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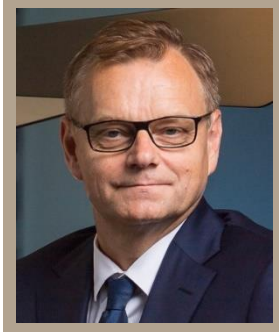
UEVP

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



As you know, the fight against antimicrobial resistance is a priority at European level. In a recent surveillance report on the consumption of veterinary antimicrobials, the figures obtained are encouraging. They underline the commitment of the entire animal health sector to the responsible use of antimicrobials in the European Union.

Furthermore, the European situation regarding transmissible spongiform encephalopathies remains similar to previous years, according to another European Commission report on the subject. The African swine fever epidemic in Europe, on the other hand, is not decreasing, and new outbreaks have been recorded in Europe. Our profession must therefore persevere in the fight against the spread of diseases and continue its mobilisation.

In order to better address these challenges, the European Commission has published several draft secondary legislation this month (pending adoption) aiming at specifying the conditions for the implementation of vaccinations (including preventive) for certain categories of diseases, the requirements for pre-clinical studies for veterinary medicinal products, as well as on the maritime transport of animals.

Piotr KWIECIŃSKI, UEVP President

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PRIORITY ISSUES

Latest EU institutional news

Latest developments on the CAP reform

Since the end of the summer break, the European Commission has approved the majority of Member States' National Strategic Plans (NSPs). Most recently, the European Commission approved the NSPs of Hungary (adopted on 7th November), Latvia and Estonia (adopted on 11th November), as well as those of Germany, Greece and Lithuania (adopted on 21st November), the Czech Republic and Slovakia (adopted on 24th November) and finally Malta (adopted on 30th November). The European Commission still has to validate 6 NSPs, before the new CAP enters into force on 1st January 2023.

In addition, the European Commission has published a draft delegated act which aims **to frame the amendment procedures and deadlines for Member States to request amendments to their national strategic plan (NSP)**. The text, which is also due to enter into force at the same time as the new CAP on 1st January 2023, aims to clarify the conditions set out in the Regulation on strategic plans. According to the draft delegated act, the European Commission will have **three months** to approve the new version of an NSP. Note also that Member States will only be able **to submit one request for modification per year,** except for requests constrained by "*catastrophic events or adverse climatic events*" which will not be counted in the maximum number of requests.

Finally, the first reflections on the next reform of the CAP post-2027 are beginning to emerge. At European Commission level, the EU Commissioner for Agriculture, Janusz WOJCIECHOWSKI, has called for the future CAP budget to be strengthened in order to ensure food security. At European Parliament level, the MEPs in charge of the previous negotiations (2013 and 2021 reform) recommended strengthening the role of the European Parliament in the upcoming negotiations, by developing more technical expertise, by taking part in the debates upstream via own-initiative reports, and by improving the relationship between the committees on Agriculture and Rural Development (AGRI) and Environment, Public Health and Food Safety (ENVI). To underline this, a study on the "*post-2020 CAP reform process*", mandated by the AGRI committee to the Directorate for Structural and Cohesion Policies, was presented to MEPs on 28th November. Its objective is to assess the "*decision-making dynamics*" of the CAP negotiations and to put forward several proposals to support the strengthening of the Parliament's political influence on the dossier.

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 8 to 10 November 2022.

The Committee adopted a positive opinion for a marketing authorisation application for **Neoleish,** a new vaccines foe the active immunisation of Leishmania-negative dogs from 6 months of age to reduce the risk to develop an active infection and/or clinical disease after contact with Leishmania infantum.

The Committee adopted several positive opinions for variations requiring assessment to align the product information application with the latest version (9.0) of the QRD template, which are **Rabitec** (grouped procedure)**, Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R**, **ProteqFlu** and **ProteqFlu-Te**, **Apoquel**, **Aservo EquiHaler** (grouped procedure) as well as **Semintra** (grouped procedure).

The Committee adopted serveral positive opinions for variation requiring assessment concerning quality-related changes for **Lydaxx** (2 procedures), **Simparica Trio** (2 procedures)**, Rhiniseng, Porcilis PCV M Hyo** (subject to worksharing procedure), **Simparica Trio**, **Librela**, **Onsior** and **Convenia**.

