EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance and signal management Experience and Trend for Future

European Medicines Agency/IFAH-Europe Info Day 2016

Presented by Peter Ekström on 17 March 2016, Chair CVMP Pharmacovigilance working party

An agency of the European Union

Experience... public

Public Bulletin

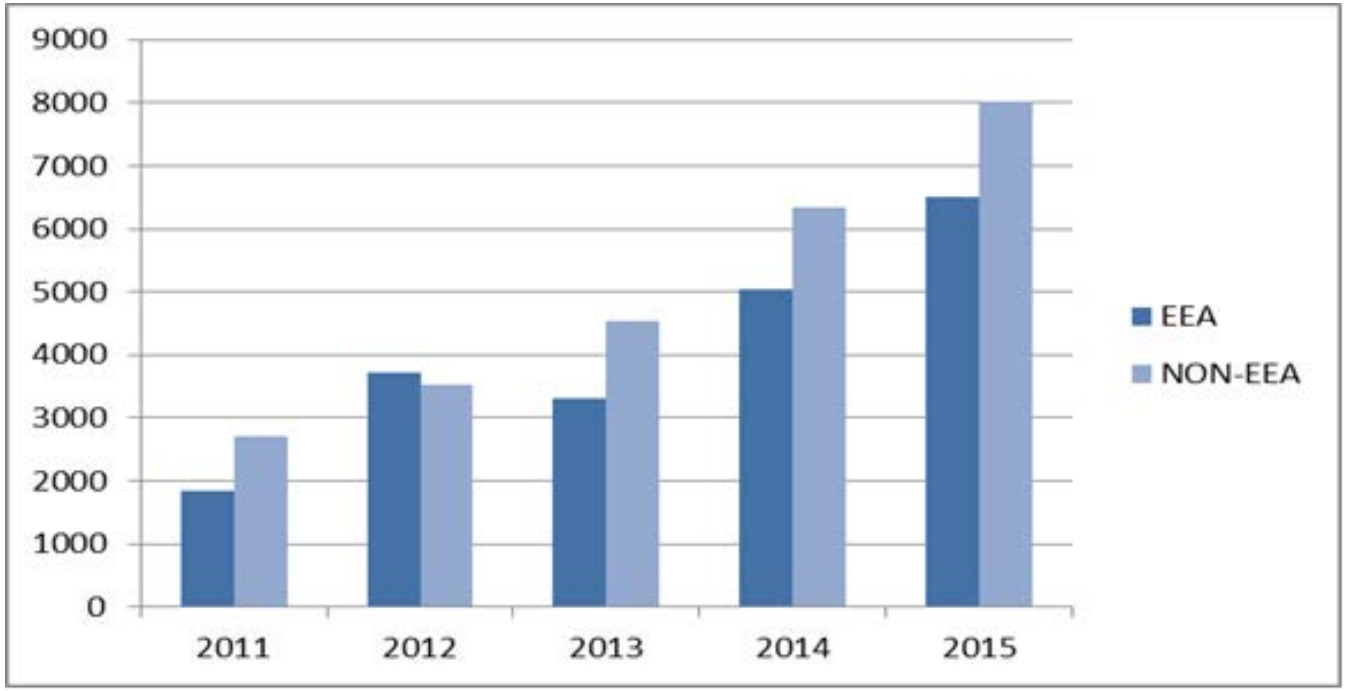
Veterinary pharmacovigilance 2015

Experience….Adverse event reports

A total of **14,387** adverse event reports relating to exposure to centrally authorised products were received in 2015,

concerning **13,847** adverse events in **animals** and **540** adverse events in **humans.**

Total number of adverse event reports for centrally authorised products reported per year to the central EU database from within and from outside the European Economic Area (EEA)



