



Association of Veterinary Consultants

**Follow-up on Veterinary Vaccine Shortage
as a Driver of Emerging Issues**

33rd EFSA StaDG-ER – 5 June 2025, Parma, Italy

Dr Rimma Ishimbaeva, AVC President

Veterinary vaccine shortages as a driver of emerging risk issues - follow up



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Content:

- AVC Introduction
- Emerging Infectious Diseases in Livestock: A Growing Threat
- Causes of vaccine shortages
- European and national regulators' actions
- Farmer signals and actions
- Animal Health organisation signals and actions
- Academia actions
- Preparedness in various countries
- Cases in Point
- Conclusion





ABOUT AVC

-  **Members:** > 60 expert veterinarians from 21 countries across 6 continents
-  **Type:** Non-for-profit entity
-  **Governing Body:** AVC Board (5 members)
-  **Membership Structure:** Regulatory Consultancies, CRO, CDMO

 www.avc-eu.de

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The background of the slide features a photograph of a sunset or sunrise over a rural landscape. Silhouettes of several cows are visible in the foreground and middle ground against a backdrop of trees and a hazy sky. The overall atmosphere is peaceful and pastoral.

The slide features a large title 'AVC MEMBERS' ENGAGEMENT' in white, bold, sans-serif font at the top center. In the top right corner is the AVC logo, which consists of a blue hexagon with a white 'AVC' monogram and a green hexagon above it. Below the title are three blue hexagonal boxes, each containing an icon and text. The first box on the left contains a person icon inside a gear, titled 'Continuous Improvement' and describes offering continued education and training. The middle box contains a person icon inside a circle with a star, titled 'Policy and Advocacy' and describes providing expert advice to authorities and participating in consultations. The third box on the right contains a network of interconnected nodes, titled 'Collaboration and Networking' and describes membership in EFSA Stakeholder Bureau and the like. The background of the slide is a light grey with white diagonal stripes on the left and right sides.

AVC NETWORK 2025

Membership:

- Europe - 49
- North America - 4
- South America - 4
- Asia - 3
- Africa - 2
- Australia - 1

63 members **21** countries

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A world map showing the locations of AVC members across the globe, with a high density of points in Europe and North America.

AVC WORKING GROUPS

Expert Composition

EFSA scope

EMA scope

Common

12 Working Groups
3-10 experts per group

Food Chain AMR

AVC Strategy Big Data & AI

Animal Welfare/ 3Rs

VICH
VMP Safety
VMP Efficacy
Immunologicals & Vaccines
VMP Limited markets
Pharmacovigilance
VMP Quality





AVC NETWORK IN EUROPE



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Belgium Ireland
Cyprus Italy
Denmark Netherlands
France Romania
Germany Spain
Hungary UK



48

members

12

countries

Veterinary vaccine shortages pose risks to animal health, food security and One Health



In an era of new emerging transboundary diseases of animals and zoonoses, the availability and accessibility of veterinary vaccines is a crucial requirement for effective disease control and prevention.

Context of the vaccine shortage: follow-up of [FVE](#) and [AVC](#) presentations (2022) and [AVC](#) presentation (2024)

Emerging Infectious Diseases (EID) in Livestock: A Growing Threat



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- Infectious diseases in livestock are increasing across the EU and worldwide.
- Recent outbreaks of Avian Influenza, Bluetongue, and Epizootic Haemorrhagic Disease have heavily impacted farmers and the food supply chain.
- The threat continues with other emerging or re-emerging diseases, such as Peste des Petits Ruminants and Sheep, Goat Pox and FMD.
- Proven control measures exist—surveillance, biosecurity, animal movement restrictions, epidemiological modelling, and **vaccination** - however:

👉 Timely **access to appropriate vaccines** remains a major challenge, especially in emergency situations

Source: IABS- International Alliance for Biological Standardization

Causes of vaccine shortage

Cause	EU & Global	
Regulatory burdens	Inflexibility in regulatory processes, lack of policies and communication among stakeholders	
Economical burden	Tariff and taxes, sanctions, business embargo	
Political situation	Geopolitical situations in various regions - manufacturers of veterinary medicines, APIs, packages, raw materials	
Supply disruption	Supply chain issues (i.e. post-COVID)	
Production issues	Quality, LMICs domestic vaccine production does not cover demand	

