

# ANSES-ANMV

French agency for food, environmental  
and occupational health safety

# ANMV presentation

- French Agency for Veterinary Medicinal Products  
(Vet only Agency)
- 70 employees
- 2921 veterinary medicinal products authorised
- Medicinal product procedures/year
  - Marketing Authorisations : 85 (2016)
  - Variations : 800 (2016)

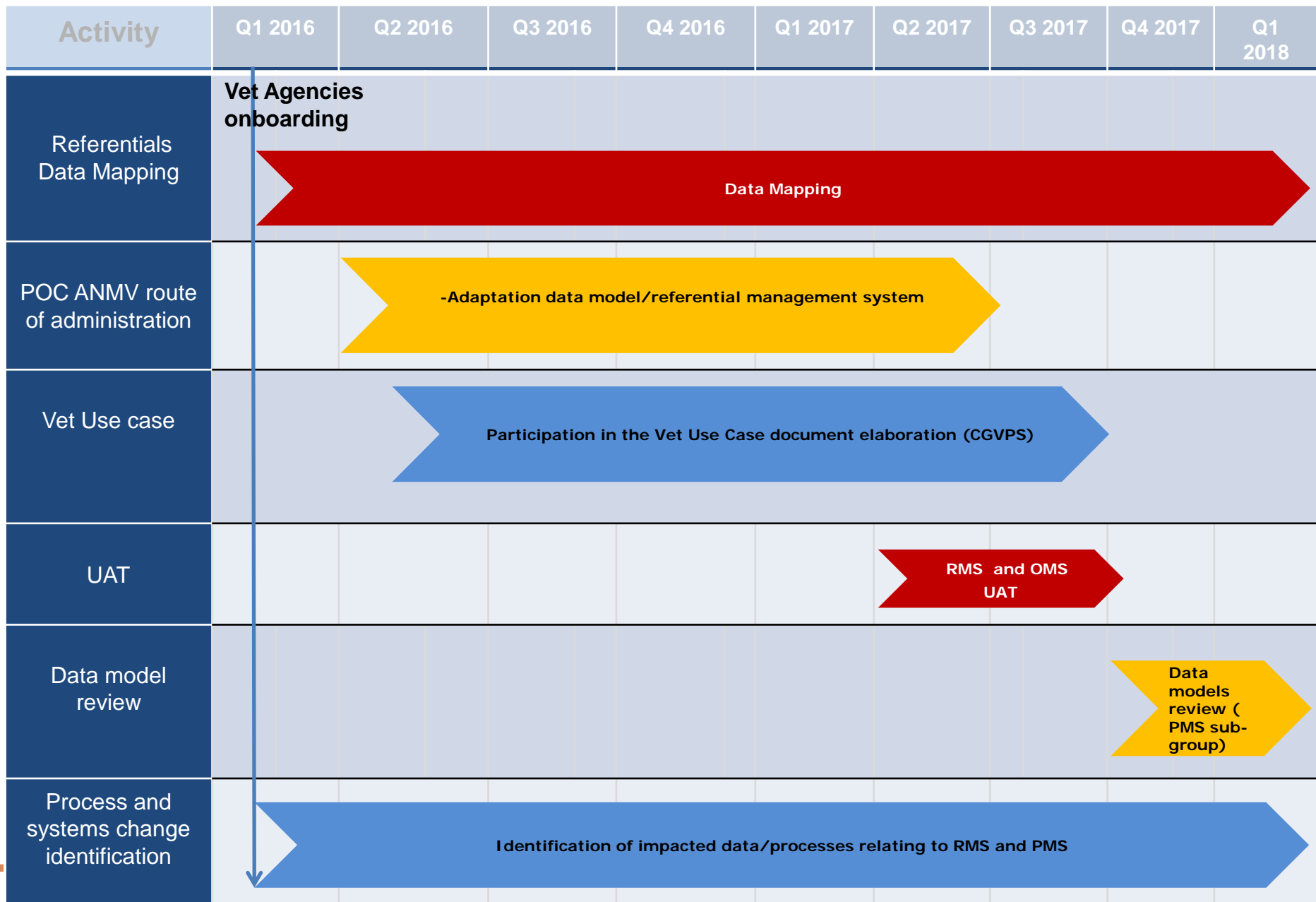


L'Agence Nationale du  
Médicament Vétérinaire

# ANMV involvement in SPOR

- Very good understanding and involvement of the Head of the Agency
  - Nominations in different SPOR Groups :
    - EU NDB
    - SPOR Task Force
    - Change Liaison
    - P Subgroup
    - Vet Subgroup (ex CGVPS)
- > 3 different skills : regulation, business, IT
- + IT developer

# Timeline



# Mapping and implementation of RMS Lists

- Referentials mapping since 2016, according to the EMA's planning
  - End-to-end Implementation test : pilot with « Route of administration »
    - Mapping
    - Adaptation of our own referential management system
    - Use of SPOR API for the exchange of data
    - Adaptation of the EudraPharm daily data export
- >This pilot on a multi-lingual list is a success and is under production today
- Workload : 8 days

# Mapping and implementation of RMS lists

- 2018
  - Implementation of different types of list
    - List with unique value without translation : variation classification, prescription status
    - List not managed in our own referential management system
- After 2018
  - List with entity and adress (linked with OMS project)
  - List of substances

# Issues concerning the mapping

- Container :
  - Not a list but a free text data
  - Impossible to map at this stage
- Unit of measurement :
  - Expression of strength in qsp (quantum satis pro) « enough quantity for »

Substance	strength	QSP	SPOR
Amoxicillin	40 mg	1 tablet of 280 mg	0,14 mg/mg
Dexamethason	10 mg	1 mL	10 mg/mL


- Legal basis
  - Issue for MA granted before 2003 (no registration of legal basis)
  - change request rejected


# Adaptation of the business national database and process

- Review of the PMS data models
- Identification of a lot of impacts on our national database and workflows
  - Impact on workflow (management of procedures)
  - Impact on national referential management system
  - Impact on the structure and content of national database
- Identification of many issues :
  - Lack of an EU unique number to identify a veterinary medicinal product (one DCP or MR procedure = one VMP authorised in several countries)
  - Many additional data compared to the Veterinary Use Cases document
    - Utility of those data for the vet domain as mandatory data ?
    - Capacity of all vet Agencies to manage all those data?



# Conclusion

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- Participation to many different meetings or groups to gather information
  - Burden
  - Taking account of Use cases vet

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- SPOR API
  - SPOR user interface (SPOR website)

Thank You  
ANY QUESTION???

