



Federation
of Veterinarians
of Europe

EMA HMA/EMA multi-stakeholder workshop on shortages

Breakout session 2C: Medicines for veterinary use

Hybrid, 1 March 2023

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The FVE network



➤ **45 national associations**

➤ **38 European countries**

➤ **4 FVE Sections**

- UEVP (*Practitioners*)
- UEVH (*Hygienists – Public Health Officers*)
- EASVO (*Veterinary State Officers*)
- EVERI (*Education, Research, Industry*)



FVE Strategy 2021-2025

PRIORITIES

- **ONE-HEALTH AND SUSTAINABILITY**
- **ONE VETERINARY COMMUNITY**
- **BEING RECOGNISED AND INFLUENTIAL**
- **VETERINARY DEMOGRAPHY AND REWARDING CAREERS**
- **EMBRACE TECHNOLOGY**

The European veterinary profession, embodied by FVE, strives to enhance animal health, animal welfare, public health and protect the environment by promoting the veterinary profession. FVE aims to support veterinarians in delivering their professional responsibilities to the best possible standard, and that this expertise is recognized and valued by society.





Lack of Availability versus Shortages

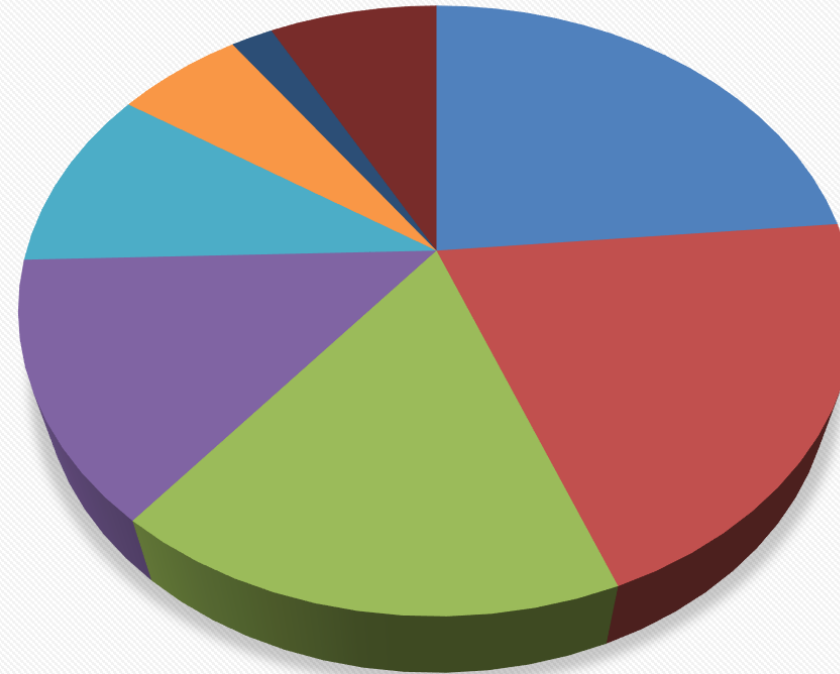


'I am short of...'



FVE Monitoring

FVE survey on lack of medicine/vaccine in Europe



- | | | |
|------------------|----------------------------|------------------|
| ■ Antibiotics | ■ Livestock vaccine | ■ Feline vaccine |
| ■ Canine vaccine | ■ Equine influenza vaccine | ■ NSAIDs |
| ■ Antiparasitic | ■ Others | |

Monitoring availability

FVE survey on lack of
medicine/vaccines in
Europe

Country	Important medicines/vaccines shortages you are aware of currently
Croatia	Anthrax vaccine, horse influenza and tetanus vaccine, then for the other medicines bovine PPD and avin PPD for tuberculosis testing
Cyprus	Feline vaccines, some canine vaccines, caninsulin, some antibiotics, cytopoint and xylazine. In large animal medicine there is shortage on Ovipast vaccine for pneumonia in lambs and Enzovac for chlamydial abortion. There are also medicines that were never marketed in Cyprus but are widely used in other EU countries (e.g. DepoMedrol).
FEEVA	Equine Influenza Vaccine has been in sort supply in recent months to the point that FEI have adjusted the vaccination requirements for competition horses. Historically Equine Herpes Virus vaccine has been unavailable. Some local anaesthetic have also been unavailable.
Finland	lokivetmab (Cytopoint ®), bedinvetmab (Librela ®), oclacitinib (Apoquel ®). At the time of writing this answer Fimes has also announced problems in availability of some vaccines (Eurican DAPPI®, Eurican Herpes®).