VMP shortage: EMA actions



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role of Consultants in the operation of Regulation (EU) 2019/6

29th AVC General Assembly

Presented by Kristina Paterson and Jana Schalansky on 5 October 2024

An agency of the European Union 

Source: EMA presentation on VMP shortages, 29th General Assembly of the AVC, 5 October, 2024, Utrecht, the Netherlands



EUROPEAN MEDICINES AGENCY

General considerations

Lack of availability vs. shortage vs. unmet medical need

 **Lack of availability:** products that are authorised but are not marketed/no longer marketed

 **Shortage:** lack of products that are authorised and marketed (*supply chain disruptions that directly prevent the availability of authorized+marketed products*)

 **Unmet medical need (therapeutic gap):** lack of authorised products

10 Role of Consultants in the operation of Regulation (EU) 2019/6
Classified as public by the European Medicines Agency

VMP shortage: EMA actions



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What is EMA doing in case of VMP shortages? (1)

Currently no process established for critical veterinary CAPs shortages

Limitations

- No (legal) shortage reporting framework for MAH
- No structured industry shortage reporting channels
- Small number of notifications

Practice followed

- Engagement with MAH to agree on possible contingencies, incl. communication, increased manufacturing and supply, regulatory flexibilities (Rapporteur, SA, CVMP involved)
- Exchanges with SPOC WP-V members on VMP shortage criticality and alternatives available
- Oral explanations at SPOC WP to review supply outlooks and companies' action plans
- Interaction with veterinary stakeholders in supply chain at EU level (e.g. FVE/CMDV - *missing SPOC members, veterinary vaccines shortages*)

15 Role of Consultants in the operation of Regulation (EU) 2019/6
Classified as public by the European Medicines Agency

EUROPEAN MEDICINES AGENCY

What is EMA doing in case of VMP shortages? (2)

Future process to address critical VMP shortages:

- Scientific expertise provided by V-Division
- Availability team coordinates shortage case management activities
- Review (internal) process applicable to human CAP shortages - and adjust it to the V-CAP shortages



16 Role of Consultants in the operation of Regulation (EU) 2019/6
Classified as public by the European Medicines Agency

Source: EMA presentation on VMP shortages, 29th General Assembly of the AVC, 5 October, 2024, Utrecht, the Netherlands

May 2025: EMA monitors situation by launching stakeholder surveys on impact of economical and geopolitical issues on availability of human and veterinary medicines

VMP availability: reporting and tracking systems



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UPD - the Union Product Database

Advance notification system- PUBLIC

UPD shows the availability of Veterinary Medicines (ca 45.625 vmp's registered)

Search by filter:

- Product name,
- Active substance,
- Countries authorized
- **Availability** per country
- etc.

Select your choice:

Route of administration: Oral use

Pharmaceutical form: Oral solution

Target species: Ornamental bird

Authorised in:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom (Northern Ireland)

Available in:

- Belgium
- Germany
- Luxembourg
- Netherlands
- Poland

0 Medicine selected (3 max.) Compare

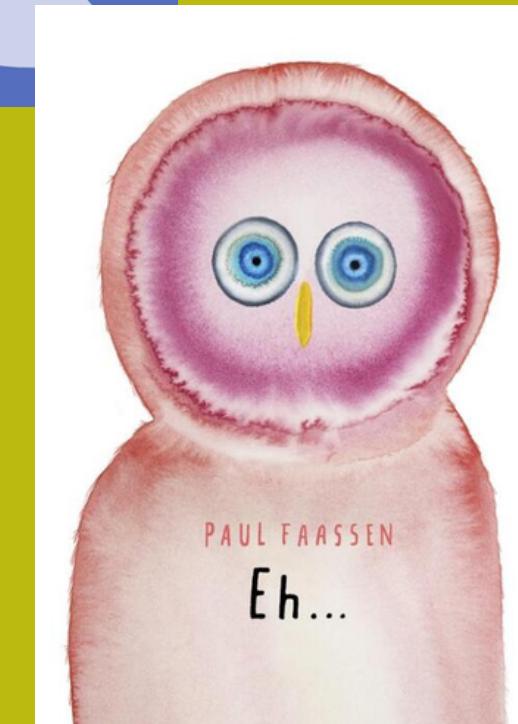
VMP shortage reporting and tracking systems: National registers



