EU NEWS

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UEVP

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

*Since the summer break, the European Parliament has organised an exchange of views on new initiatives and incentives to be put in place to improve the accessibility and availability of **antimicrobial medicines**, in order to avoid critical shortages such as those previously faced by the European Union. Access to medicines - notably veterinary medicines - is a priority for our profession.*

*On the **animal health** front, recent months have been particularly impacted by the increase in detected cases of avian influenza, African swine fever and goat pox. In response, the European Commission is taking measures to prevent, monitor and manage new outbreaks.*

*As regards the revision of the European **animal welfare legislation**, the topic was not mentioned in the State of the Union speech by the President of the European Commission and is not included for the moment in the agenda of the commissioners meetings until December. As a wide revision was in preparation, the only official announce is that a revision of the legislation regarding animal protection during transportation will be presented in December. We will keep closely following the discussions on this key topic for veterinarians.*

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 5th to 7th September 2023.

The Committee adopted two positive opinions for marketing authorization applications (for **Oxmax** and **Loxitab)**, and two positive opinions for marketing authorizations (for **Poulvac Procerta HVT-IBD** and **Prevexxion RN+HVT)**. The Committee adopted a positive opinion for a variation requiring assessment for **Solensia.** The Committee also adopted a positive opinion for a grouped variation requiring assessment for **Nexgard Spectra.**

The Committee adopted positive opinions for variations requiring assessment concerning quality-related changes for: **Evanovo, Gumbohatch** (worksharing procedure), **Felpreva**, **Nexgard Spectra**, **Nobivac DP Plus**, **Porcilis PCV M Hyo** (grouped), **ProZinc**, **Simparica**, **MiPet Easecto** (grouped, worksharing procedure), **Stelfonta**, and **Zenalpha**.

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 **Clynav, Felisecto Plus, Innovax-ND-ILT, Leucofeligen FeLV/RCP, Previcox, and Stronghold Plus.**

The Committee concluded the referral procedure for veterinary medicinal products containing **procaine benzylpenicillin** as a single active substance presented as suspensions for injection, and concluded that the benefit-risk balance remains favourable and that those marketing authorizations should be amended accordingly.

The Committee adopted an opinion recommending changes to the indications, dosage regimen, warnings on the effective use of the products, as well as to the withdrawal periods.

In addition, the Committee adopted four scientific advice reports further to requests for initial and follow-up advice concerning one immunological and three pharmaceutical products.

The Committee adopted a draft concept paper on the revision of the guideline on user safety of topically administered veterinary medicinal products, which will be submitted for a 2-month period of public consultation (until 30th November 2023).

The Committee adopted a guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation in accordance with the EU Regulation 2019/6. This guideline will be submitted to a 4-months period of public consultation (until 31st January 2024).

The Committee also adopted a guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets, to be released for a 4-month period of public consultation (until 31st January 2024).

The Committee adopted a guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation in accordance with the EU Regulation 2019/6, to be released for a 4-months period of public consultation (until 31st January 2024).

Lastly, the meeting was the occasion for several elections for the committee's working groups: Damien Bouchard (as Vice-Chair of the Antimicrobials Working Party), Cristina Munoz Madero (as Chair of the Efficacy Working Party), James Mount (as Chair of the Veterinary Pharmacovigilance Working Party) and Sara Sacristan (as Co-chair of the ESUAVet Working Group).

Latest news on antimicrobial resistance at EU level

Exchange of views within the Health Working Group of the European Parliament's ENVI Committee on incentives to improve access to antimicrobials

In August 2023, a European Parliament document was published summarising the discussions of the Health Working Group of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) at the "New incentives to improve accessibility and availability of antimicrobial medicines" workshop held on 26th October 2022.

Experts from the World Health Organisation (WHO), specializing in the medical, innovation and research sectors took part in the discussions. They examined methods of stimulating research and development in the context of the revision of European pharmaceutical legislation proposed by the European Commission on 26th April 2023.

Regarding the current situation, the present players stressed the importance of having access to a wide range of narrow- and broad- spectrum antimicrobials. They drew particular attention to problems with the availability of "old" generic antibiotics. For the WHO, the current number of approved antibacterial agents is insufficient to deal with the spread of infections due to antimicrobial resistance.

