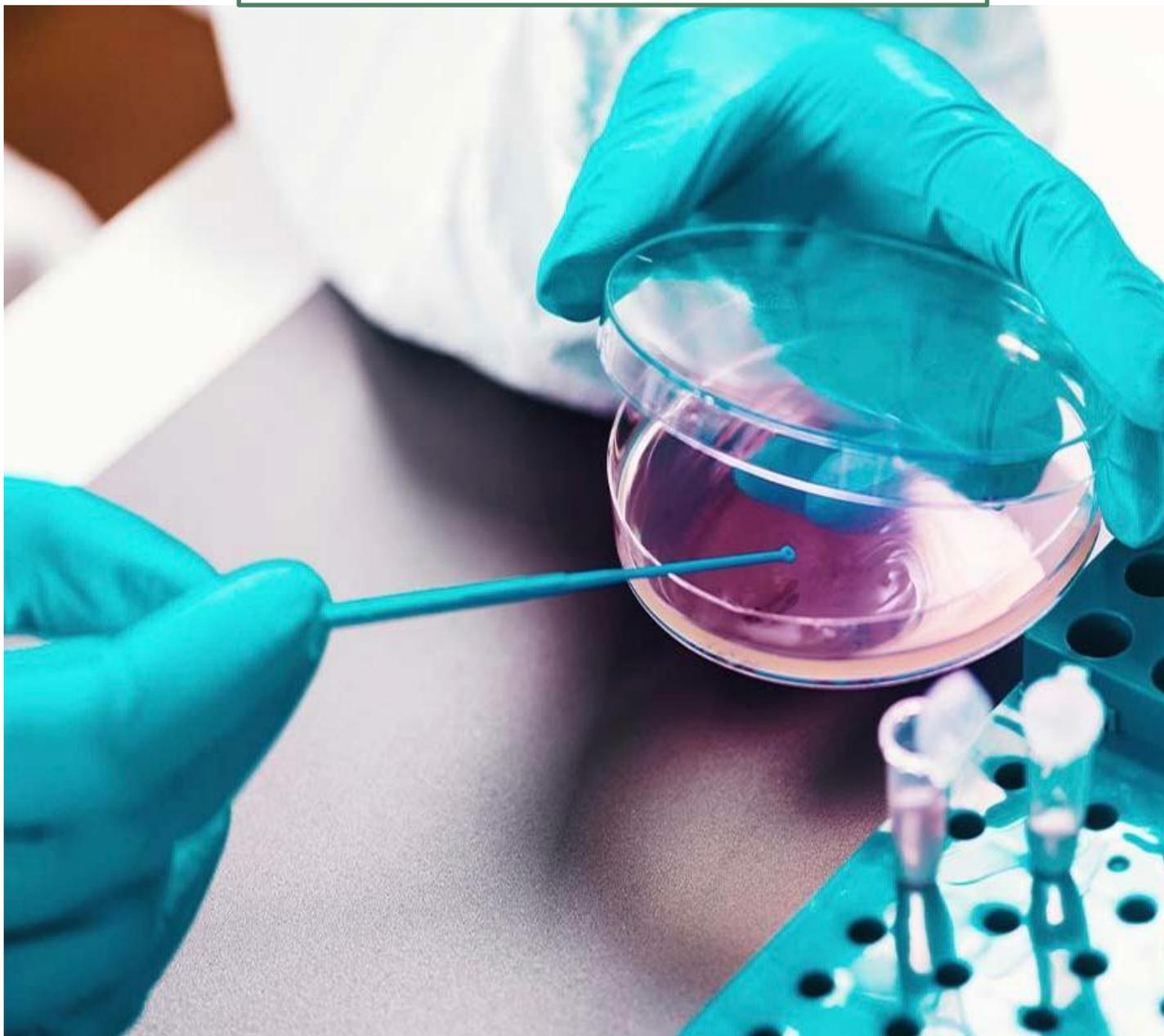




Federation
of Veterinarians
of Europe

Short survey on medicines/vaccine shortages



October 2022

Short survey on medicines/vaccine shortages

Shortages in medicines for use in human healthcare and veterinary practice are not a new phenomenon in the European Union (EU) but their exponential increase over the past years is striking. To find out what the situation is in veterinary practice is, the Federation of Veterinarians of Europe (FVE) together with the Union of European Veterinary Practitioners (UEVP) launched a survey at the end of September 2022. Twenty two national veterinary associations/chambers from 17 European countries, namely Luxembourg, Croatia, Sweden, Lithuania, United Kingdom, Germany, Denmark, Iceland, Italy, Netherlands, Greece, Finland, Slovenia, Cyprus, Latvia, Switzerland and Romania, contributed with their input. Additional contributions received from two European professional associations, namely the Federation of European Equine Veterinary Associations (FEEVA) and the Poultry Veterinary Study Group (PVSG).