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The screenshot shows the ANSES (Agence nationale du médicament vétérinaire) website. The top navigation bar includes links for News, Explore our topics, About us, Our publications, and EU_PARC. Below the navigation is a breadcrumb trail: Home > Portals > Veterinary medicinal products > Declare a stock shortage of a veterinary medicinal product to the market. The main content area is titled 'PORTAL Veterinary medicinal products'. A sub-section titled 'Declare a stock shortage of a veterinary medicinal product to the market' is highlighted with a blue box and a call-to-action button. A small image of a person in a green uniform and gloves performing a procedure on a small animal is visible in the background.

The screenshot shows the Agence nationale du médicament vétérinaire website. The top left features the French flag and the text 'RÉPUBLIQUE FRANÇAISE' with the motto 'Liberté, Égalité, Fraternité'. The main title is 'Agence nationale du médicament vétérinaire'. Below this, there is a section titled 'Bonne Pratiques pour la gestion des ruptures d'approvisionnement d'un médicament vétérinaire'. A cartoon illustration of an owl with the text 'PAUL FAASSEN Eh...' is displayed. The bottom left contains a link to '1. Définition et contexte' and a note about 'Une rupture est définie comme l'impossibilité pour un ayant droit de s'approvisionner sur le marché national en un médicament vétérinaire.'



But what about
the language?

EU Member State	National register
Austria	<ul style="list-style-type: none">Human and veterinary medicines share the same online register: medicineshortage.basg.gv.at
Belgium	<ul style="list-style-type: none">Human medicines: www.famhp.beVeterinary medicines: geneesmiddelendatabank.fagg-afmps.be
Bulgaria	<ul style="list-style-type: none">Human medicines: www.bda.bgVeterinary medicines: no online register available
Croatia	<ul style="list-style-type: none">Human medicines: www.halmed.hrVeterinary medicines: no online register available
Cyprus	<ul style="list-style-type: none">No online registers available for human and veterinary medicines
Czechia	<ul style="list-style-type: none">Human medicines: www.sukl.czVeterinary medicines: no online register available
Denmark	<ul style="list-style-type: none">Human medicines: laegemiddelstyrelsen.dkVeterinary medicines: erhverv.medicinpriser.dk
Estonia	<ul style="list-style-type: none">Human medicines: www.ravimiamet.eeVeterinary medicines: www.ravimiregister.ee
Finland	<ul style="list-style-type: none">Human and veterinary medicines share the same online register: ansm.sante.fr
France	<ul style="list-style-type: none">Human medicines: www.anses.frVeterinary medicines: www.bfarm.de / www.pei.de
Germany	<ul style="list-style-type: none">Human medicines: www.bfarm.de / www.pei.de

VMP shortage reporting and tracking systems



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Greece	<ul style="list-style-type: none"> Human medicines: www.eof.gr Veterinary medicines: no online register available
	<ul style="list-style-type: none">
Hungary	<ul style="list-style-type: none"> Human medicines: www.ogyel.gov.hu Veterinary medicines: no online register available
Ireland	<ul style="list-style-type: none"> Human medicines: www.hpra.ie/ Veterinary medicines: no online register available
Italy	<ul style="list-style-type: none"> Human medicines: www.aifa.gov.it Veterinary medicines: no online register available
Latvia	<ul style="list-style-type: none"> Human medicines: www.zva.gov.lv Veterinary medicines: no online register available
Lithuania	<ul style="list-style-type: none"> Human medicines: vvkt.lt Veterinary medicines: no online register available
Luxembourg	<ul style="list-style-type: none"> No online registers available for human and veterinary medicines
Malta	<ul style="list-style-type: none"> No online registers available for human and veterinary medicines
Netherlands	<ul style="list-style-type: none"> Human medicines (shortages of selected medicines): www.cbg-meb.r Veterinary medicines: no online register available
Poland	<ul style="list-style-type: none"> Human medicines: no online register available Veterinary medicines: www.wetgiw.gov.pl
Portugal	<ul style="list-style-type: none"> Human medicines: www.infarmed.pt Veterinary medicines: no online register available
Romania	<ul style="list-style-type: none"> Human medicines: www.anm.ro Veterinary medicines: no online register available