Participants identified several challenges, including:

- The increasing development cost of researching and developing new antimicrobials;
- The predominance of SMEs sector in Europe, with large companies having left the field due to limited profitability;
- New antimicrobial developments are still insufficient and incentives for research and development should be introduced.

Furthermore, according to the participants, **it is essential to separate the financial profitability of antibiotics from the volume of antibiotics consumed.** This should make it possible to improve the compatibility of contradictory objectives: reducing antibiotic consumption and encouraging the production of new antibiotic products despite low sales and profitability prospects.

The participants discussed two "pull" incentive options based on this logic:

- **Transferable exclusivity extensions (TEEs):** these are tradable vouchers awarded to the innovator, that can be used to extend the monopoly period of any patented drug in its portfolio or sold to another company. This option is supported by the pharmaceutical industry. For public and civil society players, this solution could lead to high costs for Member States as a result of prolonged high prices.
- **Guaranteed annual revenue:** this would be a predictable income for producers of marketed antimicrobial products whose added value in terms of public health is proven.

Some public authorities have also proposed gradually awarding rewards according to the stages of development achieved, in order to facilitate the transition from the preclinical to the clinical phase and to guarantee sustainable access to the product. This method would involve a global or European not-for-profit cooperation entity.

Latest news on animal health at EU level

Increase of the number of cases of avian influenza in Europe this summer

The European Food Safety Authority (EFSA) published a report on 28th September 2023 stating that the number of cases of avian influenza virus increased this summer in Europe. Cases of avian influenza have been recorded in domestic and wild birds in more than 20 Member States. Although EFSA notes that less and less poultry farms are affected by the virus, it continues to circulate in coastal areas to a significant extent.

In this report, EFSA recommends that preventive measures be put in place before the expected autumn migration period, to prevent the virus from spreading to other areas and to protect the health of farmed poultry.

Note that this report is in line with the emergency measures adopted by the European Commission last July, following outbreaks of highly pathogenic avian influenza in certain Member States.

Adoption of an implementing decision by the European Commission concerning goat pox in Spain

On 4th August 2023, an implementing decision of the European Commission was published on sheep pox and goat pox in the Official Journal of the European Union.

This decision follows the rise of new outbreaks of sheep pox and goat pox in Spain in recent months, and consequently amends implementing decision 2021/641 on emergency measures to combat this disease. As soon as Spain identified this increase in the number of cases of animals affected by the virus on its territory, a warning was given to the European Commission and increased surveillance of the affected areas was put in place. The new measures concern more specifically the movements of sheep and goats between protection zones and surveillance zones, which must be authorised by the competent authorities.

Adoption by the European Commission of emergency measures in response to the increase in cases of African swine fever in Italy

On 17th August 2023, the European Commission published a 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 Bulgaria, Croatia, Germany, the Czech Republic, Italy, Latvia 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.

New outbreaks of African swine fever appeared in the following regions :

- In kept porcine animals in the municipality of **Lovech in Bulgaria**, in areas currently classified as restricted zone II. This new outbreak increases the level of risk and is redefined as restricted zone III.
- In wild porcine animals in the **Liberecký region of the Czech Republic**, in areas currently classified as restricted zone II (and located in the immediate vicinity of an area currently classified as restricted zone I) - This new outbreak increases the level of risk and redefines the two restricted zones as II.
- In kept porcine animals in the **Madonas and Jekabpils Counties in Latvia**, in areas currently listed as restricted zones II. This new outbreak increases the level of risk and redefines the two restricted zones as III.
- In kept porcine animals in **the Lubelskie and, the Swietokrzyskie and Opolskie Region in Poland**, in areas currently classified as restricted zones II (and located in the immediate vicinity of an area currently classified as restricted zone I). This new outbreak increases the level of risk and redefines the three restricted zones as II.

- In wild porcine animals in **the State of Brandenburg in German**, in areas currently classified as restricted zone II (and located in the immediate vicinity of an area currently classified as restricted zone I). This new outbreak increases the level of risk and redefines the two restricted zones as II.
- In kept porcine animals in **the Vukovar Srijem County in Croatia**, in areas currently classified as a surveillance zone. This new outbreak increases the level of risk and redefines the surveillance zone into a protection zone.

