EU NEWS

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UEVP

Union Européenne des Vétérinaires Praticiens – AISBL
Union of European Veterinary Practitioners – AISBL

*Last month, the European Commission continued its initiative **on active antimicrobial substances in medicated feed**. For this purpose, a call for consultation was launched to gather the views of European stakeholders concerned by this subject. In this context, the availability of suitable antimicrobial medicines - particularly for veterinary use - is a priority for our profession.*

*On the **animal health** front, the impact of detected cases of avian influenza, African swine fever and, more recently, epizootic hermorrhagic disease still requires coordinated and targeted action. In response, the European Commission is taking measures to prevent, monitor and manage new outbreaks.*

*Despite this strong public opinion in favor of **animal welfare** (as reflected in the results of a recent Eurobarometer survey), it would appear that the expected revision of EU animal welfare legislation announced by the European Commission will not take place during this legislature, except for a potential revision exclusively linked to the protection of animals during transport. Considered an essential issue for our veterinary profession, we will keep following closely the place of this topic on the European agenda in the run-up to the next European elections.*

Volker MOSER, UEVP President

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PRIORITY ISSUES

Update on EMA activities

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP)

The Committee for Medicinal Products for Veterinary Use (CVMP) held a meeting from 3rd to 5th October 2023.

The Committee adopted a positive opinion for marketing authorization application for **Senvelgo,** a product intended for the reduction of hyperglycaemia in cats with non-insulin-dependent diabetes mellitus. In addition, they adopted two positive opinions for marketing authorizations for **Nobivac LoVo L4**, and **Bovilis Cryptium,** respectively a vaccine for the active immunization of dogs and pregrant cows.

The Committee adopted three positive opinion for a variation requiring assessment for **Suiseng Diff/A**, **CircoMax**, and **CircoMax Myco,** to add the combined uses of Suiseng Diff/A vaccine with another related product authorized nationally on the one hand, and to add the possibility of administrering CircoMax Myco intramuscularly, using needle-fee devices on the other hand.

The Committee adopted positive opinions for variations requiring assessment concerning quality-related changes for: **Clomicalm**, **Fortekor Plus** and **Porcilis ColiClos** (as well as **Porcilis PCV ID**, **Porcilis PCV**, **Porcilis PCV M Hyo** and **Porcilis Porcoli DF**).

Also, the Committee adopted positive opinions for variations requiring assessment to align the product information with the latest version (9.0) of the QRD template for **Suvaxyn CSF Marker** and **Tulinovet.**

The Committee started the referral procedure for **Procactive 300 mg/ml** suspension for injection for cattle, sheep and pigs, concerning a potential modification of an assessment for environmental safety reasons, in accordance to the Regulation 2019/6.

The Committee adopted a positive opinion recommending the establishment of the maximum residue limits status for **sodium salicylate** in poultry other than turkeys.

In addition, the Committee adopted one scientific advice report further to a request for initial advice concerning a pharmaceutical product for horses.

Following two requests, the Committee classified a nervous system product for free-moving zoo animals (lions, leopards, cheetahs, tigers, bears, great apes, others) as intended for a restricted market and eligible for authorization, and a Dermatological product for horses intended for a restricted market and eligible for authorization, in accordance with Regulation 2019/6.

The Committee adopted a guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators.

After taking into account comments received during the dedicated public consultation procedure, the Committee adopted a revised guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy. This guideline aims to address regulatory as well as technical and scientific bases.

The Committee adopted a guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD) for release for a 1-month period of public consultation. This guideline has been developed to provide specific advice on the considerations and calculations associated with the dose factor, which, in

combination with the submission of annual sales data, will facilitate the calculation and annual publication of reported adverse reactions for each veterinary drug.

The Committee also adopted a concept paper on a guideline on stability testing for variations for veterinary medicinal products for release for a 2-month period of public consultation, ending on 5th January 2024. It has been developed to address the need for a new guideline on stability testing for variations to a marketing authorisation for veterinary medicinal products.