MAIN FINDINGS

The main findings of this initiative revealed that

- Shortages in veterinary medicines and vaccines are an increasing problem in almost all countries;
- Shortages are observed for many different categories, e.g. vaccines (either for livestock or for companion animals and equines), antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs), antiparasitics and others;
- Getting reliable information on the duration and reasons for the shortage and especially on alternatives to use is not easy for the veterinary practitioners in most countries.

FVE ONGOING ACTIONS

FVE closely follows the situation and raises awareness of the regulators and relevant stakeholders. The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) in EU acknowledge the issue and strive to address shortages and enhance respective communication.

FVE keeps attention on the issue and continues to call on

- EMA and HMA to accelerate the development of an information mechanism to identify shortages and act as a hub for easy notification of practitioners about them, their duration and their extent;
- The industry and distributors to timely address potential disruptions on the market of the EU countries and to ensure availability of products in all EU countries;
- Policy makers and all stakeholders to work together on ensuring alternative solutions to observed or anticipated shortages, especially for disruptions regarding essential or unique products;
- Veterinarians to contact the Medicines Shortages Single Point of Contact (SPOC) in their country, to report observed shortages and get information about the situation. In addition, veterinarians can use the Union Product Database in case of shortages to identify alternatives for treatment and their availability in other Member States in the EU.

“Short survey medicines/vaccine shortages”

SURVEY REPORT

BACKGROUND

Shortages in medicines for use in human healthcare and veterinary practice are not a new phenomenon in the EU but their exponential increase over the past years is striking. To find out what goes on in veterinary practice, a short survey was sent out to the FVE (Federation of Veterinarians of Europe) and UEVP (Union of European Veterinary Practitioners) members between 23.09.2022 and 03.10.2022. FVE received 22 replies from the national veterinary associations or chambers in 17 European countries, namely Luxembourg, Croatia, Sweden, Lithuania, United Kingdom, Germany, Denmark, Iceland, Italy, Netherlands, Greece, Finland, Slovenia, Cyprus, Latvia, Switzerland, Romania and from two European professional associations, namely FEEVA (Federation of European Equine Veterinary Associations) and PVSG (Poultry Veterinary Study Group). The survey aimed to collect information on the current situation regarding medicine and vaccine shortages. This summary report provides an overview of the main findings of the survey.

SURVEY RESULTS:

Questions asked:

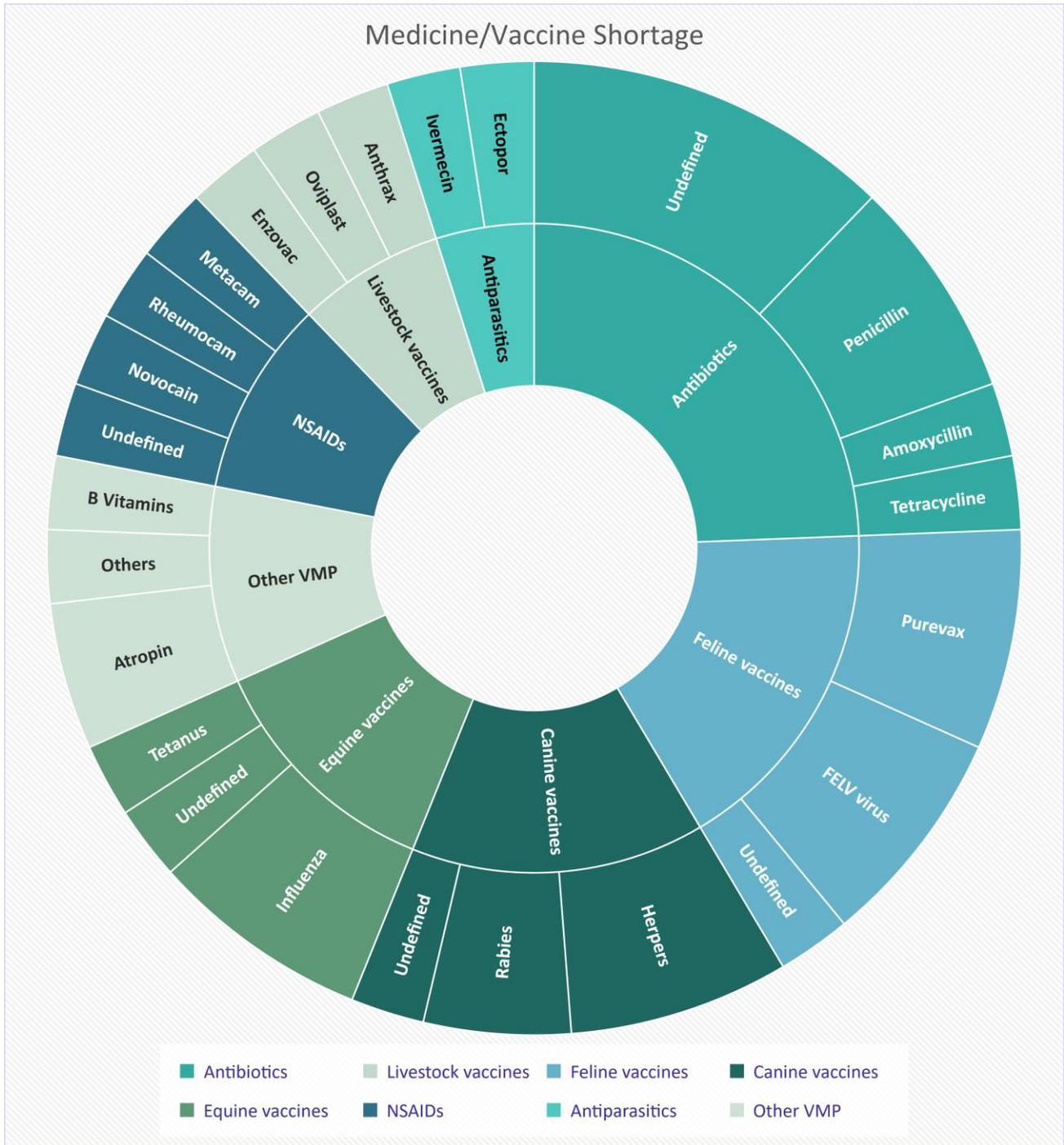
- 1. Are there any important medicines/vaccines shortages you are aware of currently? If so, can you tell us which one?**

18 out of 22 respondents answered that they were aware of current shortages in important medicines/vaccines in their country.

Of the medicines/vaccines shortages mentioned:

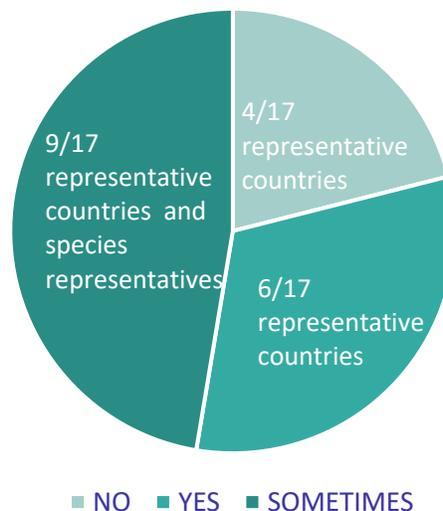
- 24% of the products mentioned were antibiotics (penicillin, amoxycillin, tetracyclines, etc).
- 21% were livestock vaccines (Anthrax vaccine, Ovipast vaccine, Enzovac, etc)
- 17% feline vaccines (FeLV virus, Purevax vaccines, etc)
- 14% canine vaccines (Herpes vaccine, Rabies vaccine, etc)
- 10% Equine vaccines (Influenza, tetanus vaccine, etc)
- 5% NSAIDs (Metacam, Rheumocam, Novocain, etc)
- 2% antiparasitics (Ectopor, Ivermectin injectable, etc)
- and 7% other medicine/vaccine shortage (Atropine eyedrops, B-vitamin complex solution, etc).

It should be noted that some of these shortages have serious consequences in public health as well, such as the lack of essential vaccines (e.g. against Rabies, Anthrax), while the lack of certain narrow-spectrum antibiotics, forces veterinarians to use antibiotics higher on the AMEG categorisation, which affects their potential to implement best practices.



2. If you have a medicines/vaccine shortage, is it easy to get reliable information on the duration, reasons or alternatives to use?

If you have a medicines/vaccine shortage, is it easy to get reliable information on the duration, reasons or alternative vaccines to use?



