



This month, the European Commission announced a series of key measures to improve response and preparation for potential future needs for antibiotic products, and thus avoid critical shortages such as those faced by the European Union last winter. Indeed, access to medicines - including for veterinary use- is a priority for our profession.

In terms of animal welfare, several significant achievements can be highlighted:

- *The European Commission has taken a decisive step towards the publication of the next revision of animal welfare legislation, which will cover a broad range of issues such as the slaughter of animals, transport and breeding conditions, among others. This publication is scheduled for autumn 2023.*
- *The European Commission has responded to the European citizens' initiative calling for « Save Cruelty-free Cosmetics - Commit to a Europe without Animal Testing » by announcing the forthcoming publication of a roadmap of legislative and non-legislative measures to reduce animal testing.*
- *Lastly, negotiations on the European Union's trade agreements on animal welfare mirror clauses are continuing, in particular with New Zealand, Australia, Mercosur and possibly the Philippines. The main purpose of these negotiations is to guarantee the reciprocity of health, social and/or environmental norms in trade, in order to preserve European standards and criteria.*

Volker MOSER, UEVP President

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PRIORITY ISSUES

Update on EMA activities

Decisions of the Committee for Medicinal Products for Veterinary Use (CVMP)

The Committee for Medicinal Products for Veterinary Use (CVMP) held a [meeting](#) from 11th to 13th July 2023.

The Committee adopted a positive opinion for a marketing authorisation for **Yurvac RHD**. The Committee adopted several positive opinions for a variation requiring assessment: for **Tessie** and **Cimalgex**. The Committee adopted a positive opinion for a grouped variation requiring assessment for **NexGard Combo**.

The Committee adopted positive opinions for variations requiring assessment concerning quality-related changes for: **Apoquel**, **CircoMax Myco** (grouped), **Enteroporc Coli AC** (grouped), **Felpreva**, **Kexxtone** and **Tulaven** (grouped).

The Committee adopted by consensus positive opinions for variations requiring assessment to align the product information with the latest version (9.0) of the QRD template for **Dexdomitor**, **Palladia**, **Panacur AquaSol**, **Porcilis PCV**, **RenuTend**, **Ypozane**, **Zactran** and **Zuprevo** (grouped).

The Committee classified an antineoplastic for dogs and an antiparasitic for honeybees as intended for a limited market and eligible for authorisation under Article 23 of Regulation [2019/6](#).

The Committee adopted a draft concept paper for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals. This proposal is submitted for a 3-month period of [public consultation](#).

The Committee adopted a concept paper on the revision of the guideline for the demonstration of efficacy of ectoparasiticides for a 3-month period of [public consultation](#).

The Committee adopted a draft guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation [2019/6](#) for a 6-month period of [public consultation](#).

The Committee adopted a [revised guideline](#) on requirements for the quality, safety and efficacy of allergen products for use in horses, dogs and cats following the close of the public consultation. The Committee adopted a revised guideline on excipients in the dossier for application for marketing authorisation for veterinary medicinal products and adopted a FAQ document on stability of tablet fractions for veterinary medicinal products.

The Committee also adopted a Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets to be released for a 6-month period of [public consultation](#).

The Committee adopted a letter to Marketing Authorisation Holders of botulinum neurotoxin-containing products, requesting information on animal use in LD₅₀ batch release testing.

The next meeting of the informal CVMP will take place on 21st and 22nd of September under the Spanish Presidency of the Council of the EU. This presidency lasts 6 months and began on July 1, 2023. At the next

meeting, the topics scheduled are persistent, bioaccumulative and toxic (PBT) substances, the assessment of 3Rs compliance of non-clinical studies, and products that can contribute to the reduction of the need for antimicrobials.

Latest news on animal health

Publication by the European Commission of recommendations to combat antibiotic shortages

On 17th July 2023, the European Commission, the Heads of Medicines Agencies ([HMA](#)) and the European Medicines Agency ([EMA](#)) jointly published [recommendations](#) to avoid shortages of important antibiotics to treat respiratory infections. These recommendations were developed by the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products ([MSSG](#)). Following this, the European Commission announced that it will take follow-up action, and if necessary, joint purchasing.