Source: Presentation on VMP shortages, Dr A.Tolkamp, 29th General Assembly of the AVC, 5 October, 2024, Utrecht

Slovakia	<ul style="list-style-type: none"> Human medicines: www.sukl.sk Veterinary medicines: no online register available
Slovenia	<ul style="list-style-type: none"> Human medicines: www.jazmp.si Veterinary medicines: www.jazmp.si/veterinarska
Spain	<ul style="list-style-type: none"> Human medicines: https://www.aemps.gob.es Veterinary medicines: https://cimavet.aemps.es
Sweden	<ul style="list-style-type: none"> Human and veterinary medicines share the same online register: https://www.lakemedelsverket.se
EEA Member State	
Iceland	<ul style="list-style-type: none"> Human and veterinary medicines share the same online register: https://www.ima.is
Liechtenstein	<ul style="list-style-type: none"> No online registers available for human and veterinary medicines
Norway	<ul style="list-style-type: none"> Human and veterinary medicines share the same online register: https://legemiddelverket.no

Veterinary vaccine shortages : signals and actions of farmers (UK)



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VACCINE SHORTAGES CONTINUE TO DISRUPT UK PIG PRODUCTION

8th Jan 2025 / By Katie Jarvis

33rd EFSA StaDG-ER – 4-5 June 2025

Significant shortages are affecting pig herds, with issues reported across livestock sectors due to recalls, failed batches, and limited imports.

Less than 10% of veterinary vaccines are manufactured in the UK; **shortages** are also seen across the EU and globally

Key contributing factors:

- Manufacturing delays and material shortages (e.g., bottles)
- Disruptions from COVID-19 and shifting production priorities
- Tight production schedules with limited flexibility
- Short shelf life and strict storage requirements for vaccines
- Economic pressures and forecasting challenges

Consequences:

- Increased antibiotic use on farms (+18% in 2023)
- Risks to animal health, antimicrobial stewardship, and supply chain resilience (Source: National Pig Association, UK)

RUMA AGRICULTURE CALLS ON UK LIVESTOCK SECTORS TO TAKE PART IN NEW SURVEY ON VACCINE AVAILABILITY



Veterinary vaccine shortages : signals and actions of animal health organisations (2024-2025)



Veterinary medicine shortage is a main topic of the AVC General Assembly 2024 presented by EMA and AVC speakers.



Committee for Medicinal Products for Veterinary Use (CVMP) **Immunological Working Party (IWP-V)** Interested Parties meeting (IP) considered signals from FVE and Animal Health Europe and agreed that there are **gaps in vaccine availability** in EU.



EMA Veterinary Innovation Day - FVE raised topic of VMP shortages and proposed initiative of creation of **essential veterinary medicines lists**, supported by AVC.



CVMP IP meeting - FVE presented slide about progress in developing **essential VMP lists**.

VMP shortages
Jana Schalansky
Head of Veterinary Strategic Support

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EU Veterinary Medicine Shortage

3. Developing lists of Essential Veterinary Medicines
The **FVE/UEVP Medicines Working Group** is planning to map the **essential veterinary medicines** across Europe.
Background documents:

- [World Veterinary Association's \(WVA\) Essential Veterinary Medicines List](#)
- [WSAVA essential medicines list for cats and dogs](#)
- [France's Lists RSFA](#)
- [AEMPS, ANMV, DGAV, HPPA report on Availability of Antimicrobial Medicinal Products and Alternatives to Their Use](#)

Sheep and goats are going to be the first species addressed.

Veterinary vaccine availability: actions of international animal health organisations (2025)



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INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION IABS-EU Meeting on Preparedness and Response to Emerging Veterinary Disease Outbreaks: *Future approaches should include EU wide authorisation options (versus a few member states) to improve the **availability** of vaccines, both proactively “**in peace time**” and re-actively “**in emergency**”.*



92nd WOAH General Session: The Animal Health Forum VETERINARY VACCINES AND VACCINATION: *many animal vaccines remain underutilised due to challenges in vaccine **availability**, access, demand and adoption*

<https://www.woah.org/en/event/92nd-general-session-of-the-world-assembly-of-delegates/#ui-id-6>

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Europe

IABS-EU Meeting on Preparedness and Response to Emerging Veterinary Disease Outbreaks

