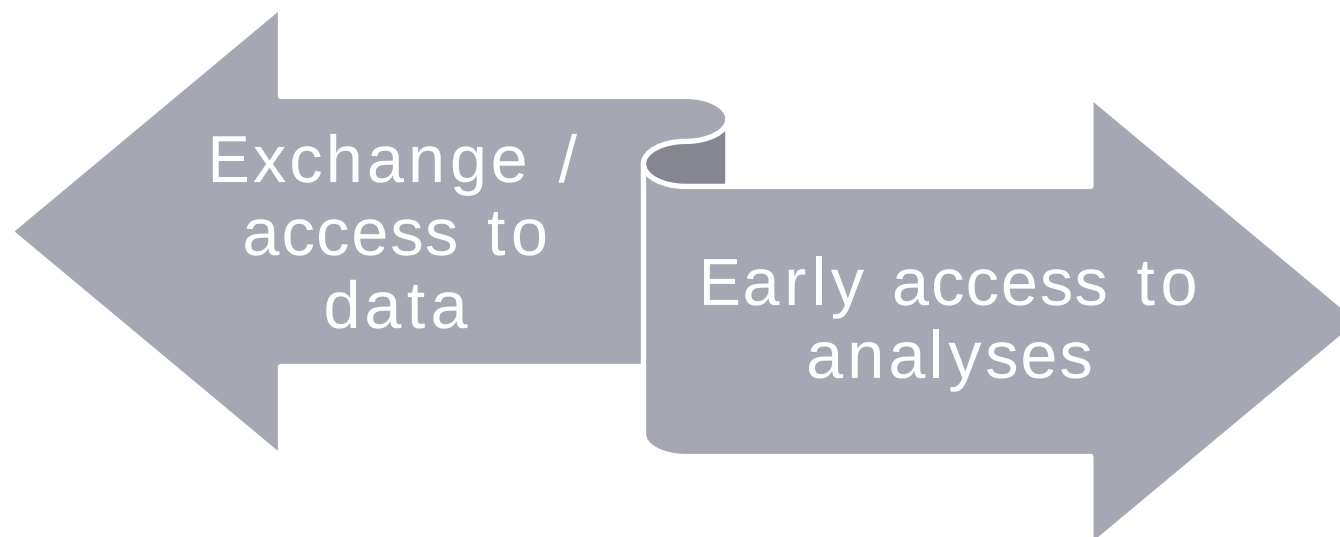
# Risk-based approach



Market exposure  
Type of product

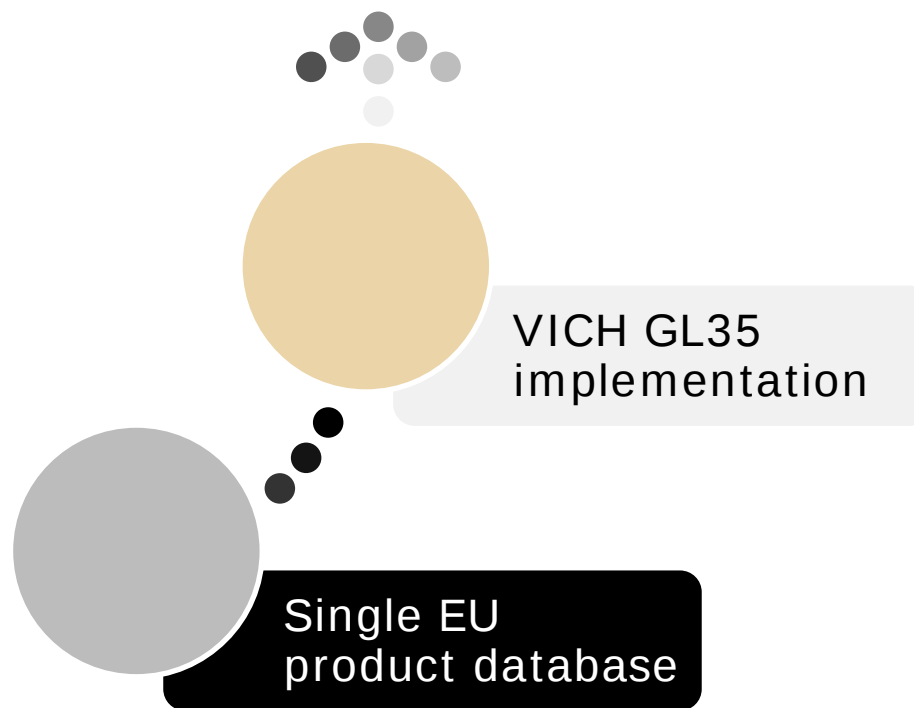


## Opportunities - international



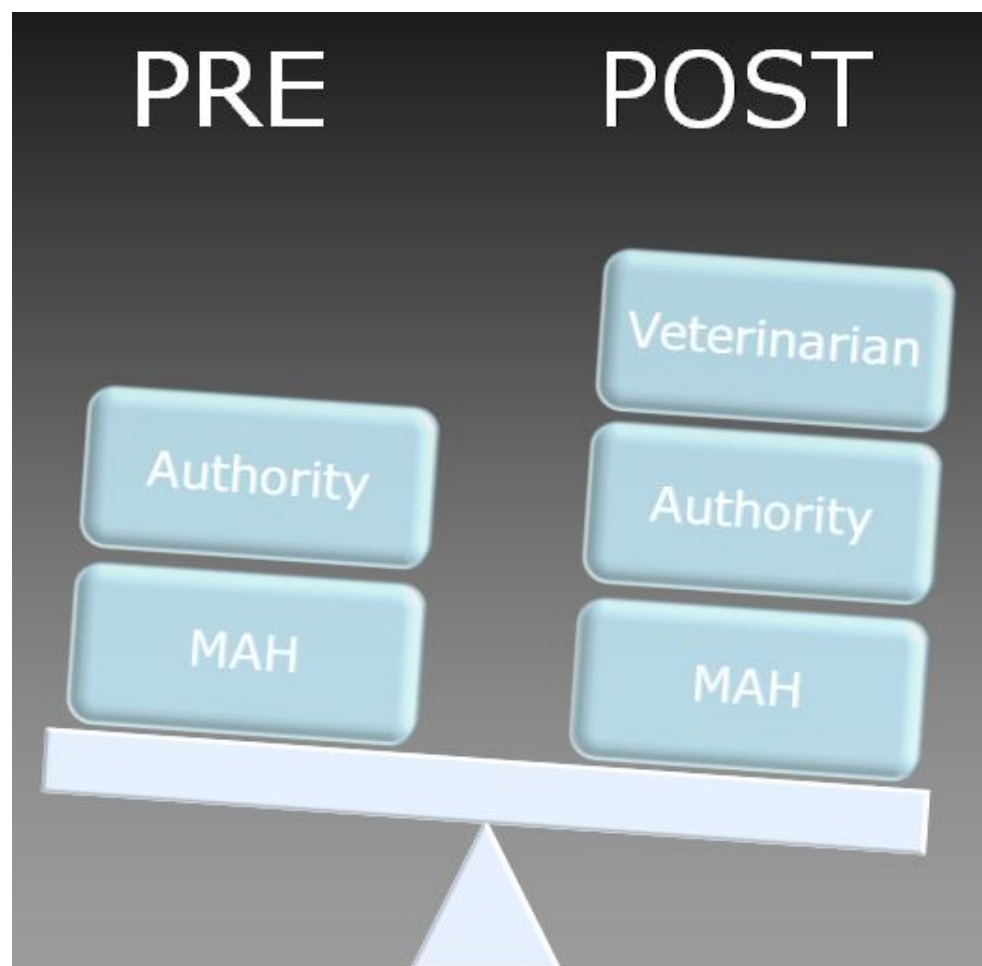


# Challenges - operational





## Challenges - underreporting





