EU NEWS

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UEVP

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

This month, several actions and studies have been launched and published concerning the fight against antibiotic resistance at European level, and more specifically the links between the use of antibiotics and antimicrobial resistance in humans and animals.

Our sector has made this a real priority, and we must continue our efforts in this direction.

In addition, with regard to animal health, the European Commission has provided clarifications and precisions concerning registrants of veterinary medicinal products and the safe and effective use of veterinary medicinal products administered orally.

Moreover, various measures have been taken to limit the spread of epidemics such as Avian influenza, African swine fever, bluetongue and epizootic hemorrhagic disease.

With regard to animal welfare, further key steps have been taken to secure a provisional EU-Chile Free Trade Agreement. The agreement includes commitments such as the recognition of animal sentience, the progressive elimination of antibiotics used as growth promoters and provisions for cooperation on animal welfare.

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 13th to 14th February 2024.

The Committee adopted positive opinions for a marketing authorisation application for **Alcort** (a treatment for inflammatory and pruritic demartoses in dogs) and **Lexylan** (a generic product for cattle, dogs and cats).

The committee adopted a positive opinion for a marketing authorization for **Divence penta**, a new vaccine for the active immunisation of cattle.

Also, the Committee adopted positive opinions for variations requiring assessment for **Strangvac, Credelio** and **AdTab.**

The Committee adopted by consensus positive opinions for variations requiring assessment concerning quality-related changes for: **Aivlosin, Bovela, Daxocox, Gumbohatch, Increxxa, Librela, Profender, Purevax RCP, Purevax RCP FeLV and Syvazul BTV**.

In addition, the Committee adopted positive opinions for variations requiring assessment to align the product information with version 9.0 of the QRD template for: **Draxxin, Incurin, Lydaxx, Ovugel, Suprelorin and Tulissin.**

The Committee classified an immunological product for horses as intended for a limited market and not eligible for authorisation in accordance with Regulation (EU) 2019/6.

The Committee adopted three scientific advice reports concerning one biological product and two immunological products for cattle, pigs, sheep and chickens, and squirrel monkeys (not yet published).

After a public consultation, the Committee adopted an annex to the guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water on compatibility studies between veterinary medicinal products and biocidal products.

Latest news on antimicrobial resistance

Publication of a joint report by EFSA concerning the use of antibiotics

On 21st February, the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) published a joint report on the use of antibiotics.

This study is the fourth joint inter-agency report on **the integrated analysis of antimicrobial consumption and the emergence of antimicrobial resistance**, analysing whether the trends are concomitant over the period 2014-2021.

Analyses were carried out to examine the links between the use of antibiotics and antimicrobial resistance in humans and food-producing animals. The report shows that the use of certain antibiotics was associated with an increase in antimicrobial resistance in both humans and animals. Furthermore, in some cases, antimicrobial resistance in human bacteria was correlated with resistance in bacteria from food-producing animals.

Thus, the report points to a 44% reduction in antimicrobial consumption in animals, while it has remained relatively stable in humans.

The report also highlights the reduction in antibiotic-resistant bacteria in countries that have reduced their consumption of antibiotics both in animals and humans. More specifically, the study underlines that E. coli bacteria, both in animals and humans, become less resistant to antibiotics as overall antibiotic consumption declines.

Overall, the report suggests that results could be improved through a reinforcement of the measures to combat antimicrobial resistance.

Publication of a consultation on a delegated regulation concerning the establishment of levels of antimicrobial active substances in non-target feed and methods of analysis of these substances by the European Commission

On 20th February, the European Commission opened a two-month scrutiny phase concerning a delegated regulation on **the establishment of specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed**.

This delegated act completes the regulation on the manufacture, placing on the market and use of medicated feed.

As a reminder, the scrutiny phase allows Member States and the European Parliament to monitor delegated acts proposed by the European Commission and to make observations or objections if they consider that they do not respect the principles or exceed the powers conferred on the European Commission.

Announcement by the European Commission of a new project on antimicrobial resistance

On 13th February 2024, the European Commission announced **the launch of a new project on antimicrobial resistance and associated infections**.