The Committee adopted a draft joint (human and veterinary) guideline on development and manufacture of synthetic peptides for release for a 6-month period ending on 30th April 2024. This guideline has been developed to address specific aspects regarding the guideline on the Chemistry of Active Substances or the guideline on Chemistry of Active Substances for Veterinary Medicinal Products.

Moreover, the Committee adopted a Question and Answer (Q&A) document on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing.

Finally, Anita Bottger was elected as Vice-chair of the Pharmacovigilance Working Party (PhVWP-V) for a 3-year mandate.

Latest news on antimicrobial resistance at EU level

Launch of a call for contributions from the European Commission for an initiative on medicated animal feed

On 12th October 2023, the European Commission launched a call for contributions for **draft initiative on medicated feed for animals**, until 9th November 2023 (included). The initiative, which takes the form of a delegated regulation, aims to complement the measures mentioned in Regulation (EU) 2019/4 on medicated feed.

The two main lines of this draft initiative are:

- The establishment of a harmonized cross-contamination level for antimicrobial active substances in non-target feed, set at 1% of the active substance contained in the medicated feed;
- The introduction and implementation of methods for analyzing antimicrobial active substances contained in animal feed.

It should be noted that contamination levels have been established on the basis of risk assessments carried out by the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). To avoid a growth-promoting or yield-increasing effect, maximum cross-contamination levels for antimicrobial active substances in non-target feed should be lower than the lowest levels resulting in a growth-promoting or yield-increasing effect.

These contamination levels are intended for three categories of animals (as mentioned in Article 2 of the Delegated Regulation), which are:

- Food-producing animals other than fish, when non-target feed is manufactured, processed, stored or transported after the manufacture, processing, storage or transport of medicated feed for aquaculture;
- Animals during the production of eggs or milk for human consumption;
- Food-producing animals intended for slaughter during the slaughter period corresponding to the longest withdrawal period for the target animal species.

This delegated regulation also includes an annex listing the active substances present in animal feed.

Latest news on animal health at EU level

Publication of a scientific opinion by the European Food Safety Authority (EFSA) encouraging preventive vaccination against avian influenza

On 10th October 2023, the European Food Safety Authority (EFSA) published a scientific opinion on the potential positive effects of preventive vaccination against avian influenza on reducing the number of outbreaks.

One of the aims of this opinion was **to evaluate the available vaccine strategies**. This study highlighted that "*despite the production of several vaccines, only a small number of these medical devices have been marketed*", explained EFSA. EFSA also pointed out that one of the difficulties faced during the study was the availability of data to identify and compare the causality and effects of preventive vaccination on the reduction of outbreaks. The report therefore underlines the need to step up research and development of new vaccines to cope with the increasing number of cases of avian influenza in Europe.

As a conclusion of its scientific opinion, **EFSA also considered that preventive vaccination was the most effective way of reducing the risk of the disease spreading and recommended this type of vaccination strategy for areas within a 3km radius of epidemic outbreaks.** More generally, EFSA reiterated that vaccination should take part of a broader and more comprehensive range of measures aimed at reducing the number of cases of avian influenza, such as **measures to monitor the number of infections**.

Finally, EFSA has announced that it will complement this work with **a second scientific opinion, focusing more specifically on monitoring measures**. The publication of this second opinion is scheduled for **March 2024**.

In parallel, following new outbreaks of avian influenza have occurred in Poland and Denmark, the European Commission is due to publish an implementing decision on 24th October 2023, setting out rules to be followed and specifying surveillance and protection zones in the two member states.

Adoption by the European commission of implementing regulations laying down special measures to tackle African swine fever

On 16th and 24th October 2023, the European Commission published two implementing regulation laying down special measures to combat African swine fever. This regulation follows new outbreaks of highly pathogenic swine fever in several Member States, including: Croatia, Lithuania, Germany, Italy and Poland.

Noted that these measures take into account the international standards, such as the Terrestrial Animal Health Code of the World Organisation for Animal Health.