Critical shortages

- Vaccines, observed for several species
- Antibiotics, especially narrow spectrum or lower classes antibiotics— *i.e. penicillin, amoxycillin, tetracyclines, etc.*

Greece	Greece - reports issues with live salmonella and Gumboro vaccines in recent months. Portugal -Some current issues with availability of mycoplasma, Pox and AE are reported. France - shortages are not unusual, but vary from week to week, month to month. A wide range of live vaccines and some inactivated vaccines have been experienced this year and some continue for many months
Romania	No problems related to the important medicines/vaccines shortages
Slovenia	Rabies vaccine from time to time and infectious disease polyvalent vaccine and dermatophytosis vaccine (Rabisin, Eurican, Purevax, Vanguard, Insol Trichophyton). Currently there is a substantial shortage of tetracyclines on market
Sweden	Equine influenza vaccine, atropine eyedrops, meloxicam, and (for laboratory animals): Hypnorm (needed for diabetes research) and Buprenorphine.
Switzerland	Almost permanent with intramammary Penicilline-Products, other first-line Antibiotics. This spring we hadn't any vaccine against Enterotoxemia/pulpy kidney disease in lambs, a lot died.
United Kingdom	Cat vaccines (which is now improving), equine influenza vaccines, intravenous fluids, particularly large 5 litre bags for equine practice

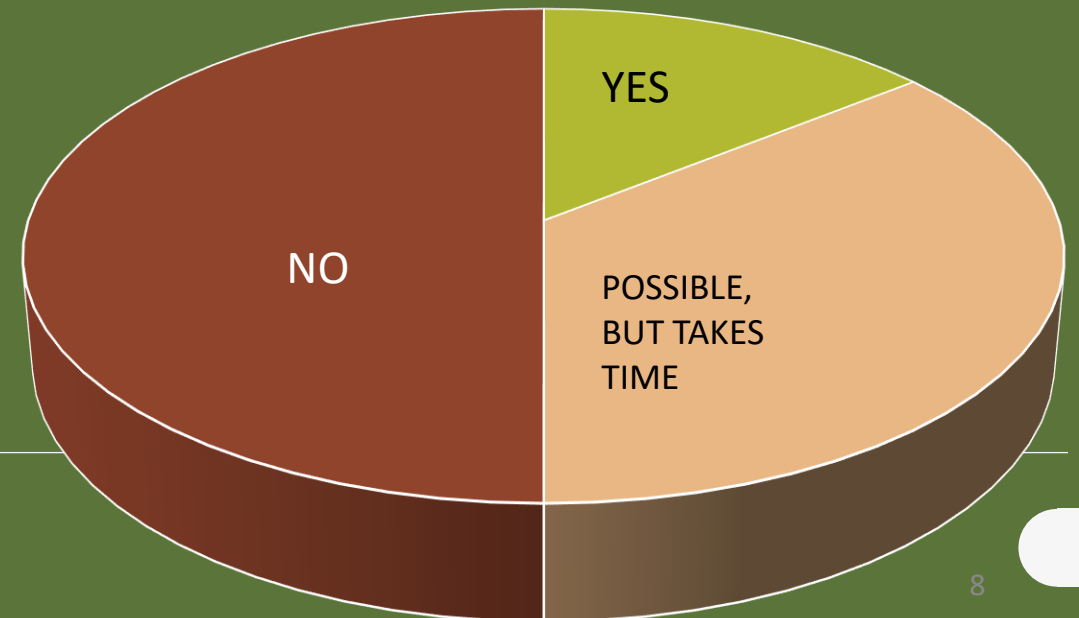
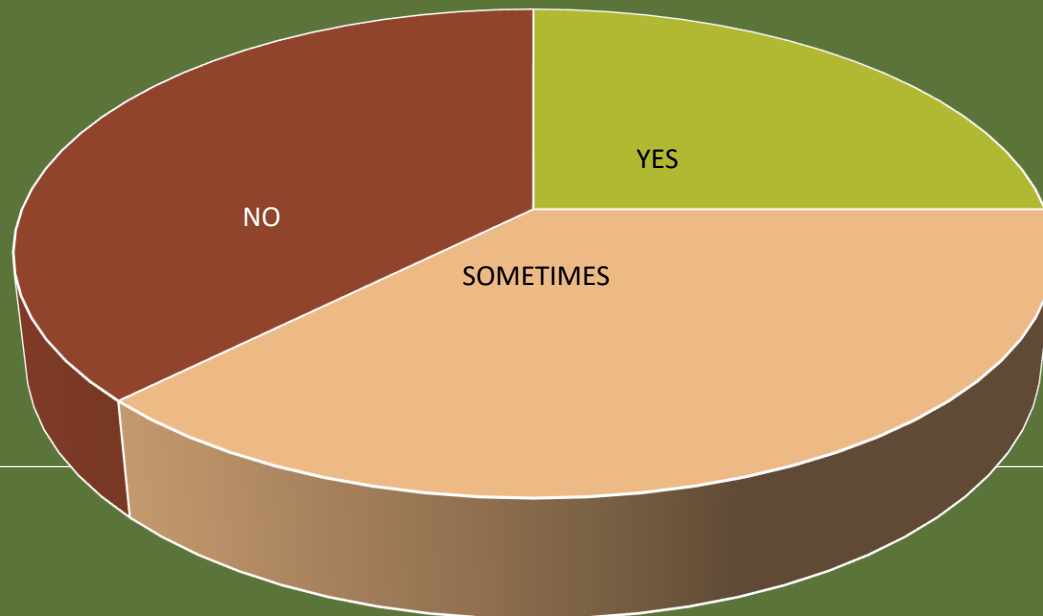