As regarding maximum residue limits, the Committee agreed to include **castor oil, hydrogenated** as a new entry in the list of substances considered as not falling within the scope of Regulation 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin. In parallel, the committee adopted an updated 'out of scope' list.

The Committee adopted a scientific advice report further to a request for initial advice for a pharmaceutical product for cats.

Following two requests for limited market classification and eligibility, the Committee classified:

- an immunological product for horses as intended for limited market and eligible for authorisation
- an Antineoplastic and immunomodulating agents product for dogs as intended for a limited market and eligible for authorisation.

As regarding pharmacovigilance, the Committee adopted recommendations for changes to the summary of product characteristics for **Solensia, Equilis Prequenza Te, Equilis Prequenza, Equilis Te,** and **Nobivac DP Plus** as the outcome of signal detection activities. In addition, the Committee agreed a revision of the incident management plan for medicines for veterinary use which was updated to reflect European Medicines Agency (EMA) organisational changes and legal references from Regulation 2019/6 on veterinary medicinal products.

Finally, the Committee adopted the mandate, objectives and rules of procedure for the European Sales and Use of Veterinary Antimicrobials Working Group (ESUVA WG) a new working group proposed to replace the voluntary European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) network. Note that the name of the Working Group has yet to be confirmed.

Latest news on antimicrobial resistance at EU level

Publication of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report by the European Medicines Agency

On 18 November, the European Medicines Agency published its 12th report on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC).

This latest report indicates that sales of antimicrobials for production animals in Europe have fallen significantly since 2011, underlining the overall animal health sector's commitment to sustainable agriculture and responsible use of antimicrobials in the EU. Indeed, for the 25 countries providing continuous sales data between 2011 and 2021, sales decreased by 47% over this period.

Sales have particularly fallen for Category B antimicrobials, which were established by the Ad Hoc Expert Group on Antimicrobial Guidance and also classified by the World Health Organization as critically important in human medicine **requiring limited/restricted use in animals**. This includes quinolones (of which Fluroquinolones have decreased by 14% since 2011, and other quinolones by 83%), third and fourth generation cephalosporins (which have declined by 38% since 2011) and polymyxins (also fallen by 83% since 2011).

As a reminder, the Farm to Fork stategy aims **to reduce the total sales of antimicrobials for farm animals and aquaculture by 50% by 2030 compared to 2018 baseline**. In 2021, Member States have already achieved about 1/3 of this overall reduction target.

Note that the Federation of Veterinarians of Europe (FVE) welcomed the report and its results and called for continued implementation of "*coordinated actions towards the prudent and judicious use of antibiotics, which are needed in both animals and humans*".

Finally, under the new Regulation on veterinary medicinal products, one of the actions will be **to extend surveillance to the use of data**. For example, reporting on antimicrobial use by species will start from 2024 and will contribute to a better understanding of the need for antibiotic use by animal species. Reports on pigs, poultry

and veal calves are expected by 2024, on animals intended for consumption by 2027 and on the rest of the animals by 2030.

Publication of a discussion paper on antimicrobial resistance by the European Parliament Think Tank

On 16 November, the European Parliament Think Tank published a paper on antimicrobial resistance entitled "*What if a 'Trojan horse' strategy could help address antimicrobial resistance?*".

This discussion paper aims to assess the consequences of antimicrobial resistance, to put the potential impacts and developments in perspective, and to consider the anticipatory European public policies that could be put in place, particularly in the field of research and development and the revision of European health legislation.

Latest news on animal health

Publication of the report on the presence of transmissible spongiform encephalopathies in 2021 by the European Food Safety Authority (EFSA)

On 30 November, European Food Safety Authority (EFSA) published a report on **the results of the surveillance of Transmissible Spongiform Encephalopathies (TSEs) in cattle, sheep and goats in 2021.** Data were submitted by the 27 Member States and 8 third countries. Note that Turkey submitted data for the first time this year.

