RÉPUBLIQUE FRANÇAISE
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A NATIONAL COMPETENT AUTHORITY PERSPECTIVE ON INNOVATION

EMA VETERINARY INNOVATION DAY
13&14 MARCH 2025

Innovation : A challenge for national competent authorities

- **New veterinary regulation (2019/6) gives a central role to EMA (art 42) for all innovative VMPs as new active substances, biotechnological processes and novel therapies**
  - *(a) veterinary medicinal products developed by means of one of the following biotechnological processes: (i) recombinant DNA technology; (ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; (iii) hybridoma and monoclonal antibody methods;*
  - *(b) veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;*
  - *(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;*
  - *(d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;*
  - *(e) novel therapy veterinary medicinal products : gene therapy, regenerative medicine, tissue engineering, blood product therapy, phage therapy; (b) a veterinary medicinal product issued from nanotechnologies; or (c) any other therapy which is considered as a nascent field in veterinary medicine.*

- **Challenge : How to remain up to date, be prepared for the assessment of this innovative dossier and play a part in fostering innovation at a national level?**
  - **Relationship with the stakeholders (industry, start-up and academia, veterinary, others NCA's)**
  - **A tiny national "sandbox"**
    - Article 110 : emergency authorisation
    - Article 2 : tailor made veterinary medicinal products (out of scope of 2019/6)

1. Relationship with stakeholders as a key point to foster innovation

Industry, start-up and academia

Meetings with industry representatives

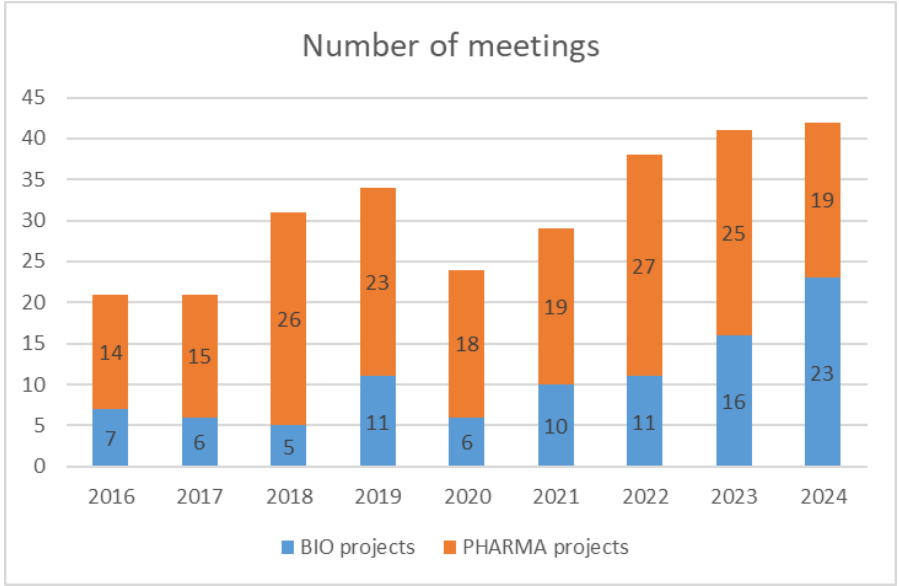
Differents types of meetings :

Meeting with the French VMP industry representatives (SIMV)

- Annual day + 4 general meeting + 6 thematic meetings / year
  - *NAMs, AMR, GCP, inspection, international,…*

Meetings requested by firms :

- Pre submission meeting
- ***Overview of their pipeline***
- ***R&D project overview at an early stage***
  - ***Guiding to go to ITF/Scientific Advice to EMA***
- ***Specific meeting for a POC study design***



Meeting with « start-up + academia + industry »

- **Participation in webinars organised by learned societies, congress**
- **Annual participation in the « Biofit » congress**
  - **Animal health**: Presented projects are innovations with a very broad theme in relation to animal well-being and health (diagnosis, prevention, vaccine, therapy, medical device, connected health, etc.).
    - Knowledge of the pipeline in a very early stage
    - Early orientation of the stakeholders especially on legal requirements and clinical trials
- **Clinical trials**
  - Some innovative fields can't be investigated by traditional experimental models (cancerology, stem cells …)
    - **Authorisation in FR for these POC studies under clinical trial status (no GMP batch, GCP-like study)**