Monitoring availability

FVE survey on lack of medicine/vaccines in Europe

If you are short of a medicines/vaccine, is it **easy to get reliable information** on the duration, reasons or alternative vaccines to use?

If you have are short of a medicine/vaccine, do you **easily source them from other EU countries?**



Only a few countries have a website listing shortages e.g. Slovenia

JAZMP Informacija na podlagi 24. člena ZZdr-2 o prisotnosti zdravil na trgu

št. odločbe/delovna šifra zdravila	zadeva	zdravilo	poročevalec	status poročevalca	datum prejema obvestila	vrsta obvestila	informacija (Op.: navedbi "99.99.9999 in "/" pomenita nedoločen datum)
245-22/2020-5	2022-1332	WONDERCEF prašek in topilo za raztopino za injiciranje za konje, ki niso namenjeni za prehrano ljudi	Vetconsult pharma d.o.o.	imetnik dovoljenja za promet z zdravilom	25.10.2022	prijava prihoda zdravila na trg	datum pričetka: 19.11.2019
NP/V/0065/001	2022-1386	CEPHALEXIN 180mg/ml suspenzija za injiciranje, 100 ml	GENERA SI d.o.o.	imetnik dovoljenja za promet z zdravilom	04.11.2022	prijava stalnega prenehanja opravljanja prometa	datum pričetka: 25.10.2022
NP/V/0353/003	2022-1387	VETOFLOK 100 mg/ml raztopina za injiciranje, 100 ml	GENERA SI d.o.o.	imetnik dovoljenja za promet z zdravilom	04.11.2022	prijava stalnega prenehanja opravljanja prometa	datum pričetka: 25.10.2022
NP/V/0184/001	2022-1388	LAKSANS 500 g peroralni prašek, 500 g	GENERA SI d.o.o.	imetnik dovoljenja za promet z zdravilom	04.11.2022	prijava stalnega prenehanja opravljanja prometa	datum pričetka: 25.10.2022
EU/2/20/267/006	2022-1389	NexGard Combo kožni nanos, raztopina za mačke 2,5 - 7,5 kg, 0,9 ml, 3 aplikatorji	Vetpromet d.o.o.	imetnik dovoljenja za promet z zdravilom	07.11.2022	prijava dejanskega ponovnega prihoda zdravila na trg po predhodno priglašeni motnji v preskrbi	datum pričetka: 04.11.2022
NP/V/0156/001	2022-1452	GEOMYCIN F 1 g intrauterine tablete, šaktla z 10 tabletami	GENERA SI d.o.o.	imetnik dovoljenja za promet z zdravilom	09.11.2022	prijava motnje v preskrbi	datum pričetka: 07.07.2022, napovedani datum konca: 01.12.2022
EU/2/99/013/001-002	2022-1453	HALOCUR 0,5 mg/ml, peroralna raztopina za teleta; prenosna 500 ml platenka iz polietilena visoke gostote s 490 ml peroralne raztopine, prenosna 1000 ml platenka iz polietilena visoke gostote z 980 ml peroralne raztopine	Intervet International B.V.	imetnik dovoljenja za promet z zdravilom	15.11.2022	prijava motnje v preskrbi	datum pričetka: 01.02.2023, napovedani datum konca: 01.08.2023

