



# 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







# Association of Veterinary Consultants

## 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](http://www.avc-eu.de)



## AVC CONSTITUTION: AIMS AND OBJECTIVES


☒ Ensure professional standards of its members are maintained at a high level by following a Code of Good Practice

☒ Inform the outside world of the existence of experienced veterinarians able to provide expertise to industry, governments and other organisations

☒ Promote the dissemination of published information related to the members' activities, including the use of veterinary medicines, feed additives, animal feed, and food safety and provide a forum to assist its members in keeping abreast of scientific and veterinary progress.

☒ Promote the image of the veterinary profession to the public and the world


## AVC MEMBERS' ENGAGEMENT



### Continuous Improvement

Offering continued education and training:


- AI in Digital Pathology, Veterinary Consultancy Management, 2023, Nice
- VMP Shortage, 2024, Utrecht
- T&D, 2025, Bordeaux



### Policy and Advocacy


Expert advice to European and national authorities:

- Participation in EFSA and EMA public consultations & working group discussions
- Providing topics, presentations and comments on regulatory & scientific issues



### Collaboration and Networking

- Membership in EFSA Stakeholder Bureau and StaDG-Emerging Risks
- Representation in the EMA CVMP, CMDv, PhVWP, IVMPs
- Collaboration with Animal Health organisations: FVE, AHE, Access VetMed, FEFANA...



## 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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## AVC WORKING GROUPS

Food Chain AMR

AVC Strategy Big Data & AI

Animal Welfare/ 3Rs

Expert Composition


EFSA scope

EMA scope

Common

12 Working Groups  
3-10 experts per group

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



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# AVC NETWORK IN EUROPE



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



48

members

12

countries

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[www.avc-eu.de/list-of-members.html](http://www.avc-eu.de/list-of-members.html)



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



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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




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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 covers demand	

# VMP shortage: EMA actions




Source: EMA presentation on VMP shortages,  
29<sup>th</sup> 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 SPOCv members, veterinary vaccines shortages)

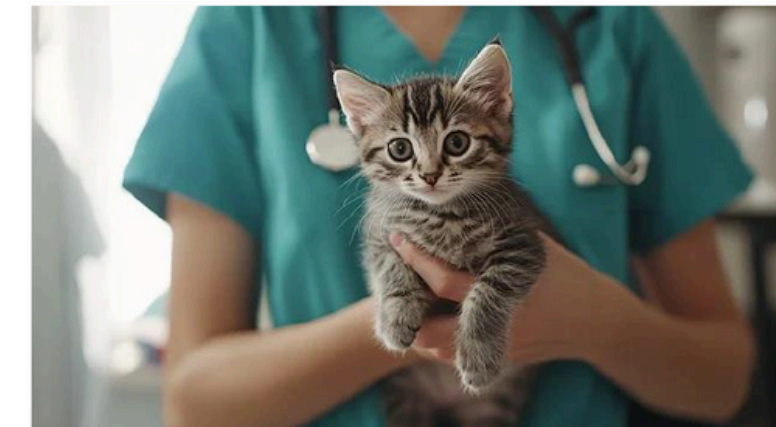
15 Role of Consultants in the operation of Regulation (EU) 2019/6

Classified as public by the 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, 29<sup>th</sup> General Assembly of the AVC, 5 October, 2024, Utrecht, the Netherlands

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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:

The screenshot shows the EMA website search results for 'Fungitraxx'. The left sidebar contains filters for Pharmaceutical form, Target species, ATCvet code, Authorised in, Available in, and Marketing authorisation holder. The main content area displays the following details:

- 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

At the bottom, there is a 'Compare medicines' button and a status bar indicating '0 Medicine selected (3 max.)' with a 'Compare' button.