Date: 25-26 March 2025 - Venue: Pullman Hotel Centre Midi, Brussels, Belgium

92nd General Session | **World Assembly** | GS

World Organisation for Animal Health
Paris, May 25-29, 2025

92GS/Tech-01/En
Original: English
May 2025

Technical Item

VETERINARY VACCINES AND VACCINATION:
from science to action – reflections for change

Veterinary vaccine availability: signals and actions of academia

Research to Development (R2D) translation is critical for vaccine availability

Many needs in new and improved vaccines for Europe but also transboundary disease potentially threatening EU e.g. ASF, CSF, African horse sickness (AHS) etc.

Focus on work in LMICs to improve availability of vaccines:

- E.g. FMD endemic in most sub-Saharan Africa, conventional vaccines needed.
- Lumpy Skin Disease (LSD) spreading in Europe. More vaccine needed.
- Contagious bovine and caprine pleuropneumonia (CBPP and CCP) better quality vaccines needed.
- Vector borne disease spreading north e.g. BTV (Bluetongue virus) and many strains with limited cross reactivity. More vaccine needed.



Project: to connect academia and researchers with the Animal Health industry, to improve translation R2D and new vaccine delivery.

Sources: International Veterinary Vaccine Network (IVVN) <https://www.intvetvaccnet.co.uk/>, Professor Andrew Peters, Arpexas, UK

VMP availability issues & preparedness in various countries



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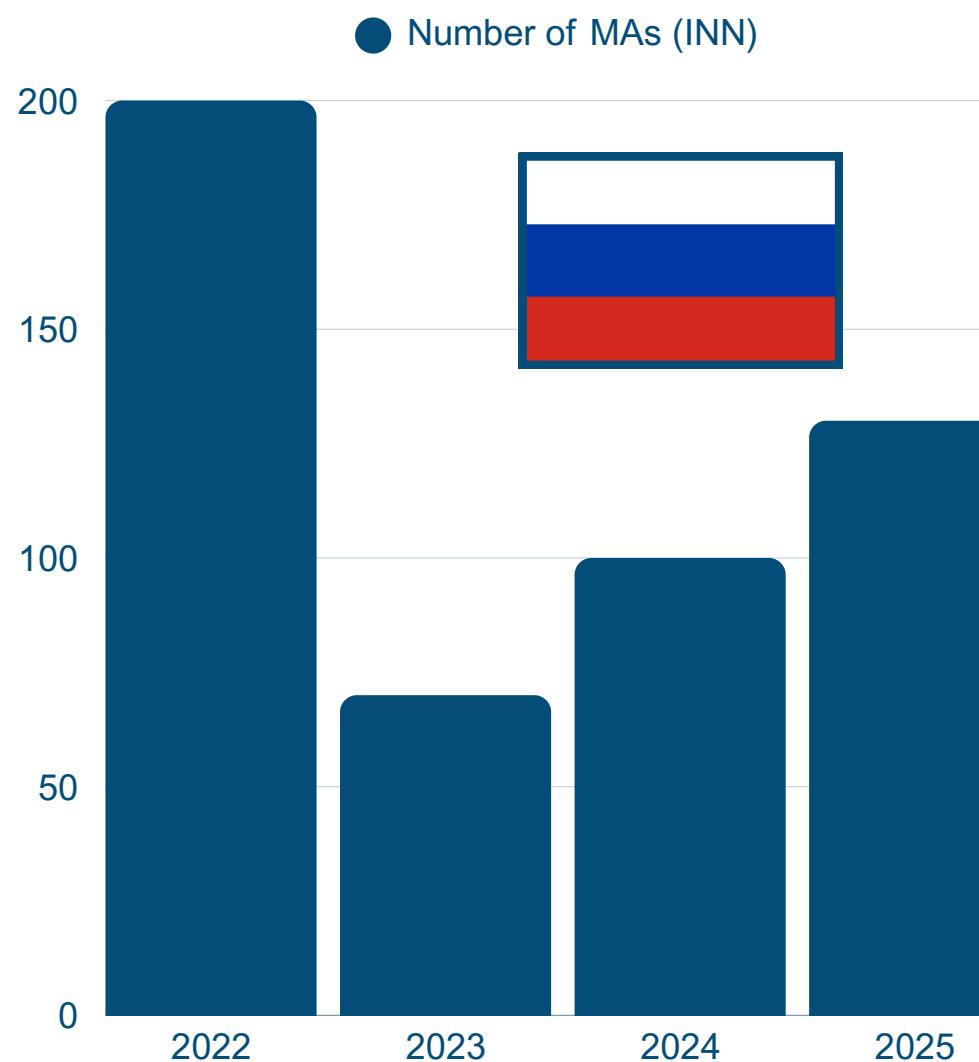