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2%



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21%



4%



2%



46%

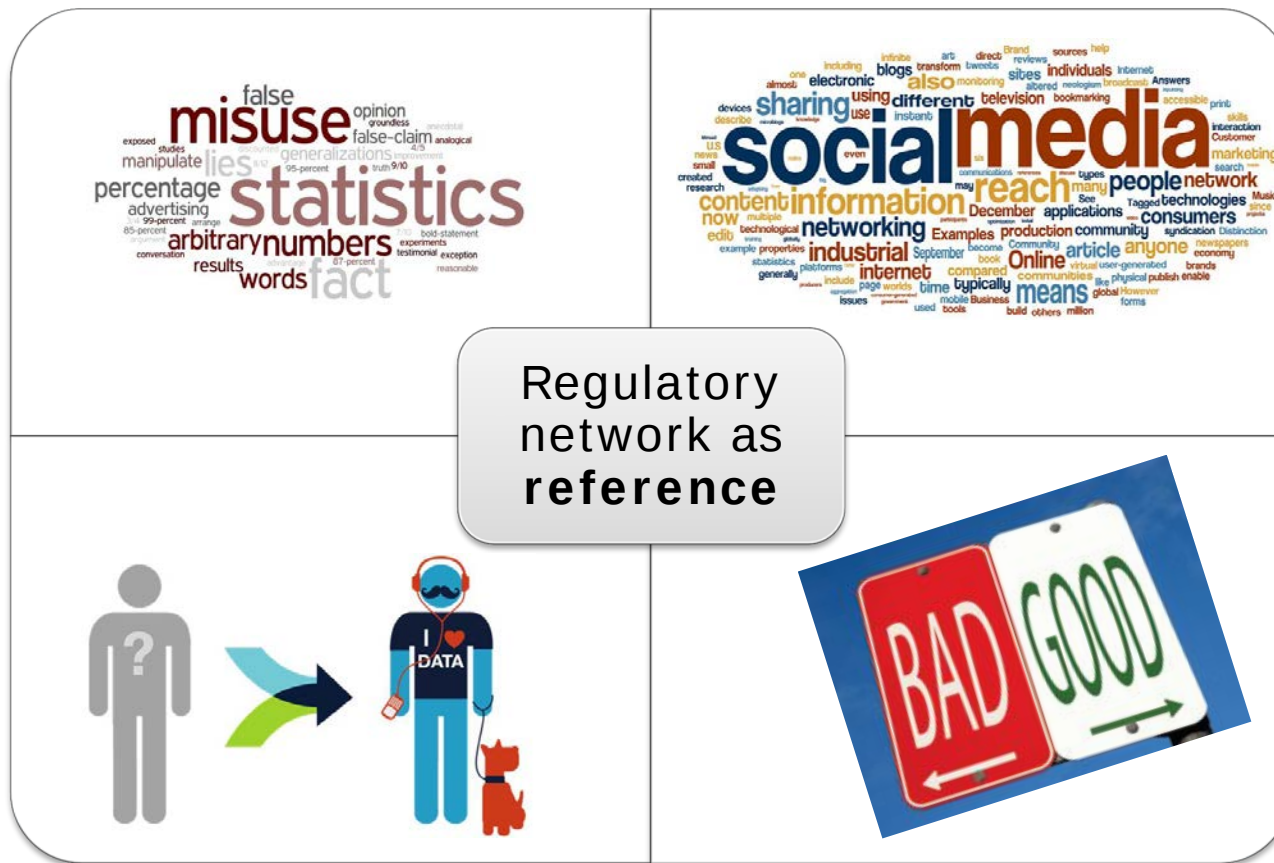


14%



0.08%

## Challenges – Access to data versus misuse





## Next steps

Product database

VICH compliant  
reporting system

PhVWP-V /  
Industry  
workshop 2014

Finalisation of recommendation on  
pharmacovigilance surveillance and  
signal detection of veterinary  
medicinal products

Implementation  
of signal  
detection for all  
authorised VMPs

**Development of veterinary  
signal detection**



# Questions