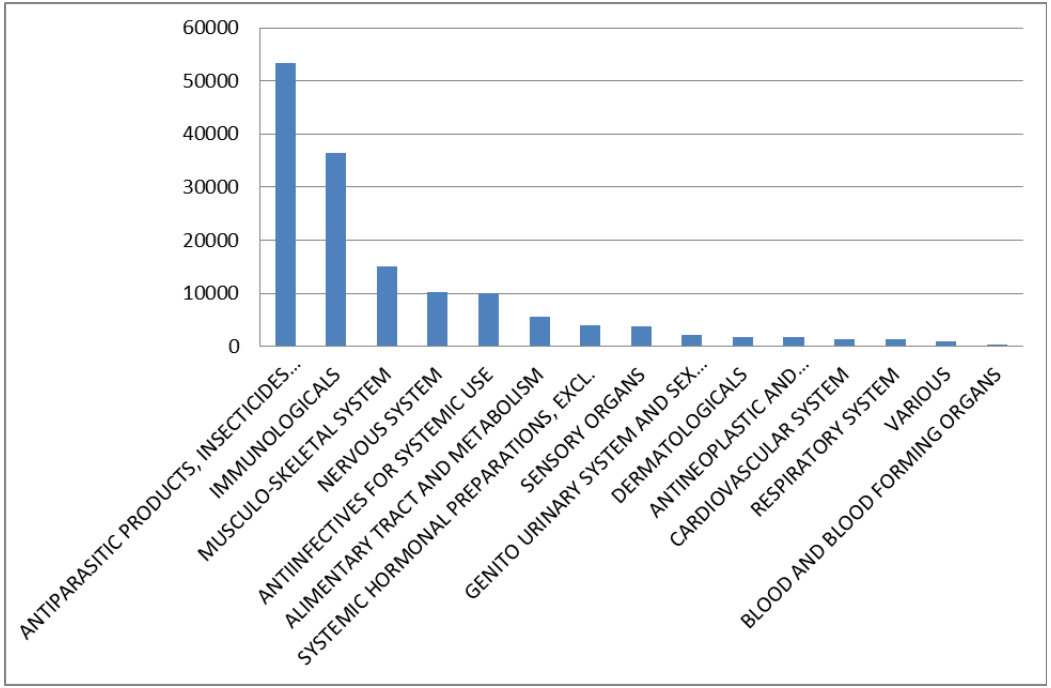
Experience….gained

- In total approximately **170,000** reports in EudraVigilance Veterinary (EVVet).
- There are now **170** veterinary medicinal products that have been authorised via the centralised procedure since 1995.
- The EMA's CVMP and its PhVWP-V reviewed during 2015 in total **157 periodic safety update reports** provided by the MAHs.
- The monitoring of centrally authorised veterinary medicinal products resulted in 2015 in **383** surveillance reports. Presented and discussed in PhVWP

Centrally authorised products: summary statistics on reports by target species, including reports in humans (Reports received between 1 January 2015 and 31 December 2015.)

Species	Species	Number of Safety Report ID	Total reacting animals included in the reports
Companion animals	Canine/dog	9515	10,041
	Feline/cat	2914	3,490
Food producing animals	Bovine/cattle	261	3,322
	Caprine/goat	27	4,072
	Chicken	19	286,073
	Equine/horse	222	461
	European rabbit	366	3,016
	Ovine/sheep	31	958
	Porcine/Pig	431	278,363
Others	Others	61	65,261
Human	Human	540	NA

Number of adverse event reports classified by ATC coded type of product until 2015.