The **JAMARAI 2** (Joint Action Antimicrobial Resistance and Healthcare-Associated Infections 2) project, which is receiving 50 million euros in support as part of the EU4Health programme, aims in particular to reduce the risk of citizens being exposed to antibiotic-resistant bacteria.

To this end, the project will have to meet the following objectives:

- Strengthen coordination between Member States and countries of origin
- Improve the responsiveness of healthcare systems
- Guarantee access to essential medicines and medical devices
- Protecting citizens

In concrete terms, the project will be implemented through concrete actions and capacity building through various support programmes including pilot projects, mentoring and observation activities, on-site visits and training.

Latest news on animal health at EU level

Publication of a Communication on guidelines for applicants for veterinary medicinal products by the European Commission

On 14th February 2024, the European Commission shared a communication **specifying the guidelines on the rules for placing veterinary medicinal products on the market**.

This communication responds to the Regulation on veterinary medicinal products and aims to help stakeholders comply with their obligations under the said Regulation.

As a reminder, a communication is not legally binding; it is primarily a means for the European Commission to share its interpretation, guidance or analysis on issues related to specific European policies.

This communication covers the marketing of veterinary medicines, from the application for authorization to the approval, including their life cycle and even environmental protection.

- **Marketing authorization**: The European Commission lists all the different forms of marketing authorization that may exist. These include marketing authorization granted at national level, and marketing authorization granted under a centralized procedure (by the European Commission). The European Commission also points out that, barring exceptions, the same holder cannot use both the national and centralized procedures for the same veterinary medicinal product.

- **Application for marketing authorization**: The European Commission details general principles, such as electronic submission of applications, and the documents and information required. It also reviews the conditions of marketing authorizations. These authorizations can be modified at the request of the holder.

- **Authorization lifecycle**: The European Commission takes another look at the continuous updating required for marketing authorizations for veterinary medicinal products. This continuous updating is the responsibility of the authorization holder.

- Finally, the communication also includes information on **the protection of technical documentation, environmental protection and human health considerations**.

For further information, we invite you to consult the document via the following link: here.

Publication of a delegated act laying down rules for the effective and safe use of veterinary medicinal products for oral administration

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On 7th February 2024, the European Commission published a delegated act laying down rules for the **effective and safe use of veterinary medicinal products for oral administration**.

The aim of this delegated regulation is to define standards concerning adequate measures to ensure the effective and safe use of veterinary medicinal products prescribed for oral administration, excluding medicated feed. It specifically concerns the mixing of water with a veterinary medicinal product, or the manual mixing of a veterinary medicinal product with food, for food-producing animals.

The main aim of this act is to reduce the risks associated with the misuse of these medicines, which can lead to undesirable effects, the spread of antibiotic resistance, a deterioration in the quality of animal feed and environmental risks. It thus completes the regulation on veterinary medicinal products.

Note that article 3 of the delegated act sets out the obligations to be met by veterinarians when prescribing this type of medicinal product:

- Take into account the diagnosis and personal characteristics of the animal;
- Consider the characteristics of feed or water that may affect the assimilation or efficacy of the drug;
- Evaluate the expertise of the animal keeper.

In addition, veterinarians are responsible for informing owners of the risks associated with improper disposal of feed or water containing medicines, and for advising them on the best way to improve disposal.

Animal keepers are also subject to certain obligations (set out in Articles 7 and 8):

- Responsibility for the equipment used to prepare medicinal products;
- Provision of relevant information to the veterinarian;
- Implementing the necessary measures to avoid contamination of foodstuffs or to ensure disposal of medicinal products.

Publication of two implementing decisions concerning new outbreaks of avian influenza

On 9th and 23rd February, the European Commission published two implementing decisions concerning new outbreaks of avian influenza. The regions affected by new surveillance and protection zones are as follows:

- Bulgaria in the regions of **Plovdi, Dobrich** and **Veliko Tarnovo**
- Denmark in the municipality of **Aabenraa, Slagelse** and **Sorø**
- Germany in the states of **Hesse, Mecklenburg-Vorpommern** and **Schleswig-Holstein**
- Hungary in the county of **Győr-Moson-Sopron**
- Poland in the regions of **Greater Poland, Łódź, Lublin, Lubusz Voivodeships, Opole** and **Warmian-Masurian voivodeships**
- Slovakia in the **regions of Bratislava, Nitra** and **Trnava**
- Croatia in the county of **Brod-Posavina**
- Czeck republic in the regions of **Pardubice** and **Vysočina**
- Italy in the region of **Veneto**

Moreover, on 6th February, the implementing act releasing 46.7 million euros from the CAP crisis reserve was published in the Official Journal of the European Union. The purpose of this text is to support Italian poultry farmers who were seriously affected by influenza in 2022.