ANIMAL HEALTH

BENNO THERAPEUTICS
Vaccine | Canine cancer | Tumor vasculature

DAMOCLES DIAGNOSTICS – DAMAST
Point of Care | Diagnostic test | Fast AST

FINDIMMUNE – WOOF
Oral melanoma | Squamous cell carcinoma | Immunotherapy

INRAE TRANSFERT
SVCV | Vaccine platform | Host-pathogen model

INRAE TRANSFERT
Influenza A virus | Vaccine | H5N1

GHENT UNIVERSITY
Bacterial infections | Antibiotic resistance | Pyoderma

VAXINANO
Nasal vaccines | Delivery system | Platform

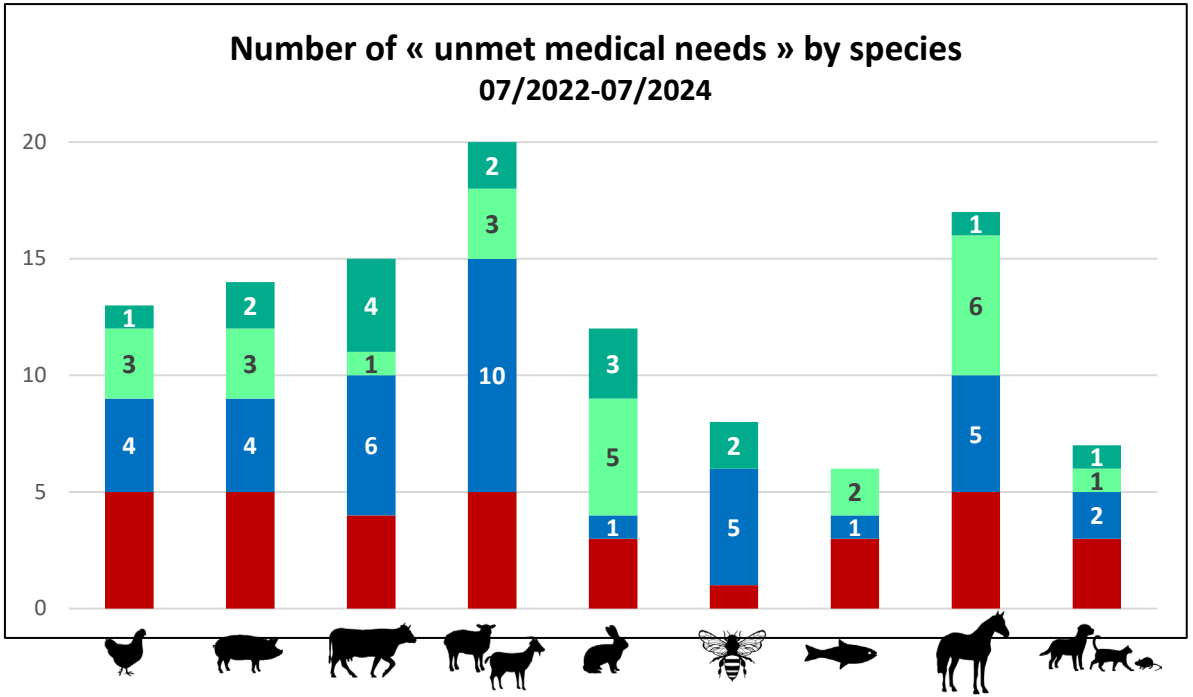
AIHERD
Dairy | Monitoring | Detection

Veterinarians and academia

Relationship with veterinary association and therapeutical gaps identification

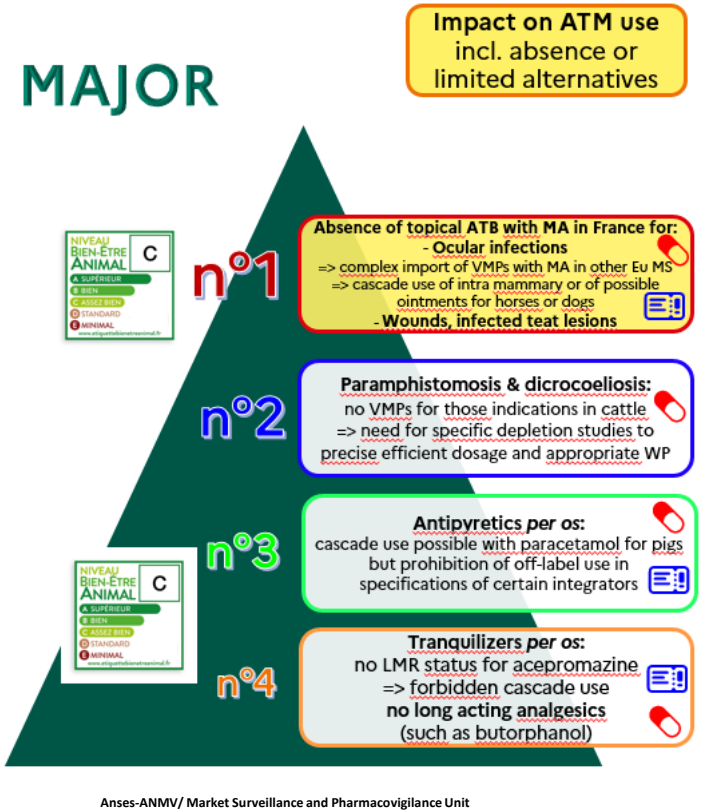
Feedback 2022-2024

25% to 67% : solved or in process to be solved (green color)



- 4 meetings/year with our veterinary expert committee
  - ½ practicioners
  - ½ academics
- A meeting every two years for each group of species with vet specialists (ruminants, pets, pigs, poultry, fish,..)
- Web posting
- Action plan to solve the problem

Gaps in Cattle sector
Hearing of 30/05/23



Anses-ANMV/ Market Surveillance and Pharmacovigilance Unit