Fig. Vaccine import to Russia

Increasing production of domestic vaccines:

- in 2022, the share of **domestic vaccines** in the total volume was 40%
- in 2023, about 53.5%

Sources: Rosselkhoznadzor, NVA-National Veterinary Association, AVPHARM, Association of foreign veterinary pharmaceutical manufacturers, RF

(Source: JMAFF)

4. Efforts for stable supply of VMPs in Japan

- Act for dealing with food supply difficulties
 - Promulgated on June 21, 2024
 - To be enforced by June 21, 2025
- Background:
 - Increasing risk of a major shortage of food supply in Japan
 - Frequent occurrence of abnormal weather,
 - Spread of livestock infectious diseases,
 - Heightened geopolitical risks,
 - Increased demand for grains in livestock farming,
 - Intensified import competition, etc.



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Japan: Efforts for Stable Supply of Veterinary Medicines

4. Efforts for stable supply of VMPs in Japan

Key points of the act

1. Unified government policy under the government task force
2. Measures according to the stage of food supply shortage
3. Designation of important foods and materials
4. Measures in peacetime (reporting and stockpiling)
5. Measures to secure supplies in emergencies
6. Financial guarantees

- Vaccines
- Antiseptic drugs
- Medicines for farm animals (not determined yet)

Source: Presentation "Japan: Efforts for Stable Supply of Veterinary Medicine", Dr Y.Ujimasa, 29th General Assembly of the AVC, 5 October, 2024, Utrecht

Veterinary Vaccine Gap: Wildlife Rabies as a Case in Point



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⚠ Current Challenges to Vaccine Availability

- Outdated vaccine portfolio: Most ORVs were developed 30+ years ago
- From 15+ vaccines → only 2 meet WOAH standards remain in use
- Lack of competition: Limited manufacturers = vulnerable supply chain
- Regulatory gaps:
 - Eastern Europe: Some ORVs licensed domestically only
 - Unclear compliance with WOAH safety/efficacy standards



🧬 Recombinant vs. Attenuated Vaccines – A Divided Market

- North America: Prefers recombinant (GMO-related concerns less prominent)
- Europe: Tends to use highly attenuated vaccines
- → Regulatory and public concerns reduce flexibility in vaccine selection

❗ Implications

- Without a diverse, stable vaccine supply, future ORV campaigns are at risk
- Sustaining rabies control in wildlife requires urgent focus on vaccine innovation and access

Strategic HPAI Vaccination campaign aligned with Bird Migration as a Case in Point



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Timeline of Vaccination Campaigns in France

October, 2023: 1st national vaccination campaign targeting ducks

- Aligned with autumn bird migration
- Goal: Vaccinate 60+ million ducks by September 2024