New products on market

Stop commercialisation

Back on market after shortage

Notice of shortage with expected duration

Only a few countries have a website listing shortages e.g. Belgium

The image shows a screenshot of a website interface with a blue header bar. Below the header, there is a navigation bar with two tabs: 'Human use' (light blue) and 'Veterinary use' (dark blue, currently selected). Below the tabs, there are three white cards, each with a title, a count, a description, and a 'Go to the full list >' button.

Category	Count	Description
Unavailable medicines	8 last 30 days	List of medicines that are temporarily unavailable or for which the commercialisation is interrupted or stopped.
Medicines that have become available again	13 last 30 days	List of medicines available again following temporary unavailability or interruption of commercialisation.
Medicines new on the market	1 last 30 days	List of medicines that have recently become available.

Only a few countries have a website listing shortages e.g. Belgium


Medicine	H/V	Status	From	To	
Retardoxi 20 % LA 200 mg/ml inj. sol. i.m. vial 250 ml	V	Available		30 March 2023	Keep me informed
		Stop of commercialisation	31 March 2023		
Bravoxin inj. susp. s.c. 50 ml	V	Temporarily unavailable	1 February 2023	23 March 2023	Keep me informed
Tranquigel 35 mg/g or. gel pre-filled syr. 12 g	V	Temporarily unavailable	1 February 2023	17 March 2023	Keep me informed
Avinew Neo efferv. tabl. 10 x 1 (1000 doses)	V	Temporarily unavailable	1 February 2023	30 May 2023	Keep me informed
Stomorgyl 750000 IU - 125 mg tabl. 20	V	Temporarily unavailable	25 January 2023	19 June 2023	Keep me informed
Furexel Combi 15.5 mg/g - 77.5 mg/g or. paste or. syr. 7.74 g	V	Temporarily unavailable	24 January 2023	22 March 2023	Keep me informed
Ingelvac PRRSFLEX EU inj. susp. (lyoph. + solv.) i.m. vial 100 doses (100 ml) + 100 ml	V	Temporarily unavailable	11 January 2023	15 February 2023	Keep me informed
Zerofen Vet 4% 40 mg/g 2.5 kg	V	Stop of commercialisation	9 January 2023		Keep me informed
Fixplan 200 IU/ml inj. sol. (lyoph. + solv.) i.m./s.c. vial 5000 IU + 25 ml	V	Stop of commercialisation	6 January 2023		Keep me informed
Levaveto 750 mg/g pwrdr. for drinking water 10 x 100 g	V	Stop of commercialisation	5 January 2023		Keep me informed

50% shortage
50% stop
commercialisation

Only a few countries have a website listing shortages e.g. Denmark

Product	Expected period	Cause
Promethazine "Actavis" 25 mg film-coated tablets	September 2022 - August 2023	Delays at manufacturers
Marcain Adrenaline 5 mg/ml + 5 microg/ml solution for injection (Paranova)	Start February - mid-March 2023	Delivery difficulties
Arthrotec Forte 75+0.2 mg tablets with modified release (100 pcs.)	End November 2023 - unknown	Commercial reasons
Arthrotec Forte 75+0.2 mg tablets with modified release (20 pcs.)	March 2023 - unknown	Commercial reasons
Synarela 200 micrograms/dose nasal spray, solution	Start March – end May 2023	Delays at manufacturers
Tresiba 100 Penfill 100 U/ml solution for injection in cartridge	Start February – end February 2023	Increased sales/demand
Arthrotec Forte 75+0.2 mg tablets with modified release (100 pcs.)	Mid-January – mid-February 2023	Other things