According to these implementing regulations, the following regions have been recognised as having surveillance and protection zones:

- The areas of **Jurbarkas district municipality, Molėtai district municipality, Marijampolė municipality, Šakiai district municipality, Kazlų Rūda municipality, Vilkaviškis district municipality, Širvintai district municipality and Ukmergė district municipality** (Lithuania).
- The **Osijek – baranja county**, as well as the **Zadarska Region** and the **Vukovar Srijem County** (Croatia).
- The **Mazowieckie Region, Pomorskie and Łódzkie Regions** (Poland).
- Finally, the **regions of Sardinia and Lombardia** (Italy).

In contrast, the region of **Western Macedonia** (Greece) and certain areas of the **Pomorskie and Łódzkie** regions (Poland) are no longer considered as surveillance regions.

Reopening of Italian borders following containment of the spread of epizootic hemorrhagic disease

On 12th October 2023, the Italian Department of Agriculture announced the reopening of Italian market borders. Indeed, due to the increase in the number of cases of epizootic hemorrhagic disease at the end of September, trade in bovine animals intended for fattening were interrupted within a 150km zone around the areas of contagion, mainly in the Pyrénées-Atlantiques and Hautes-Pyrénées regions in France. These exchanges with French farmers represent a colossal market for Italy, which is the leading importer of young French bovines.

Note that the reopening of Italian borders is nevertheless accompanied by a special sanitary protocol to ensure that the number of contaminated cases does not rise again. The measures included in this protocol are as follows:

- Disinfection of bovines before departure for Italy
- PCR testing of bovines prior to departure for Italy
- Monitoring of bovines in infected areas
- Control of marked zones and movement restrictions

These measures are intended to limit the spread of bovine contaminated by the epizootic haemorrhagic disease.

However, as far as measures are concerned, the Fédération Nationale Bovine (FNB) is calling for the cost of PCR tests not to be billed to farmers. If a bovine should test positive, the FNB is calling for a special mechanism to authorize the slaughter of the animals, while offering financial compensation from the State to offset the animal's loss compared to its initial value.

In order to provide farmers with the best possible support, and to better assess the impact of the disease on their animals, around forty "test farms" have been established in the departments most severely impacted.

OTHER ISSUES

Latest news on international trade

EU-Australia trade agreement : Several European animal conservation groups call for animal welfare to be included in trade agreement

Several European associations (including *Eurogroup for animals*, *Australian Alliance for Animals* and *Animals Australia)* have called on the European Union and Australia to include animal welfare in their trade agreement.

As negotiations for this free trade agreement draw to a close, animal welfare advocates are stressing the importance and necessity of including this objective in their trade agreement, as the only way to ensure that these provisions are respected.

According to them, existing trade agreements worsen rather than reduce the negative consequences of intensive farming. In fact, Australian beef destined for the European Union could come from Australian feedlots, whose practices could cause respiratory and digestive problems in the animals. They therefore reiterate that it is essential for the European Union and Australia to establish preferential prices for beef from more sustainable feeding systems, and to exclude beef from these feedlots.

Among the thorniest sticking points is the issue of animal welfare during transport. The European associations consider Australian regulations on the long-distance transport of animals are "*minimal and almost unenforceable*", and therefore are calling for EU standards in this field to be taken into account in the trade agreement.

Finally, the last key divergence concerns agricultural component, and more specially the issue of bovine and ovine meat production. Indeed, at the last meeting on 29th October, which was initially intended to be the "final meeting" before agreement, this specific issue was largely compromised. While the opening of the European market to Australian meat imports appeared to have been stabilized, the outcome of the negotiations now seems more uncertain.

Latest news on animal welfare at EU level

Declaration of the European Commission on the future revision of animal welfare legislation

On 17th October 2023, the European Commission published its work programme for 2024, which groups all the initiatives planned for the coming year. This programme lists the priority initiatives that the European Commission would like to see adopted before the end of the current mandate.

However, the absence of the revision of animal welfare legislation from this work programme is notable. The only official announcement on this subject was made by European Commissioner Maros SEFCOVIC, in charge of the Green Deal, who announced at his hearing in the European Parliament on 3rd October 2023 **that a proposal to revise the legislation on the protection of farm animals during transport could be presented in December 2023**. No details were given concerning the other aspects of the revision of the legislation (for which impact studies have yet to be carried out).