In its [press release](#), the European Commission states that if demand is similar to previous winters, supply should match demand. However, in the interests of better preparedness, recommendations to ensure sufficient supplies have been drawn up:

- **Increase production of the most important antibiotics.**
- **Monitor trends in supply and demand-** note that this recommendation is linked to the [conclusions](#) of the June 2023 European Council.
- **Raise public awareness on the prudent use of antibiotics.**

On 20th July 2023, the European Commission then [announced](#) immediate follow-up measures via the European Health Emergency Preparedness and Response Authority ([HERA](#)) to guarantee the availability of essential medicines. These measures have been taken in cooperation with the industry. To this end, the HERA Board met with industry representatives on 20th July 2023, to discuss antibiotic shortages, safety, continuity, and availability of medicines. The aim was to effectively implement the European Commission's recommendations.

The European Commission and EMA have announced that they will continue their exchanges with the industry over the summer ahead of the next MSSG meetings and the next HERA Board meeting, scheduled for mid-September 2023.

In this context, the Commissioner for Health and Food Safety Stella KYRIAKIDES stated *"Working to find solutions to ensure the sufficient supply of key antibiotics ahead of next winter is a key priority for us. With HERA, we have taken immediate action to follow up on this work with the industry. Our main objective is to ensure that all citizens have immediate access to the antibiotics they need this winter. Engaging with industry partners is essential to understand how we can best help on the ground"*.

Update on special control measures for African swine fever in Europe

The European Commission has updated, with three implementation decisions published on July 5th and 19th, and August 3rd 2023, the establishment of the special control measures for the African swine fever, in accordance with implementing regulation [2023/594](#).

New outbreaks of African swine fever have occurred in several regions of the European Union:

- Among wild porcine animals in the **Calabria region of Italy** in non-regulated zones, some of which become restricted zones II and others III.

- Among wild porcine animals in the **Mazowieckie region of Poland** in a restricted zone I that has become a restricted zone II.
- Among kept porcine animals in **Central Macedonia in Greece** in a restricted zone I, which becomes a restricted zone II.
- Among kept porcine animals in restricted zones II in **Marijampolė county in Lithuania, Lubelskie, Wielkopolskie and Mazowieckie regions in Poland, Madonas, Krāslavas and Vidzemes region in Latvia, Võru and Põlva counties in Estonia and in Montana region of Bulgaria**. These areas become restricted zones III.
- Among wild porcine animals in restricted zones I in the regions of **Mazowieckie and Zachodniopomorskie in Poland**, these zones become restricted zone II.
- Among wild porcine animals in restricted zones II in the regions of **Podkarpackie and Mazowieckie in Poland, Lombardy and Liguria in Italy, and in the German Land of Brandenburg**. These areas are close to restricted zones I. The latter become restricted zones II.
- Among kept porcine animals in **Central Macedonia in Greece** in a restricted zone III close to a restricted zone I which becomes a restricted zone II.
- Among wild porcine animals in **Northern Macedonia in Greece**, in the proximity of non-restricted zones, the latter become restricted zones I

The situation has improved in the **German Land of Brandenburg**, with no outbreaks among both kept and wild porcine animals in the last twelve months. Some restricted zones II have become restricted zones I, and some restricted zones I have been removed from the list.

In addition, the European Commission published [an implementing decision](#) on 27th July 2023 concerning the African swine fever situation in **Croatia**. Following the confirmation of outbreaks in wild porcine animals in the **Karlovacka region** on July 13th 2023 and pending the inclusion of the affected area of Croatia in the list of restricted zones II of implementing regulation [2023/594](#), the implementing decision establishes the same measures as for restricted zones II. In addition, shipments of pigs and pig products are prohibited from the area.

EFSA publishes report on highly pathogenic avian influenza

On 13th July 2023, the European Food Safety Authority ([EFSA](#)) published a [report](#), accompanied by a [press release](#), on the highly pathogenic avian influenza situation in Europe between April and June 2023.

Between 29th April and 23rd June, **98 outbreaks of highly pathogenic avian influenza were reported among domestic birds and 634 among wild birds in 25 European countries.**

The EFSA states that the overall situation has improved, but the report refers to a cluster concentrated in south-west France, involving mulard ducks for foie gras production.

Several seabird species were particularly affected by the epidemic, notably black-headed gulls, with increased mortality observed in adults and young birds. According to the study, compared with the same time last year, dead seabirds were more frequently found inland, rather than just along the coast.