Only a few countries have a website listing shortages e.g. France

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Publicité

Qualification des produits

Ruptures

[Bonnes Pratiques pour la gestion des ruptures d'approvisionnement d'un médicament vétérinaire \(10/02/2023\)](#)

[Historique des ruptures critiques clôturées \(14/02/2023\)](#)

Ruptures critiques en cours

[Rupture PROTEQFLU-TE SUSPENSION INJECTABLE POUR CHEVAUX - Actualisation \(14/02/2023\)](#)

[Rupture ECTHYBEL - Actualisation \(14/02/2023\)](#)

[Rupture EURICAN HERPES 205 - Actualisation \(14/02/2023\)](#)

[Rupture PARVOKAN - Actualisation \(14/02/2023\)](#)

[Rupture MASIVET - Actualisation \(14/02/2023\)](#)

[Rupture SYNCRO-PART 30 MG - Actualisation \(02/02/2023\)](#)

[Rupture TUR-3 - 20/01/2023](#)

[Rupture EQUIP ARTERVAC EMULSION INJECTABLE POUR CHEVAUX ET PONEYS - 16/01/2023](#)

Only a few countries have a website listing shortages e.g. France

Nom du médicament vétérinaire	PROTEQFLU-TE SUSPENSION INJECTABLE POUR CHEVAUX
Laboratoire exploitant	BOEHRINGER INGELHEIM ANIMAL HEALTH
Date de la rupture	07/07/2022
Principe actif	Virus canarypox recombiné Grippe (vCP2242) Virus canarypox recombiné (vCP3011) Anatoxine Clostridium tetani
Indications	Immunisation active des chevaux âgés de 4 mois et plus contre la grippe équine afin de réduire les signes cliniques et l'excrétion virale après infection, et contre le tétanos afin de prévenir la mortalité.
Motif de la rupture	Problème qualité en production
Date prévisionnelle de remise à disposition	Fin mars 2023
Observations particulières	<p>Il est possible d'avoir recours à deux autres vaccins contre la grippe équine et le tétanos, toutefois distribués sous allocations et pouvant présenter aussi de brèves difficultés d'approvisionnement :</p> <ul style="list-style-type: none"> - EQUIP FT (ZOETIS) - EQUILIS PREQUENZA TE SUSPENSION INJECTABLE POUR CHEVAUX (INTERVET INTERNATIONAL) <p>Pour une vaccination contre la grippe équine seule, le vaccin PROTEQFLU SUSPENSION INJECTABLE POUR CHEVAUX (BIAH) est de nouveau durablement disponible.</p>

→ Name product, MAH and active ingredients

→ Reason and when expected to come back on the market

} Suggested alternatives!!




We need to better monitor & forecast availability and shortages

- Monitoring availability is important for animal health, animal welfare and/or public health, food production;
- Important to monitor lack of availability especially for major diseases and essential veterinary medicines
- Need to do this in a 'One Health' way



Aims new veterinary medicines legislation:

- Address the public health risk of antimicrobial resistance (AMR)
 - Increase **availability of veterinary medicinal products**; and **improve the functioning of the internal market**
 - Reduce administrative burden
 - Stimulate competitiveness and innovation
- 



Take-away reflections (1):

- Veterinary side: serious availability problem (less shortage problem)
- Veterinarians lack essential products: e.g. certain vaccines, narrow-spectrum antimicrobials, etc. Shortages make this worse
- We need to better monitor & forecast availability and shortage especially for essential products



Take-away reflections (2):

- We need enhanced **communication** towards practitioners on shortages but also alternatives (UPD in the future could help)
- We need enhanced **collaboration** between veterinary associations, competent authorities (e.g. via vet reps in SPOC network) and industry – on EU and national level
- We need to **measure whether the Regulation reaches its goal**: namely to increase availability and facilitate the single market.



THANK YOU FOR YOUR ATTENTION



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