3. If you have a medicine/vaccine shortage, do you easily source them from other (EU) countries?

- Respondents from 2 countries replied that it is easy to source medicine/vaccine from other (EU) countries.
- Respondents from 6 countries replied that it is not easy at all.
- Respondents from 9 countries, FEEVA and PVSG said that it is possible but it depends on the product and it needs time.

MAIN FINDINGS

- Shortages in veterinary medicines and vaccines are an increasing problem in almost all countries;
- Shortages are observed for many different categories, e.g. vaccines (either for livestock or for companion animals and equines), antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs), antiparasitics and others;
- Getting reliable information on the duration and reasons for the shortage and especially on alternatives to use is not easy for the veterinary practitioners in most countries.

CAUSES OF THE OBSERVED SHORTAGES

Four main reasons can be identified behind shortages, namely economic related issues, manufacturing and quality issues, regulatory issues and supply chain issues.

Economic causes comprise profit margins that are too low for industry, notably for generic medicines or for products for limited markets, which leads to a halt in the commercialization due to unprofitable sales. They vary in nature and have complex interplays amongst themselves and with other root causes: market conditions, pricing policies, tender practices, cost-containment measures, commercial withdrawals.

Issues in the manufacturing process of veterinary medicinal products, especially of vaccines. The manufacturing processes are complex and require the implementation of high-quality standards to ensure the efficacy and safety of the produced medicines. Any detected issue with any of the components used to produce a medicinal product may lead to a shortage. There are several examples of how **manufacturing and quality issues** can cause shortages: Good Manufacturing Practices (GMP) issues, Manufacturing capacity, Natural disaster, Manufacturing lag times, Surges in demand, Active Pharmaceutical Ingredient (API) and Excipient supply. A recent example is the transformation of several veterinary medicines manufacturing sites into COVID vaccine site during the pandemic. These premises have now been re-transformed into a veterinary medicines processing facility, which is a lengthy and complex process.

Supply chain problems. The veterinary medicines supply chain is complex and involves many actors. It refers to disruptions, such as interruption in production and/or supply due to quality issues, lack of an essential part of the manufacturing process, outsourced active pharmaceutical ingredients (API), location of manufacturing capacities outside the EU that increase reliance on non-EU actors upon which controls are limited.

Finally, shortages would be partially due to **regulatory measures** and an increased administrative burden, in particular difficulties due to growing binding compliance with a large set of Good Manufacturing Practices (GMP) and environmental norms.

FVE ACTIONS TO RAISE AWARENESS ABOUT SHORTAGES OF VETERINARY MEDICINES

FVE discussed this issue with the European Medicines Agency (EMA), the Coordination group for mutual recognition and decentralized procedures for veterinary medicinal products (CMDv) and other stakeholders. EU regulators and national competent authorities are well aware of the problem with shortages that currently occurs both in the human healthcare and the veterinary sector.

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) in EU acknowledge the issue and strive to address shortages and enhance respective communication. Improving the availability of medicines authorised in the European Union (EU) is a key priority for the

European Medicines Agency (EMA) and the European medicines regulatory network. Shortages or other problems with the availability of medicines create challenges for the medicine supply chain, with a potentially serious impact on human and animal health. EMA is working on **EU-level coordination to tackle supply disruptions**. The HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use is providing strategic and structural solutions to tackle disruptions in the supply of medicines and ensure their continued availability in the EU. EMA plays a key role in coordinating the EU response to medicine supply issues caused by crises such as major events or public health emergencies. To alleviate the problem, EMA developed a **webpage** that links to all the national member websites on which shortages in veterinary medicines/vaccines are reported. They have also set up the **SPOC (Single Point of Contact)** task force to improve information sharing on important shortages between Member States, EMA and the European Commission. The SPOC task force allows Member States to share information on availability problems with medicines as well as information on medicines that could be used as an alternative and are available in other Member States. This can help to prevent and better manage shortages. Links to all national shortage websites and the SPOC contact point per country are available in Table 1. Practitioners are encouraged to consult their national website and contact the SPOC representative in their country to find solutions with respect to shortages of essential products. In addition, veterinarians may consult the EMA **Veterinary Medicines information website**, which is a public interface of the Union Product Database, enabling everyone with an interest in veterinary medicines to find information, such as potential treatment alternatives. While information about existing shortages is not currently available on UPD, this is still a helpful tool for the veterinarian. Its search features and view information on all authorised veterinary medicines in the EU / EEA allows for an easy identification of authorised products in the different veterinary medicines in the EU Member States.