The report concludes that the Bovine Spongiform Encephalopathy (BSE) situation in Europe remains similar to previous years. Only six atypical BSE cases were confirmed in the EU in 2021, from France, Germany and Spain. For sheep, the analysis of data since 2011 has confirmed the significant decrease in the occurrence of encephalopathies over the last decade.

Publication of a draft delegated act by the European Commission on the conditions for carrying out vaccinations (including preventive vaccinations) for the prevention and control of transmissible animal diseases (category A)

On 28 November, the European Commission published a draft delegated act (and its annex) supplementing the rules on the use of certain veterinary medicinal products for the prevention and control of certain listed diseases of Regulation 2016/429 on transmissible animal diseases.

The objective of this delegated act is to lay down, for each category A **disease, specific conditions for the implementation of vaccination** as regards the type of vaccines used, the extent of the vaccination areas, the targeted animal populations, disease surveillance, restrictions on the movement of animals and their products and recovery periods.

Note that in order to prevent the spread of a category A disease and the need to apply drastic disease control measures, Member States may decide to use **preventive vaccination** against a category A disease. However, if necessary, **accompanying provisions** to mitigate the risks in the movement of vaccinated animals and their products are mentioned in the text. Finally, after the end of the vaccination phase, **an exit strategy** is presented to allow Member States to demonstrate the absence of infection and to recover the health status they had before the outbreaks of the Category A disease concerned and the use of vaccination. This exit strategy includes specific enhanced clinical and laboratory surveillance during the pre-defined recovery period for each Category A disease.

Category A disease is considered to be "*a listed disease which is not normally present in the European Union, and for which immediate eradication measures must be taken as soon as it is detected*", says the European Commission. Whereas **category B** implies that "*all Member States must fight to eradicate it throughout the Union*".

If no objections are registered until 28 January by the co-legislators, this delegated regulation will enter into force on the 20th day following its publication in the Official Journal of the European Union, and will be directly applicable in all member states.

Further outbreaks of African swine fever in Lithuania and Germany and update of special control measures

The European Commission has updated, by an implementing act, the special control measures for African swine fever applicable for a limited period of time by the Member States which are mentioned in the restricted zones and listed in the Annex to the Regulation 2016/429 on transmissible animal diseases.

Following the recent outbreaks of African swine fever in pigs kept in Lithuania and outbreaks in wild porcine in Germany, and taking into account the current epidemiological situation in the European Union, the regionalisation in these Member States has been reviewed. It was concluded that the district (apskritis) of Šiauliai in Lithuania and the Land Brandenburg in Germany are now included in the list of new restricted and demarcated areas.

Note that the measures provided for in the implementing act are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

Publication of a draft delegated act by the European Commission amending the requirements of good laboratory practice for veterinary medicinal products as regards pre-clinical studies

On 23 November, the European Commission published its draft delegated act amending the requirements for compliance with good laboratory practice for veterinary medicinal products set out in Annex II of Regulation 2019/6.

According to the European Commission, certain references to the requirements for **pre-clinical studies** set out in Annex II of Regulation (EU) 2019/6 need to be adapted to take account **that compliance with good laboratory practice is not required for efficacy studies, but only for safety studies.**

Note that this provision is in conformity with the opinion issued by the European Medicines Agency.

If no objections are registered until 23 January by the co-legislators, this delegated regulation will enter into force on the 20th day following its publication in the Official Journal of the European Union. This provision will be retroactive and will be considered to have entered into force on 28 January 2022.

Submission for consultation of two secondary legislation texts by the European Commission concerning the maritime transport of animals

The European Commission has submitted for consultation, until 6 December, two secondary legislation texts aiming at strengthening the legislation on the transport of animals by sea:

- The draft implementing act details the practical arrangements for the registration of animals during transport by sea. It establishes a common electronic database that can be consulted by all Member States in order to facilitate control by national authorities. The database should contain the expiry date of the certificates of the animals transported, information on the maximum area available for the animals and the type of animals that the vessels may transport.
- The draft delegated act aims at improving the control of vessels transporting animals. In particular, the competent authorities of the place of departure will have to ensure that the transporter has an emergency plan that meets the requirements of the European Commission.