Field needs on new products : maping of unmet medical needs by species in France

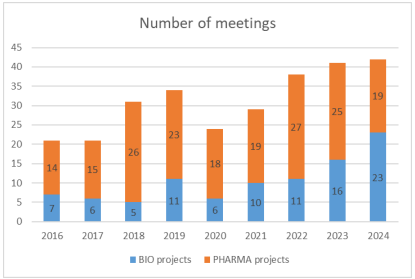
- reseau-francais-sante-animale.net/le-rfsa/cartographie-des-gaps-therapeutiques/

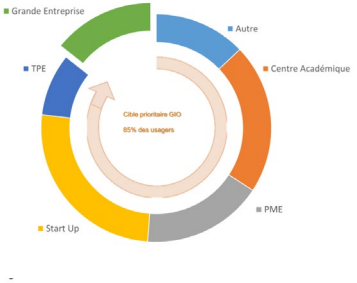
NCAs

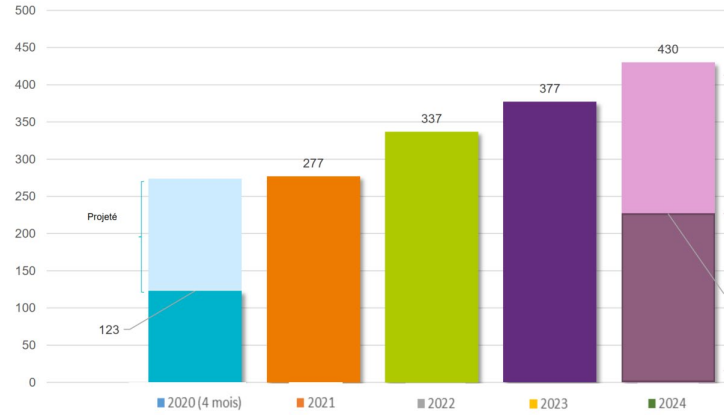
Relationship with NCAs

- **Within our mother agency (ANSES)**
  - **Strong network of reference laboratories :**
    - *Research on strains including new vaccines (ASF, vaccination for wildlife, studies for minor species,…)*
- **Others NCA's :**
  - **ANSM (french human medecine agency): Strong relationships with our human colleagues**
    - *Workshops on novel therapies (phagotherapy, monoclonal antibodies,…)*
    - *Workshop on ERA*
    - *MNAT project on quality*
    - *GIO (Innovation and orientation platform)*

ANMV meetings with industry







ANSM GIO meetings

Strong relationship with stakeholders (industry, academia, start-up, veterinary) according to our deontology rules appears to be a key point :

- **To guiding, supporting and facilitating innovation**
- **For NCA being ready and agile to assess novel therapy dossier**