The European Commission subsequently adopted further provisional emergency measures on 31 August in response to the growing number of cases of African swine fever in Italy. Following the identification of numerous cases in the **Lombardy region of Italy**, the information was transferred to the European Commission and the area was demarcated so that it could be subject to the measures provided for under European legislation. Italy pointed out in particular that pig farms were affected (in addition to the wild boar previously diagnosed).

Lastly, the Joint Research Centre (JRC) published a technical report on 29 August 2023 on the progress of the African swine fever vaccine, outlining the advantages and limitations of the different types of vaccine, as well as the legislative framework for the development of veterinary medicines.

OTHER ISSUES

Latest news on international trade

Statement by the European Commission's DG SANTE on mirror clauses concerning animal welfare

At an event organized on 20th September 2023, entitled "European Animal Welfare Symposium", **Andrea GAVINELLI**, Head of Unit in charge of animal welfare at the European Commission's DG SANTE, spoke on the subject of mirror clauses in the context of the future revision of European animal welfare legislation.

On this occasion, he explained that while "*a large proportion of our imports come from countries that already have animal welfare certifications*", the problem lay with "*imports from other countries such as Brazil*". In that sense, he reminded that the European Union must "*be able to respect animals, whether they are raised in Europe or elsewhere*". In this context, the European Commission is currently working on several options to ensure reciprocity. He underlined that "*Today, for the slaughter of animals, we have standards in the European Union that must be applied to all imported meat [...].* ***One option could be to require certain animal welfare elements to be certified at the time of export***". However, Andrea GAVINELLI did not return to the thorny question of the timetable for presenting the revision proposal.

Latest news on animal transport conditions

Publication by the European Commission of a report on shortcomings in Croatian animal protection control practices

On 9th August 2023, the European Commission published a report highlighting the limitations of the Croatian system for controlling the protection of animals transported by sea to third countries. The report is based on an audit carried out by the Food and Veterinary Office of the European Union (FVO), the aim of which was to analyze and measure the effectiveness of Croatian actions dedicated to animal protection.

The assessment focused on measures relating to transport by ship to third countries. The audit revealed that the Croatian measures present several shortcomings and do not fully meet the objective of minimizing the risk of injury to animals during this type of transport. A further error was also identified in the inspection of boats, which was not carried out properly, and which could give rise to potential risks for animals.

With this audit, the European Commission has taken into account the risks likely to be associated with the transport of animals by sea, and will therefore include these elements in the next revision of the animal welfare legislation.

Publication of a report by the European Union's Food and Veterinary Office (FVO) expressing reservations about the way in which the Netherlands controls animals and goods entering the Union

On 8th September 2023, the European Union's Food and Veterinary Office (FVO) published a report on official controls on animals and goods entering the EU. The report highlights the fact that controls in the Netherlands are not systematically carried out in accordance with current EU regulations. One of the most frequently identified shortcomings concerns the control of consignments of animal and non-animal goods in transit.

Three elements are at the center of these dysfunctions:

- Carrying out documentary controls
- Places where checks are carried out
- Frequency of identity and physical checks.

This lack of effective controls has led to non-compliance with minimum European requirements, and more generally to the certification of animals and goods passing through Dutch checkpoints being called into question with regard to European regulations.

Publication by the European Commission of a report on bovine identification

On 30th August 2023, the European Commission published a report on the technical and economic feasibility of introducing compulsory electronic identification of cattle throughout the EU. It should be noted that electronic animal identification systems were introduced into European regulations as early as 2003, under a regulation that was subsequently revised.

This report presents the benefits of electronic bovine identification :

- Faster, more accurate reading than conventional eartags
- Dynamic reading and direct data entry into databases
- Reduced potential errors due to inaccurate manual database entry
- Simplified notification of animal movements in the database.

At regulatory level, since 2021, the rules for bovine identification and declaration have been defined in the Animal Health Regulation. Currently, the use of electronic cattle identification is relatively low in Member States (representing less than 1% of operators), as they consider the current system to be sufficient.