As regards transmission to mammals, the virus has been observed in 24 domestic cats and one caracal in Poland. EFSA points out that all cases of contamination of mammals are genetically close to viruses previously observed in wild birds and poultry. However, uncertainties remain as to the source of infection.

Furthermore, EFSA mentions the detection of two cases of a form of the virus in humans in the UK, and three human infections in China, including one death.

The risk of contamination remains low for the general population in Europe, and low to moderate for people with professional exposure to infected birds or mammals.

On 21st July 2023, the European Commission published an [implementing decision](#) concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza. This decision amends implementing decision [2021/641](#) concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza.

Following outbreaks on poultry farms and among captive birds in the municipality of **Nyborg in Denmark, in the Land of Schleswig-Holstein in Germany, in the departments of Pas-de-Calais, Landes and La Réunion in France, in the Lombardy region of Italy, in the Małopolskie voivodship of Poland and in the municipality of Gotland in Sweden**, the protection and surveillance zones in France, Germany and Poland are modified. New protection and surveillance zones are added in Germany, Poland, Denmark, Italy, and Sweden.

OTHER ISSUES

Latest news on animal welfare

Approval of the impact assessment on the revision of European legislation on animal welfare

In July 2023, the Regulatory Scrutiny Board (RSB) validated the second version of the European Commission's impact assessment on the [future revision](#) of animal welfare legislation, expected in the 3rd quarter of 2023.

As a reminder, the first version of the document received a negative opinion from the RSB on 10th May 2023, requiring changes to be made to the document. According to the board, the cost-benefit ratio of the future revision had not been sufficiently taken into account. **The board had asked the European Commission to clarify the potential benefits of the measures envisaged, requested greater transparency on the costs of the measures, strengthen the analysis relating to competitiveness, justify the claim that food safety would not be affected by the legislative proposal, and rework animal welfare labelling so that it is better articulated with the [future proposal](#) on sustainable EU food systems, also due to be proposed in the 3rd quarter of 2023.**

Prior of the publication of the European Commission's legislative proposal, the debate surrounding animal transport conditions within the European Union continued. On 11th July, 2023, three animal protection associations - [L214](#) in France, [Ethical Farming Ireland](#) and [Eyes on Animals](#) in the Netherlands - [published a video](#) denouncing the conditions under which calves are transported between the three European countries. According to them, these conditions do not comply with the [Regulation](#) regarding the protection of animals during transport. In the [press release](#), L214 declared that it had submitted a complaint to the European Commission against the three countries.

The European Commission responds to the European Citizens' Initiative on animal testing

On 25th July 2023, the European Commission [responded](#) to the [“Save Cruelty-free Cosmetics - Commit to a Europe without Animal Testing”](#) European Citizens' Initiative (ECI).

As a reminder, the ECI is a way for European citizens to encourage the European Commission to work on a specific subject. To introduce an ECI that is considered valid, it requires at least one million signatures from seven different member states.

The “*Save Cruelty-free Cosmetics - Commit to a Europe without Animal Testing*” ECI was registered on 30th June 2021, with signatures collected during a period of 1 year (between 31st August 2021 and 31st August 2022). The ECI was therefore declared valid on 25th January 2023.

Through this European Citizens' Initiative, the European Commission is called upon to:

- **Guarantee and strengthen the ban on animal testing for cosmetics.**
- **Amend the EU Chemicals Regulation.**
- **Commit to a legislative initiative that would establish a roadmap for phasing out animal testing.**

In its [response](#) to the ECI, the **European Commission announces the forthcoming publication of a roadmap of legislative and non-legislative measures to reduce animal experimentation**. The main lines of its upcoming actions are as follows:

- **The preservation and reinforcement of the ban on animal testing for cosmetics.** While the EU [Regulation](#) on cosmetics products prohibits the distribution of cosmetics that have been tested on animals, the European Commission has stressed that this ban does not currently extend to innocuousness tests under the EU [Regulation](#) on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). The Court of Justice of the European Union is currently examining the legal relationship between the two texts.
- **The abolition of animal testing as far as possible under the REACH Regulation.** In collaboration with stakeholders, the European Commission will draw up a roadmap for conducting chemical safety assessments without resorting to animal testing.
- **The modernisation of science:** to begin - the European Commission has made it clear that it does not agree with the idea of a legislative proposal to phase out the use of animals in research, training, and teaching. However, the European Commission reaffirmed its financial support for the development of alternative methods and its intention to launch a series of actions to explore the possibilities of coordination between member states and national authorities on this subject.