A tiny innovative « sandbox » for NCAs : Health situation (art 110) and tailor made VMP (art 2.1)

1. Health situation (art 110)

Art 110-2 : A tiny sandbox for vaccines

2019/6 Articles		*Common VMP*		*Innovative VMP*		
		Decentralised or national	Centralised	Decentralised	national	Centralised
Art 8	**Complete MA :** An application for a marketing authorisation shall contain the following ……Annex II					
Art 25	**MA under exceptionals circunstances :** By way of derogation from point (b) of Article 8(1), in exceptional circumstances related to animal or public health, an applicant may submit an application which does not meet all requirements of that point, for which the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided.					
Art 116	**Health situation :** By way of derogation from Article 106(1), a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is **authorised in another Member State.**	*Import autorisation from EU countries*				
Art 110-2	**Emergency authorisation** : By way of derogation from Article 106(1) of this Regulation, and in the absence of a veterinary medicinal product as referred to in Article 116 of this Regulation, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EU) 2016/429 or an emerging disease as referred to in Article 6 of that Regulation, a competent authority may allow the use of an **immunological veterinary medicinal product not authorised within the Union**.				Immunological VMP	

Emerging disease as HPAI

(Compte tenu d'une situation sanitaire nécessitant une vaccination en urgence,) la présente autorisation temporaire d'utilisation (ATU) a été attribuée en prenant en compte une balance bénéfice risque jugée positive du vaccin au vu des éléments fournis avec néanmoins un niveau de preuve limité concernant les mentions du résumé des caractéristiques du produit (RCP).

ANNEXE DE LA DECISION D'AUTORISATION TEMPORAIRE D'UTILISATION

INFORMATIONS DISPONIBLES SUR LE MEDICAMENT VETERINAIRE

Date de validité de l'Autorisation Temporaire d'Utilisation : 01/04/2025

NOM DU MEDICAMENT VETERINAIRE

CEVA RESPONS AI H5, SUSPENSION CONGELEE ET DILUANT POUR INJECTION

COMPOSITION QUALITATIVE ET QUANTITATIVE

Chaque dose de 0,2 mL contient :

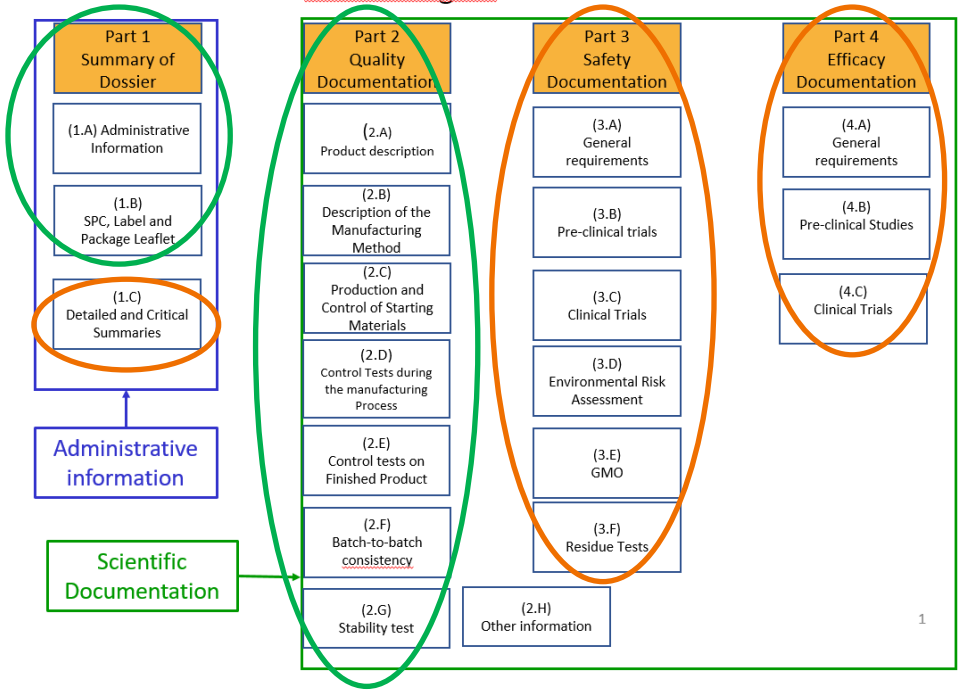
Substance(s) active(s) :
ARN auto-amplifiant, codant l'hémagglutinine virale du virus de l'influenza aviaire H5 ≥ 1 UR*