Latest news on animal welfare at EU level

State of the Union speech addressed by the President of the European Commission: vagueness persists over progress on animal welfare legislation

On 13th September 2023, Ursula VON DER LEYEN gave her annual State of the Union speech to the European Parliament. This event is an opportunity for the President of the European Commission to take general stock of the past year, while also looking to the future by announcing forthcoming initiatives. This year's speech takes place in a special context, as not only it is her last term of office, it is also the last before the European elections next spring.

Animal welfare was not mentioned in her speech, causing strong reactions, particularly from MEPs in the Greens/EFA group. The Animal Welfare Intergroup sent a letter to Ursula VON DER LEYEN on 6th September 2023, stressing "*the need to revise the current legislation*", originally scheduled for autumn 2023.

This review should notably cover these topics :

- Animal transport (including improved travel conditions)
- Animal welfare in farms (for example elimination of cages for farm animals)
- Animal welfare during killing (with a ban on crushing male chicks)
- The introduction of European animal welfare labelling.

Then, at the end of September, the European Commission published its agenda for the next two months, and **the absence of animal welfare from the European Commission's forthcoming work is notable**. The only official announcement on this subject is the recent statement by European Commissioner Maros SEFCOVIC in charge of the Green Deal, who announced at his hearing on 3rd October that a revision proposal of the legislation on the protection of animals during transport will be presented in December.

Publication of a scientific report by the European Food Safety Authority (EFSA) on the protection of cats and dogs in breeding (for commercial purposes)

On 14th September 2023, the European Food Safety Authority (EFSA) published a new scientific report at the request of the European Commission, entitled "Scientific and technical assistance on welfare, housing and health aspects of cats and dogs in commercial breeding establishments". The report is intended to support the introduction of possible European regulations for the protection of cats and dogs in commercial breeding (for sport, hunting and pleasure).

In particular, the report discusses cosmetic surgery on dogs and cats, and concludes that such practices should not be carried out unless they are essential to the health of the animals. EFSA also provides information on pregnancy and mating practices for dogs and cats, which must be monitored and minimum periods observed between each pregnancy.

Finally, EFSA points out that **the protection of dogs and cats is still not the subject of detailed regulation at European Union level, and that progress is needed in several areas** that are at the center of this report. The absence of any reference to this subject in the State of the Union speech (dated 13th September 2023), either in the publication of the October/November programme (dated 26thSeptember 2023) questioned the issue of the revision of this legislation. However Commissioner Maros Sefcovic in charge of the Green Deal, announced during his audition on 3third October, that he will present a proposal in December to revise the rules on the transport of farm animals.

The European Commission meets the organizers of the "No Fur in Europe" European Citizens' Initiative

On 20th July 2023, the European Commission announced that it had met with the organizers of the "No Fur in Europe" European Citizens' Initiative (ECI). It was Vice-President Věra JOUROVA and Commissioner for Health and Food Safety Stella KYRIAKIDES who met with the organizers of this ECI.

As a reminder, an ECI is a way for European citizens to encourage the European Commission to work on a specific issue. For an ECI to be considered valid, at least one million signatures from seven different Member states are required.

The "No Fur in Europe" ECI recently collected over 1.5 million signatures, making it the 10th ECI to be validated. Once a sufficient number of signatures have been collected, it is customary for the European Commission to invite the ECI organizers to present their proposal in detail.

The European Citizens' Initiative calls on the European Commission not only to ban the farming and killing of animals for fur production, but also to prohibit the placing on the single European market of farmed animal fur and products containing farmed animal fur. A public hearing was hold at the European Economic and Social Committee on the 20th September 2023, but will be followed soon by another at the European Parliament. For its part, the European Commission has until 14th December 2023 to present its official response.

At the Agriculture and Fisheries Council meeting on 26th June 2023, **several ministers of agriculture from the Member states called for a ban on breeding animals for fur production**. Austria, Germany and the Netherlands, supported by Belgium, Cyprus, the Czech Republic, Estonia, Lithuania, Luxembourg and Slovakia, sent an information note on the subject to the other Member states ahead of the Council meeting.