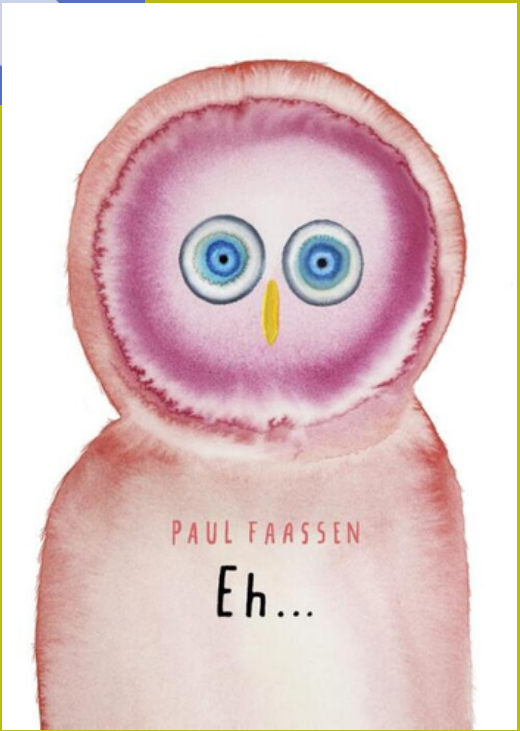
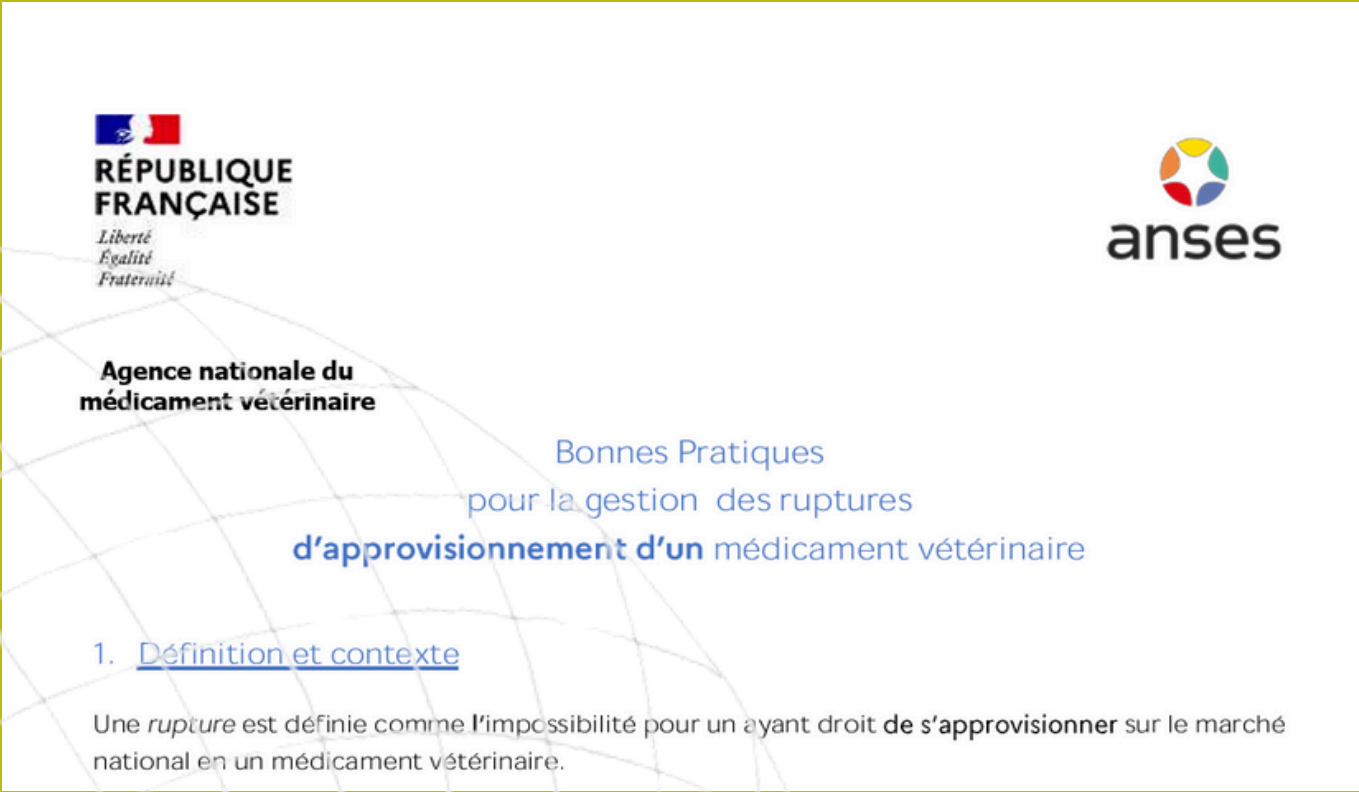