Initially planned for the 3rd quarter of 2022, their adoption should take place un the coming weeks. They will therefore come before the European Commission's review of animal welfare legislation, expected in 2023. This is a follow-up to the commitment of the European Commissioner for Health and Food Safety, Stella KYRIAKIDES, who promised to strengthen the rules on maritime transport as early as 2022, after two ships loaded with cattle went astray in the Mediterranean Sea.

OTHER ISSUES

Latest news on animal welfare

State of Play of the Review of Animal Welfare Legislation

At a conference on 9 November, a representative of the Directorate-General for Health and Food Safety (DG SANTE) gave an update on the state of play of the revision of the animal welfare legislation, which is expected to be adopted in the 3rd quarter of 2023.

Indeed, the evaluation revealed shortcomings in the current legislation: the legislation lacks tools and indicators to measure animal welfare, the provisions are imprecise and the language used remains vague - posing problems of implementation by the Member States - and the potential of new technologies is not sufficiently exploited.

The European Commission has reiterated its intention to propose four regulations, concerning:

- Breeding conditions
- Transport conditions
- Conditions for killing animals
- Animal welfare labelling.

The presence of veterinarians on board ships, better supervision of the transport of vulnerable animals, a ban on cages and individual confinement, restrictions on mutilations (including dehorning), changes to the regulations on imported products, and video surveillance in slaughterhouses are all options already mentioned.

Note that the evaluation of animal welfare legislation is on the agenda of the next Agriculture Council, bringing together the ministers of the Member States, on 11 and 12 December. Ahead of the meeting, the Czech Presidency sent delegations an internal note summarising the conclusions of the assessment carried out by the European Commission and calling for the introduction of "*progressive provisions to avoid jeopardising the economic viability of farmers".* The Czech Presidency will also ask the Member States to give their opinion on this point.

Publication of the European Parliament resolution on improving EU rules on wild and exotic animals that can be kept as pets in the Union via a European positive list

On 24 November, the European Parliament presented its resolution to create an EU 'positive list' to "*regulate the trade in wild and exotic animals and restrict their keeping as pets*".

The aim of the list is to clarify which species, based on science-based criteria, are suitable for keeping as pets. According to MEPs, a positive list is more feasible than a restrictive (so-called negative list), which would prohibit the keeping of species.

This proposal is not legally binding and is intended to give the European Parliament's position on the subject. As a reminder, at Council level, several EU Agriculture Ministers also called for the establishment of such a positive list of animals that can be kept at private homes last May.

Publication of the revised action plan against wildlife trafficking by the European Commission

On 9 November, the European Commission published a new version of its action plan against wildlife trafficking.

The new roadmap, which runs until 2027, is built around four main axes:

- Preventing wildlife trafficking and tackling its root causes
- Strengthening the legal and policy framework to combat wildlife trafficking
- Enforce regulations and policies to effectively combat wildlife trafficking
- Strengthen the global partnership between source, destination and transit countries in combating wildlife trafficking.

The Communication, while not legally binding, proposes a series of actions such as addressing **the risks of the spread of zoonotic diseases linked to illegal wildlife trade.** The Communication was welcomed by European animal welfare organisations, including Eurogroup for Animals, which however called for the action plan to be complemented by additional measures.

Publication of the first survey on pet welfare in the context of the war in Ukraine

The animal welfare organisation Four Paws, together with 18 other local Ukrainian organisations, conducted a survey **on the welfare of pets during the war in Ukraine**, with the aim of helping to mobilise support for shelters and volunteers in the country.

The survey revealed problems of abandoned pets, unsterilised animals living on the streets, and lack of food for pets, strays and shelter animals. The new data also reveals that more than 150,000 cats and dogs are in need of humanitarian assistance in Ukraine.

The organisations helped to establish the *Ukrainian Pet Association Worldwide* (UPAW), which aims to provide humanitarian aid to animals in the region. Despite logistical difficulties in the country, UPAW has managed to distribute 944 tonnes of humanitarian cargo to animals, including food for dogs and cats living in shelters or on the streets, as well as the distribution of medicines and veterinary equipment.

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