As a reminder, the protection of farm animals during transport is one of the four components of the revision announced by the European Commission last April, which includes: welfare during farming, slaughter, transport and finally animal welfare labelling.

This announcement was strongly criticised both by European associations and by MEPs such as Tilly Metz (Greens/EFA), who pointed out that the European Commission had committed to present a legislative review of the entire package (composed of the four parts) of the text by the end of the year. Following this, the Intergroup on Animal Welfare and Conservation - chaired by MEP Tilly Metz - sent a letter to the European Commissioner reiterating the issues at stake and the need to publish a review of European legislation on animal welfare.

Adoption by the Council of a regulation on the labelling of organic pet food

On 9th October 2023, the Council adopted a regulation on the labelling of organic pet food. This regulation is part of the *Farm to Fork* strategy presented by the European Commission in May 2020, which aims to "make Europe's food supply healthier and more sustainable". More specifically, this strategy aims to promote organic production, with the aim of achieving a 25% share of European agricultural land by 2030.

The aim of this regulation is to align the rules for pet food labelling with those for human food labelling. What's new is the addition of a logo on the labelling of pet food, providing that 95% of the agricultural ingredients are organic. The aim of this logo is to make it easier for consumers to identify the composition of foodstuffs. The regulation provides for a transitional period of six months to allow producers of these pet food products to include the organic logo on their products.

In the same logic, the European Parliament's Intergroup on Animal Welfare and Conservation stated at its meeting on 5th October 2023 that "*animal welfare is an essential element of food sustainability, and improving animal welfare should go hand in hand with changing food consumption patterns towards diets containing fewer and better quality products of animal origin*".

Publication of a Eurobarometer on Animal welfare by the European Commission

On 19th October 2023, the European Commission published a Eurobarometer on animal welfare. Among the elements highlighted by this Eurobarometer, **animal welfare appear to be "essential" by the Europeans surveyed**. Results include the following:

- 84% of Europeans felt that farm animal welfare protection should be improved in their member state.
- 83% of those questioned said they were in favor of reducing animal transport times.
- 74% expressed their wish for better protection of the welfare of pets.

These data may testify to the importance that European citizens attach to animal welfare.

Despite strong public opinion, it would appear that the expected revision of the EU legislation on animal welfare announced by the European Commission will not be forthcoming during this mandate. As a reminder, the European Commission's recent statements, as well as its work program for 2024, make no mention of animal welfare legislation. For this reason, the CEO of Eurogroup for animals declared "*Today, the disconnect between civil society and European politics has become even more evident*."

Parliamentary hearing on the "Fur Free Europe" initiative to end fur farming

On 12th October 2023, a hearing on the "Fur Free Europe" initiative was held at the European Parliament. At this hearing, most MEPs showed their support for this European Citizens' Initiative (ECI), which calls for a **ban on the farming and slaughter of animals for fur production**. In addition to this ban, the ECI also calls for a **ban on the marketing of fur and fur products in the European Union.**

The European Commission, which validated the "Fur Free Europe" initiative in June 2023, must now respond by the end of December.

Several MEPs have already voiced their support for this ECI, including Martin HAUSLING (Greens/EFA, Germany), who considers that "*there is no economic reason to maintain this industry*", as well as Martin HOJSIK (RE, Slovakia), who would like to see the ban extended to imports. However, Mazaly AGUILAR MEP (CRE, Spain) pointed out that such a ban could also lead to an increase in imports from third countries.

The European Commission will therefore have to take into account both animal welfare and the potential economic and social consequences of banning fur in the European Union.

Publication of SCHEER report on animals used for scientific tests

On 6th October 2023, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) published its final opinion on Annexes III and IV of the Directive on the protection of animals used for scientific purposes.

The aim of the report is to summarize the current situation and make several recommendations concerning the welfare of zebrafish and passerines in captivity.

These recommendations include guidelines on essential parameters for housing zebrafish in captivity, as well as assessments of euthanasia methods, including hypothermia, and housing requirements to safeguard the welfare of various species of passerine birds in captivity.