# VMP shortage reporting and tracking systems:

## National registers



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But what about the language?

### National registers of shortages

The table below contains the national registers of shortages for **human** and **veterinary** medicines.

Please note that the information in these national registers may not be available in English.

EU Member State	National register
Austria	<ul style="list-style-type: none"><li>Human and veterinary medicines share the same online register: <a href="https://medicineshortage.basg.gv.at">medicineshortage.basg.gv.at</a></li></ul>
Belgium	<ul style="list-style-type: none"><li>Human medicines: <a href="http://www.famhp.be">www.famhp.be</a></li><li>Veterinary medicines: <a href="https://genesamiddelendatabank.fagg.afmps.be">genesamiddelendatabank.fagg.afmps.be</a></li></ul>
Bulgaria	<ul style="list-style-type: none"><li>Human medicines: <a href="http://www.bda.bg">www.bda.bg</a></li><li>Veterinary medicines: no online register available</li></ul>
Croatia	<ul style="list-style-type: none"><li>Human medicines: <a href="http://www.halmed.hr">www.halmed.hr</a></li><li>Veterinary medicines: no online register available</li></ul>
Cyprus	<ul style="list-style-type: none"><li>No online registers available for human and veterinary medicines</li></ul>
Czechia	<ul style="list-style-type: none"><li>Human medicines: <a href="http://www.sukl.cz">www.sukl.cz</a></li><li>Veterinary medicines: no online register available</li></ul>
Denmark	<ul style="list-style-type: none"><li>Human medicines: <a href="http://laegemiddelstyrelsen.dk">laegemiddelstyrelsen.dk</a></li><li>Veterinary medicines: <a href="http://erhverv.medicinpriser.dk">erhverv.medicinpriser.dk</a></li></ul>
Estonia	<ul style="list-style-type: none"><li>Human medicines: <a href="http://www.ravimiamet.ee">www.ravimiamet.ee</a></li><li>Veterinary medicines: <a href="http://www.ravimiregister.ee">www.ravimiregister.ee</a></li></ul>
Finland	<ul style="list-style-type: none"><li>Human and veterinary medicines share the same online register: <a href="http://www.medicines.fi">www.medicines.fi</a></li></ul>
France	<ul style="list-style-type: none"><li>Human medicines: <a href="http://ansm.sante.fr">ansm.sante.fr</a></li><li>Veterinary medicines: <a href="http://www.anses.fr">www.anses.fr</a></li></ul>
Germany	<ul style="list-style-type: none"><li>Human medicines: <a href="http://www.bfarm.de">www.bfarm.de</a> / <a href="http://www.pei.de">www.pei.de</a></li></ul>

# VMP shortage reporting and tracking systems



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

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

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



# 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



**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**

May 13, 2025 5:17 pm Admin





# 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, DGA, HPRA 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 pro-actively “in peace time” and re-actively “in emergency”.*



92nd WOAHA 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**

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

**92<sup>nd</sup> General Session**  
World Organisation for Animal Health

**World Assembly**  
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 CCPP) better quality vaccines needed.
- Vector borne disease spreading north e.g. BTV (Bluetongue virus) and many strains with limited cross reactivity. More vaccine needed.