*: Unité Relative (test sérologique) par comparaison avec un vaccin de référence

Assessment of the Art 110 file : RESPONS VACCINE

- **Regulatory innovation**
  - **Authorisation of a sequencial submission**
- **Flexibility**
  - **Evaluation of benefit of the immediate availability > risks linked to lack of certain data**
- **Very short timetable**

Dossier structure: immunological VMP



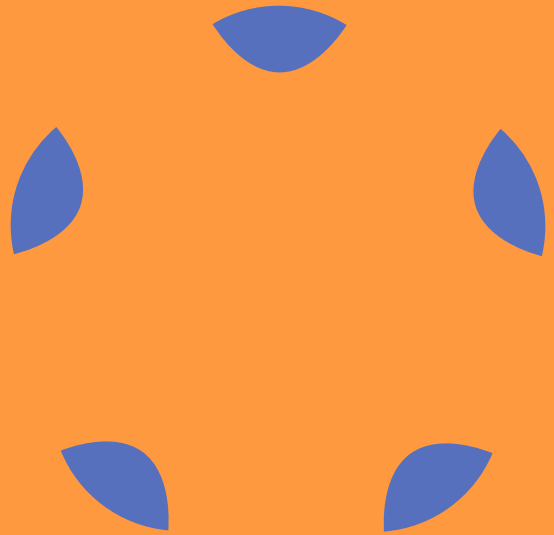
0 Full assessment part

0 Sufficient but not complete data provided

Our main objectives:

- Taking the health situation into account
- Making the best VMPs available including innovative solutions
- In accordance with EU 2019/6

2. Tailor made VMP : *Example of bacteriophages*

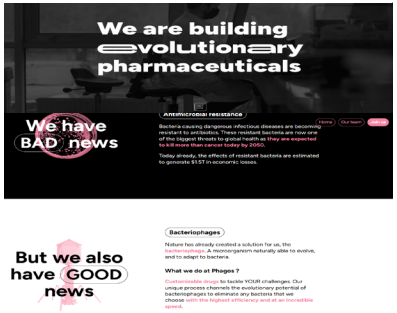


Tailor-made treatment

- *Article 2 :* **Scope :** This regulation shall apply to veterinary medicinal products **prepared industrially** or by a **method involving an industrial process** and intended to be placed on the market.
  - French regulation for “non industrially prepared VMP” :
    - **Art. L. 5142-1-2 (Public health code) :** The preparation of veterinary medicinal products not falling within the scope of Regulation (EU) 2019/6 of December 11, 2018, excluding extemporaneous preparations :
      - **Qualified person** : is carried out by a qualified person or a company or organization employing a qualified person who has obtained an authorization for this purpose issued by the French National Agency for Food, Environmental and Occupational Health Safety.
      - **Pharmacovigilance obligation :** “This activity is subject to pharmacovigilance obligations,
      - **Specific GMPs** : “It is carried out in compliance with good practice, the principles of which are laid down by decision of the Director General of the ANSES

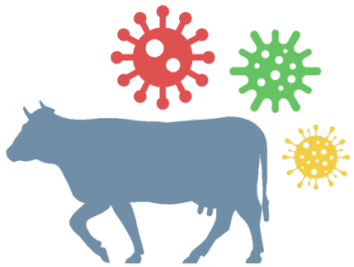
Exemple of use of this French regulatory sandbox :

- **Authorisation of the first veterinary phage therapy platform** that enables the creation of tailor-made phage therapies using the same production and analysis process.



Infection

- Diagnosis at field level
- Sampling



Manufacturing process

- Isolation
- Identification
- Platform process
- Quality controls

Final product

- Tailor-made treatment : « *Cocktail » of bacteriophages*

Our main objectives:

- **Fostering innovation at a local scale**
- **Making new tailored made solutions available for vets**
- **Adquiring knowledge on these solutions for assessment of future standardized product derived from tailor made experience.**

Conclusion

- **EMA is the pivot point for innovation in the VMP field**
- **Relationship and trust with stakeholders is a key component**
- **NCA can be “innovative” in a tiny space to promote innovation at a national level and improve their assessment experience**
- **My final thought : *“A wider “regulatory sandbox” would be useful at national level”***