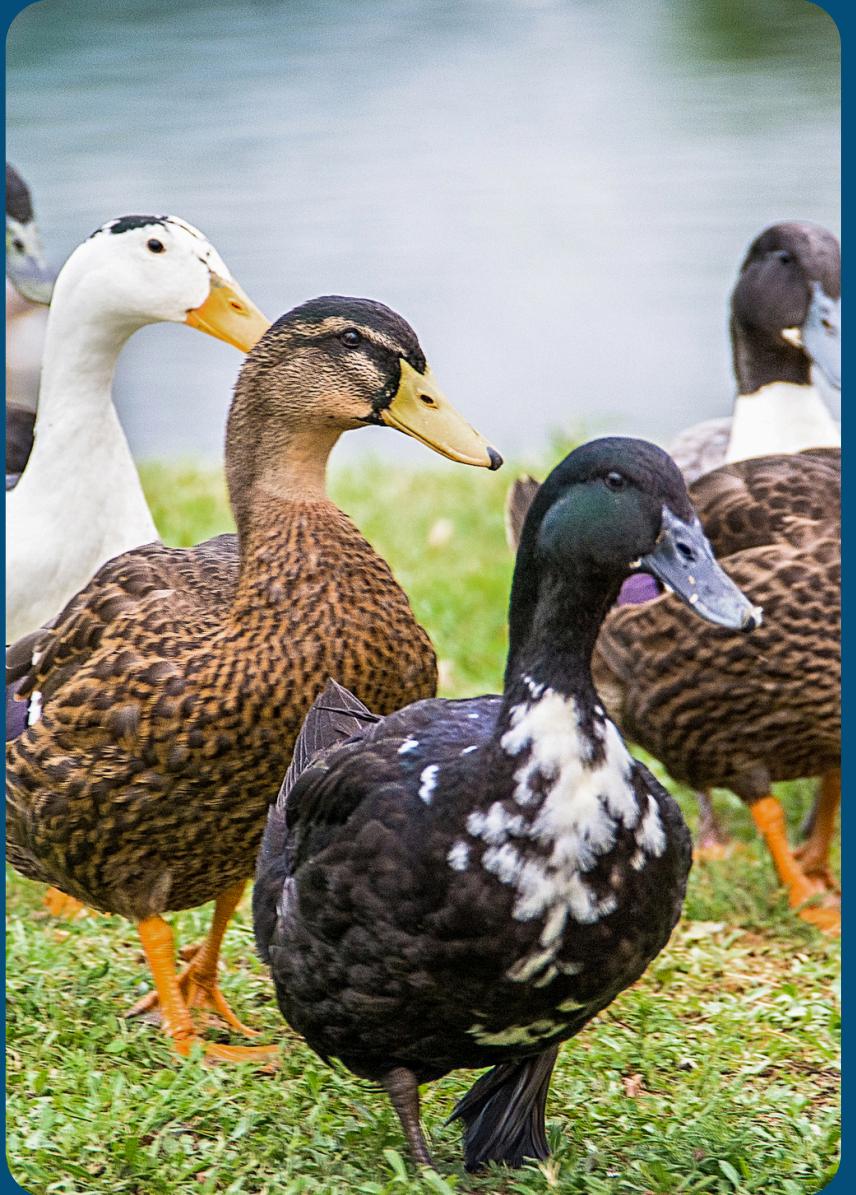
October, 2024: 2nd campaign

- 68 million vaccine doses ordered
- State covers 70% costs

Outcomes

- +12.1% increase in poultry output (2024 vs 2023)
- Enhanced outbreak prevention during high-risk periods
- Gradual reopening of export markets (e.g. US, Canada lifted bans in early 2025)

Sources: Anses, Reuters



Veterinary vaccine shortage as a driver of emerging issues



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Thoughts and suggestions 2024

- Enhance stakeholders collaboration (WOAH, FAO, EU Commission, EFSA, EMA, ECDC, Animal Health organisations and academia)
- Create and maintain lists of essential veterinary vaccines and VMPs
- Monitor the territories near migration pathways and sites. Introduce strategic animal vaccination and treatment campaigns in these territories
- Inform and educate veterinarians (and public?) how to respond to the veterinary medicine shortage emergency

Updates 2025

- Developing various **lists of essential veterinary medicines** by different stakeholders
- Successful implementation of animal vaccination and treatment campaigns considering the bird migration cycle on national level (France, Avian Influenza, Anses, 2023, 2024)
- Web platforms, events - global and national authorities, FVE, EuFMD

Veterinary vaccine shortage as a driver of emerging issues - Conclusion



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Veterinary vaccine shortages and availability issues, identified by stakeholders worldwide, pose growing risks to animal and human health and threaten global food security.

While many national and international efforts are underway, there's a strong call for a harmonised EU-level One Health strategy to strengthen preparedness.



Should vaccine availability be viewed as an Insurance Policy, rather than a Fire Department?



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Special thanks to AVC members, Professor Andrew Peters, Dr Antoinette Tolkamp and Dr Yuki Ujimasa, for their contributions

Dr Rimma Ishimbaeva, AVC President, Member of StaDG-ER

33rd EFSA StaDG-ER – 4-5 June 2025



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THANK YOU

• • •

DR RIMMA ISHIMBAEVA