TABLE 1: Medicines Shortages Single Point of Contact (SPOC) representatives*

Country	Medicine shortage register	SPOC representative	E-mail
Austria	https://medicineshortage.basg.gov.at (DE)	Martina Unteregger	-
Belgium	https://www.famhp.be (EN)	Sybille Schotte	info.medicines@fagg-afmps.be
Bulgaria	http://www.bda.bg/bg/ (BG)	Emilia Stoyanova	bfsa@bfsa.bg
Croatia	http://www.halmed.hr/en (EN)	Josipa Cvek	veterinarstvo@mps.hr
Cyprus	No online register available	Helena Panayiotopoulou	director@vs.moa.gov.cy
Czechia	http://www.sukl.cz (CZ)	Jakub Velik	uskvbl@uskvbl.cz

Denmark	https://laegemiddelstyrelsen.dk (DK)	Trine Aalund Rasmussen	dkma@dkma.dk
Estonia	http://www.ravimiamet.ee (ET)	Klara Saar	sam@sam.ee
Finland	http://www.fimea.fi (FI)	Johanna Linnolahti	
France	https://ansm.sante.fr (FR)	Flore Demay	sylvie.goby@anses.fr
Germany	https://www.bfarm.de (DE) / www.pei.de (DE)	Thomas Johannes Brouwers	pei@pei.de
Greece	http://www.eof.gr (GR)	Eletheria Thomaidou	relation@eof.gr
Hungary	https://www.ogyei.gov.hu (HU)	Ernő Horváth	ati@nebih.gov.hu
Ireland	https://www.hpra.ie/ (EN)	Darren Scully	info@agriculture.gov.ie ieinfo@hpra.ie
Italy	https://www.aifa.gov.it/en/web/guest/farmaciacarenti (IT)	Domenico Di Giorgio	sanita.animale@sanita.it
Latvia	https://www.zva.gov.lv (LV)	Kristīne Edolfa-Kalniņa	pvd@pvd.gov.lv
Lithuania	http://vvkt.lt/lit (LT)	Linās Mažeika	info@vmv.lt
Luxembourg	No online register available	Magali Boers	ministere-sante@ms.etat.lu
Malta	No online register available	Caroline Muscat	
Netherlands	https://www.cbg-meb.nl/onderwerpen/medicinformatie-medicijntekorten (NL) (Information on shortages of selected medicines)	Kim Notenboom	
Poland	No online register available	Tomasz Lisiewski	gif@gif.gov.pl

Portugal	https://www.infarmed.pt (PT)	Susana Alves	dirgeral@dgav.pt
Romania	https://www.anm.ro (RO)	Alina-Titina Iordache	icbm@icbm.ro
Slovakia	https://www.sukl.sk (SK)	Zuzana Porubská	uskvbl@uskvbl.sk
Slovenia	http://www.jazmp.si (SI)	Matjaž Marc	info@jazmp.si
Spain	https://www.aemps.gob.es (EN)	María Esplugues Argente	
Sweden	https://lakemedelsverket.se (SE)	Johan Andersson	registrator@mpa.se
Iceland	https://www.lyfjastofnun.is (IS)	Margrét Lilja Heiðarsdóttir	ima@ima.is
Liechtenstein	No online register available	Vlasta Zavadova	
Norway	www.noma.no (NO)	Guri Wilhelmsen	post@noma.no

**Information on the table has been extracted from the [EMA website](#) at the time of writing this report. Please consult online information for updates on relevant contact points.*

CONCLUSIONS

The survey's findings made it clear that several EU Member States are facing shortages in veterinary medicines. Currently, there is not a good flow of information about ongoing or anticipated shortages of veterinary medicinal products, their duration and extent in the EU. EMA and HMA try to address such issues and enhance communication about ongoing or anticipated shortages. Nonetheless, there is still a need for competent authorities to accelerate the development of an information mechanism to identify shortages and act as a hub for easy notification of practitioners about them, their duration and their extent. The industry and distributors have also an important role on timely addressing potential disruptions on the market of the EU countries and ensuring availability of products in all EU countries. Policy makers and all stakeholders should work together on ensuring alternative solutions to observed or anticipated shortages, especially for disruptions regarding essential or unique products. Veterinarians are encouraged to contact the SPOC representative in their country to report observed shortages and get information about ongoing issues. Additionally, practitioners should make use of the Union Product Database, which is an important tool for veterinarians enabling them to find alternatives for treatment and their availability in other EU Member States.

ACKNOWLEDGEMENT

FVE thanks all FVE and UEVP members for answering the survey.