Note that in September 2021, the European Parliament had adopted a [resolution](#) “Plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education” calling for an accelerated transition to animal-free innovation in research, regulatory testing and education. In its resolution, the European Parliament had called for a Europe-wide action plan to phase out procedures involving animal testing for scientific and regulatory purposes.

Latest news regarding international trade

Ongoing negotiations of the European Union's trade agreements

On 29th June, 2023, MEPs criticized the ineffectiveness of mirror clauses in trade agreements during a debate in the European Parliament's Committee on Agriculture and Rural Development (AGRI) with John CLARKE, Director of International Affairs at the European Commission's Directorate-General for Agriculture and Rural Development (DG AGRI). **The European Commission is due to publish a study on the cumulative effects of free-trade agreements on the agricultural sector in autumn 2023.** In parallel, negotiations on trade agreements with several third countries are continuing:

- **European Union - New Zealand**

The [June 2022 agreement](#) between the European Union and New Zealand was signed on July 9th, 2023, and must now be ratified by both parties. The aim is to implement the agreement in 2024. **Eurogroup for animals welcomed the agreement, which addresses animal welfare concerns: “the EU managed to obtain an animal welfare condition for one of the animal products most traded between the partners”** namely beef. “We

welcome the explicit exclusion of meat derived from commercial feedlots from the list of products benefitting from preferential access”.

On 19th July 2023 members of the Agriculture and Rural Development Committee (AGRI) met to discuss the [draft opinion](#) of Michaela ŠOJDROVÁ (EPP, Czech Republic) on this free trade agreement. Although the MEPs consider the agreement to be “balanced”, they are concerned about the potential cumulative effects with the conclusion of other free trade agreements. John CLARK, Director of International Affairs at the European Commission’s Directorate-General for Agriculture and Rural Development (DG AGRI) commented that **the European Commission is due to present a study on the cumulative effects of free-trade agreements in autumn 2023.**

▪ European Union - Australia

While the European Union had hoped to conclude an agreement during the visit of an Australian delegation to Brussels led by Don FARRELL, Australian Minister for Trade, the exchanges were unsuccessful. **The European Commission presented its proposal on 10th July 2023. Don FARRELL explained that he would first have to discuss the matter with other Australian ministers in view of certain points of tension, in particular beef and sheep quotas.**

▪ European Union - Mercosur (South American Common Market)

An EU-CELAC (Community of Latin American and Caribbean States) summit was scheduled to take place in Brussels on 17th and 18th July 2023, in the presence of European and CELAC heads of state. The European Commission had hoped to conclude the trade agreement, but the European Union recently asked for an additional protocol on environmental aspects. Mercosur is expected to make its counterproposal at the end of August.

In a [press release](#) issued on 17th July 2023, European Commission Vice-President Valdis DOMBROVSKIS, Brazilian Foreign Minister Mauro VIEIRA, Argentine Foreign Minister Santiago CAFIERO, Paraguayan Foreign Minister Julio César ARRIOLA and Uruguayan Foreign Minister Francisco BUSTILLO announced that they have **“reaffirmed their determination to work towards the conclusion of the Agreement between the EU and MERCOSUR by the end of 2023”.**

Finally, in a [press release](#) dated 18th July 2023, [Eurogroup for animals](#) explains that free-trade agreement **“grant further unconditional market access to animal based products, leading to an increase in the trade and further fuelling the intensification of farming both in the EU and abroad. This trend not only implies poor animal welfare conditions, but also raises public health concerns in terms of zoonoses and antimicrobial resistance (AMR). Intensification of animal production also generates high levels of deforestation, impacting the welfare of millions of wild animals”.** The NGO organized an [event](#) “A new EU-Latin America trade relationship for the 21st Century” on 17th July with stakeholders from European and South American civil society. The event was supported by Green/EFA MEPs Thomas WAITZ (Austria), and Tilly METZ (Luxembourg), and by S&D group with MEP Christophe CLERGEAU (France).

▪ European Union – Philippines

On 31th July 2023, during a visit by European Commission president Ursula von der LEYEN to the Philippines, the European Commission announced in a [press release](#) the **intention of the European Union and the Philippines to relaunch negotiations on an “ambitious, modern, and balanced free trade agreement (FTA) – with sustainability at its core”.**