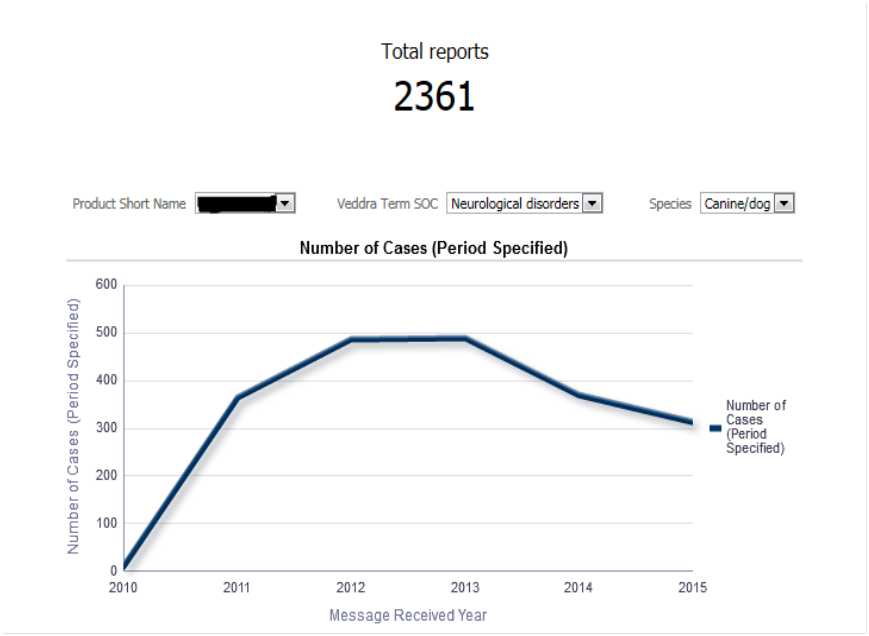


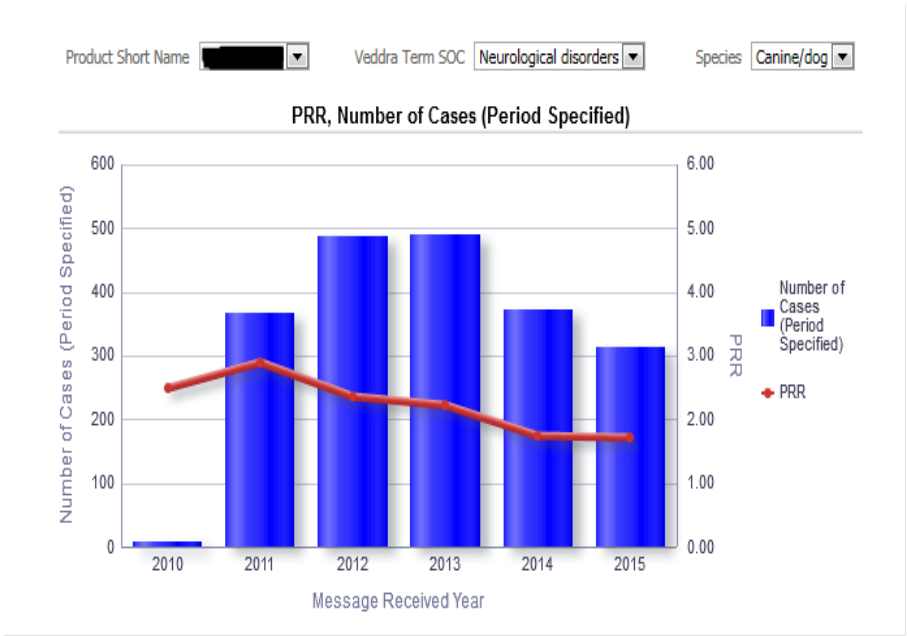
With that Experience….collaboration, smarter way of working

Action:

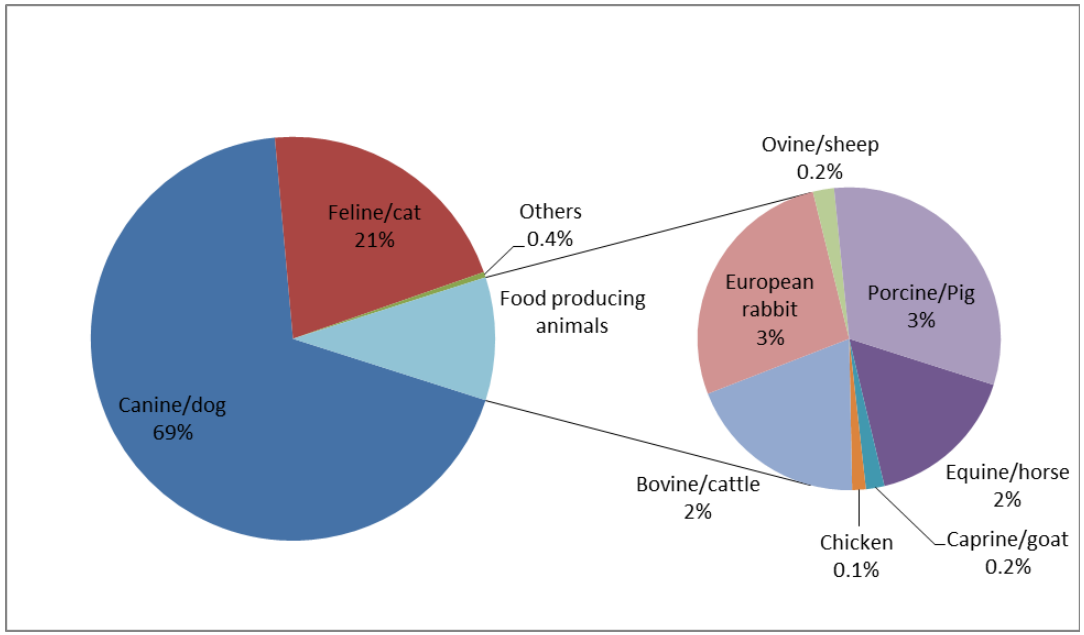
- Antiparasiticides subgroup
  - The scope of the sub-groups work is limited to companion animals and to tick and flea products (to start with)
  - More then 10 products
  - Several rapporteurs and there pharmacovigilance experts involved
  - Tailored DWH queries developed
  - Analysis strategies developed
  - Benefit/Risk discussion

DWH queries and display of information





% of adverse event reports by species for reports received during 2015 related to the use of centrally authorised products



Experience and Future…..

The data also show very few adverse event reports related to veterinary medicinal products used in **food producing animals**

➢Most likely explained by underreporting.

Action:

➢A focus group on promotion of pharmacovigilance reporting on food producing animals planed for November 2016

The focus group aims to discuss with all stakeholders and in particular with veterinary specialists for the different food producing species.