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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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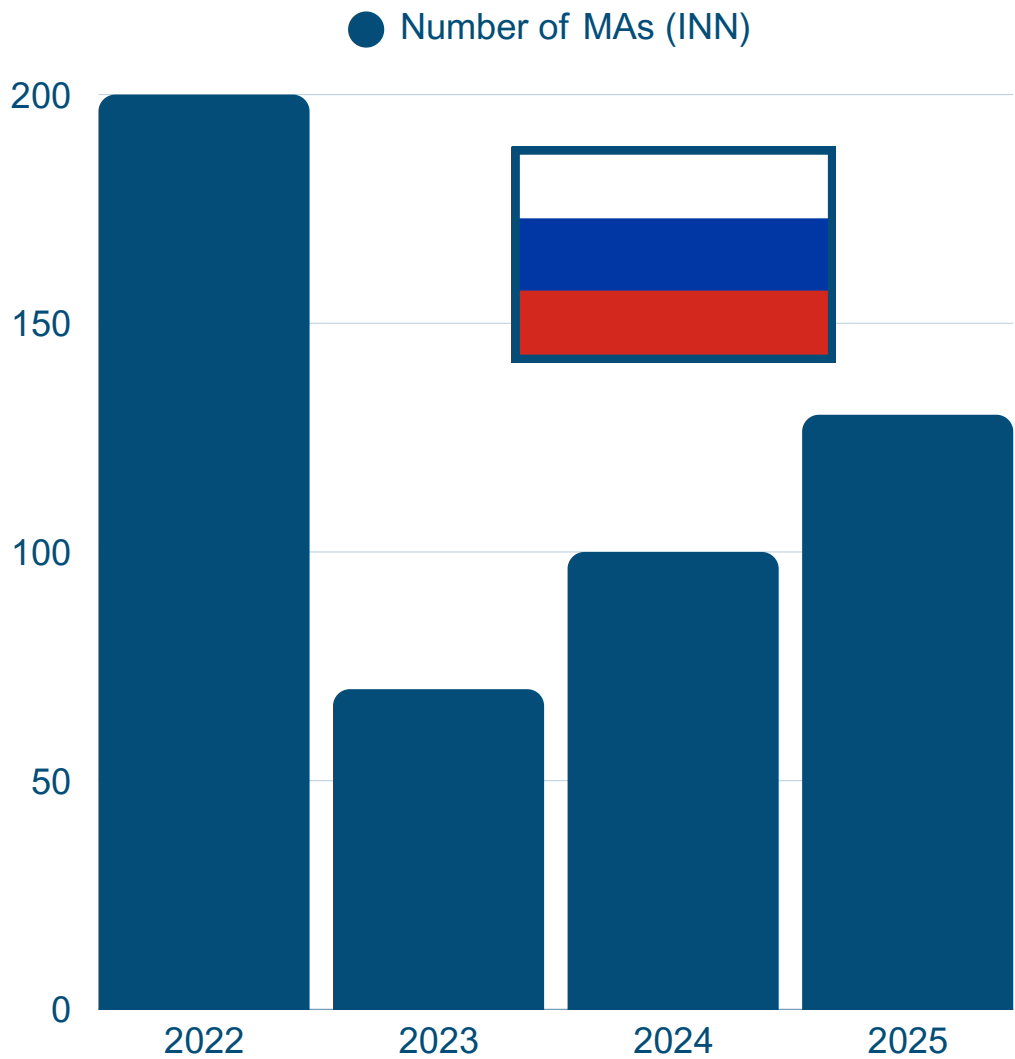


Fig. Vaccine import to Russia

Increasing production of domestic vaccines:

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

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

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.

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: JMAFF)  
Source: Presentation “Japan: Efforts for Stable Supply of Veterinary Medicine”, Dr Y.Ujimasa, 29<sup>th</sup> 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 WOAHA standards remain in use
- Lack of competition: Limited manufacturers = vulnerable supply chain
- Regulatory gaps:
  - Eastern Europe: Some ORVs licensed domestically only
  - Unclear compliance with WOAHA 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

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Source: Scientific and Technical Review Retrospective:  
special edition for WOAHA's centenary | 2024 | Challenges  
and opportunities for the next miles in global rabies control



# 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: 1<sup>st</sup> 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

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

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# THANK YOU



**DR RIMMA ISHIMBAEVA**



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