Debate on African swine fever, bluetongue and epizootic haemorrhagic disease in the European Parliament's Committee on Agriculture and Rural Development (AGRI)

On 13th February 2024, the European Parliament's Committee on Agriculture and Rural Development (AGRI) held a meeting at which the European Commission's Head of unit for Animal Health, Francisco REVIRIEGO-GORDEJO, presented an update on the European Commission's work on animal diseases.

His presentation focused on African swine fever, bluetongue disease and epizootic haemorrhagic disease. More specifically, he provided the following information:

- Regarding the **African swine fever**: He stressed that the European Commission's efforts were continuing, in the aim of developing a vaccine, with over €25 million invested in research to date. He also stressed the importance of cooperation between all political bodies at all levels to effectively combat this disease.

- Regarding the **epizootic haemorrhagic disease**: He reported a significant increase in the incidence of the disease between 2022 and 2023, with spread from Spain and Italy to France and Portugal. He pointed out that the disease would not be subject to the EU's eradication programme and that the European Commission did not have the appropriate legal basis to finance veterinary measures or a suitable vaccine to combat the disease effectively.

- Regarding the **bluetongue disease**: Although technologies and vaccines seem to be available, there are still gaps in the marketing of these vaccines.

Moreover, the European Commission published on 29th February an implementing decision concerning **outbreaks of swine fever in Europe**. This decision reports an improvement in the situation in Poland and Croatia. Indeed, the Wielkopolskie region in **Poland** will move from a restriction zone to a protection zone, and in **Croatia**, the Zadarska region will no longer be subject to restrictions.

Publication of a European Commission evaluation of the Regulation on additives for use in animal nutrition

On 28th February, the European Commission published an evaluation of the regulation on additives for use in animal nutrition. The evaluation was based on 5 criteria: **effectiveness, efficiency, coherence, relevance** and **added value**. According to the results of this evaluation, the regulation was considered to be effective overall, with objectives that are still relevant.

However, there is still room for improvement:

- The regulation could better integrate **the sustainability aspects of animal production**. Specific categories of additives promoting sustainability could be created, and there is a need to ensure a consistent environmental risk assessment for all types of livestock.

- It is stressed that the Regulation has had a positive impact **on antimicrobial resistance**. However, further efforts are needed to improve the clarity, consistency and overall effectiveness of the regulation.

- Additional measures could **reduce the administrative and regulatory burden**, in particular by simplifying the authorisation procedure and extending the period of validity of authorisations.
- There are still gaps in the application of the legislation, particularly regarding **the traceability of imports and exports to third countries**. Measures need to be taken to resolve these problems and improve the effectiveness of the Regulation as a whole.

- It is recommended that **innovation in feed additives be encouraged**, particularly with regard to their sustainability and their ability to improve animal welfare.

OTHER ISSUES

Latest news on international trade

Free trade agreement between the European Union and Chile

On 29th February, the plenary session of the European Parliament voted in favour of modernising the trade agreement between the European Union and Chile.

The Advanced Framework Agreements and the provisional Free Trade Agreement will provide better access to the Chilean market and an increase in import quotas for Chilean products, particularly meat.

Regarding animal welfare, the agreement includes commitments such as the recognition of animal sentience, the progressive elimination of antibiotics used as growth promoters and provisions relating to cooperation on animal welfare.

While these provisions have been generally welcomed, some stakeholders such as Eurogroup For Animals have raised a number of concerns:

- The dynamic of intensification of the livestock sectors in Chile is likely to be fuelled by this agreement, which encourages increased market access for animal products, without any mention of animal welfare.

- The chapter on food sustainability does not include sufficiently concrete provisions on animal welfare.

- The absence of the new EU approach to Trade and Sustainable Development (TSD)

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