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13 May 2015
EMA/CVMP/PhVWP/901279/2011
Committee for Medicinal Products for Veterinary Use

Recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products

Draft adopted by CVMP with regard to centrally authorised products	13 June 2013
Draft agreed by Pharmacovigilance Working Party	24-25 September 2013
Adopted by HMA-V	29 November 2013
Endorsed by CVMP for release for consultation	12 December 2013
End of consultation (deadline for comments)	30 June 2014
Agreed by Pharmacovigilance Working Party	28 January 2015
Adopted by CVMP	10 April 2015
Adopted by HMA-V	13 May 2015
Date for coming into effect	1 October 2015

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6 November 2015
EMA/CVMP/PhVWP/590073/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

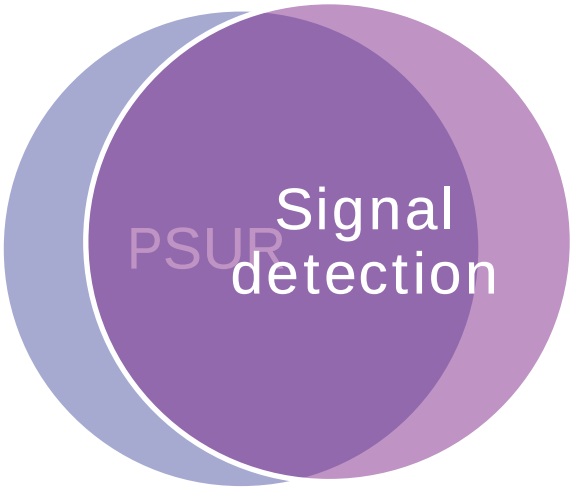
Concept paper for revision of the recommendation for the basic surveillance of EudraVigilance Veterinary data

Agreed by CVMP Pharmacovigilance Working Party	September 2015
Adopted by CVMP for release for consultation	6 November 2015
Start of public consultation	20 November 2015
End of consultation (deadline for comments)	29 February 2016

The proposed recommendation will replace 'Recommendation for the basic surveillance of Eudravigilance Veterinary data' (EMA/CVMP/PhVWP/471721/2006).

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

Concept paper for revision of the recommendation for the basic surveillance of EudraVigilance Veterinary data



Providing a comprehensive and streamlined surveillance process involving periodic safety update report (PSUR) assessment and signal detection within the framework of the current legislation. For CAPs.

What could that be?

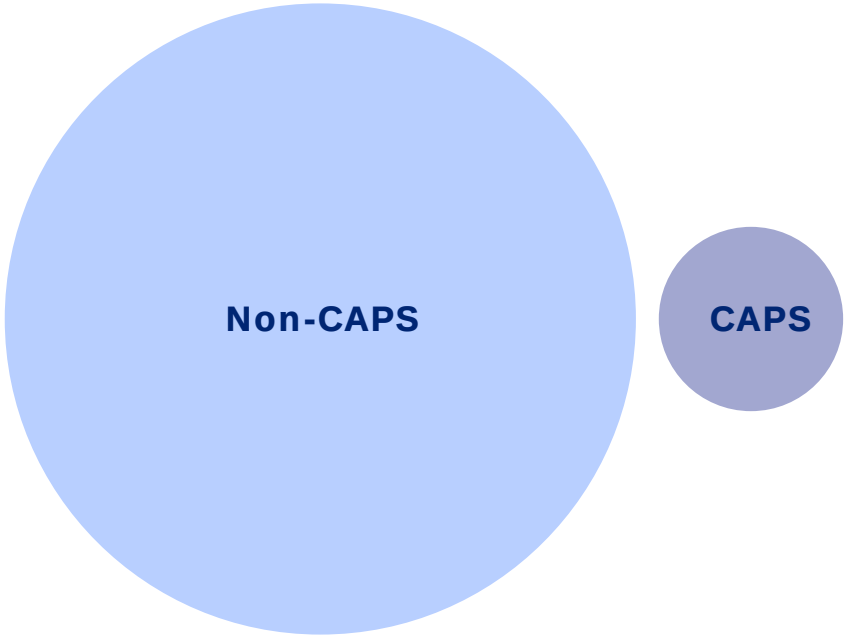
all AEs – Earlier pilot, no line listings ?

Company access DWH data for analysis? is this possible?

PSUR – sales data, could DWH have sales data ? initiative ongoing, included bar code, E-Health

Future
Work Plan 2016, plenary meetings…..

- Surveillance workshop 25 May 2016
- PhVWP-V interested party meeting 28 September
- A focus group on promotion of pharmacovigilance reporting on food producing animals planed for 23 November 2016


Non-CAPS
CAPS

Future ….in and outside EEA

- **EVVet 3**
  - VICH compliance
- **VICH**
  - Other VICH regions starting also with signal detection
  - Other VICH regions also considering reporting third country reports
- New Legislation Veterinary Medicinal Products
- Populating the EU **Veterinary Medicinal Product Database**.
- **Union Database** for all AEs
- **WHO** Collaborating Centre The Uppsala Monitoring Centre (UMC)
  - Why not veterinary pharmacovigilance?

Thank you for your attention