EU NEWS

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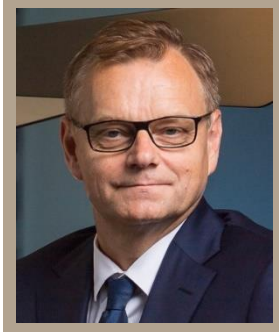
UEVP

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



In mid-February, a further step towards the finalisation of the delegated act aiming at establishing control measures for antibiotics used as growth promoters for animals or animal co-products imported to the European Union was accomplished with the publication of the European Medicines Agency (EMA) opinion on the designation of antimicrobials for the treatment of certain infections in humans.

In parallel, following the implementation of the veterinary medicines regulation at the end of January, transitional measures have been applied to ensure the continuity of supply of veterinary medicines, which may have a direct impact on the practice of our profession.

Additionally, we welcome the decision of the European Parliament to adopt its report on animal welfare on farms, continuing to make it a priority.

Last but not least, in these difficult times UEVP would like to express our full support and readiness to help our colleagues in Ukraine. Our thoughts now are with Ukrainian veterinarians and their families. Anyone who wishes to provide practical aid is welcome to visit: http://vetsforukraine.com

Piotr KWIECIŃSKI, UEVP President

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PRIORITY ISSUES

Latest EU institutional news

Latest developments on the CAP reform

In parallel to the adoption of a series of secondary legislative acts (delegated and implementing acts) which have to be adopted in order to allow the implementation of the CAP reform regulations before the entry into force on 1st January 2023, **Member States are required to submit to the European Commission their respective National Strategic Plans (NSPs).**

Although the initial deadline was 1st January 2022, many countries have encountered significant delays. The last latecomers (Germany, Romania and Bulgaria) have now regularised their situations. To date, only Belgium has yet to submit its NSP.

Subsequently, **the European Commission has to send its comments** to each member state. According to the European Commission, some two dozen comment letters prepared by the Directorate General for Agriculture and Rural Development (DG AGRI) are now being examined by the other Directorates General. These documents consist of a political introduction to summarise the Commission's assessment and a series of technical remarks. Once the inter-service consultation is complete, the comment letters will then be submitted to the cabinets of the European Commissioners. After validation, they will be published and **will open a period of negotiations between the European Commission and the designated Member States, which will then return a revised version of their NSP.**

The **letters to latecomers will be published no longer than three months after the date of submission of their NSPs**, as required by the Strategic Plan Regulation.

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 15th to 16th February 2022.

The Committee adopted the scientific advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

The Committee adopted two positive opinions for a marketing authorisation application for **Chanaxin**, a new generic product for the treatment of bovine infectious and respiratory disease, as well as for **RenuTend,** a new product to improve healing of injuries of tendons and suspensory ligaments in horses.

The Committee adopted four positive opinions for a type II variation application concerning quality-related changes for: **Forceris** (grouped), **Strangvac**, **Tulissin,** and **Veraflox** (grouped).

The Committee also adopted several positive opinions for type IB variation applications for **Purevax RCPCh FeLV, Purevax RCP FeLV, Purevax RCP, Purevax RC and Purevax RCPCh** (Feline calicivirosis vaccine - inactivated, feline viral) as well as **Metacam and Novem (Meloxicam)** concerning quality-related changes.

The Committee started a procedure for **veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection**. The matter was referred to the Committee by Germany under Article 82 of Regulation 2019/6 due to concerns that the authorised duration of treatment for

some of the concerned products might not be sufficiently long to ensure effective use of these medicines, which could also contribute to the development of antimicrobial resistance. In this context, the CVMP invites all stakeholders to submit data relevant to this procedure.

The Committee agreed to include **benzoic acid, zinc salt**, **neodecanoic acid, calcium**, and **tripropylene glycol** as new entries in the list of substances with regard to residues of veterinary medicinal products in foodstuffs of animal origin, under the heading of excipients.

The Committee adopted four scientific advice reports and endorsed one clarification of a scientific advice concerning pharmaceutical, biological and immunological products. The target species were dogs (three products), ducks (one product) and cats (one product).

Following four requests for classification, the CVMP classified a immunological product for horses and a immunological product for chickens as intended for a limited market but not eligible for authorisation concerning Article 23 (applications for limited market) under Regulation 2019/6, as well as immunological product for turkeys as intended for a limited market and eligible for authorisation concerning Article 23 under Regulation 2019/6.

Regarding pharmacovigilance, the Committee reviewed the Periodic Safety Update Reports (PSURs) for **Arti-Cell Forte, Comfortis, Daxocox, ProteqFlu, ProteqFlu-Te**, and **Simparica Trio** and concluded that no further action was required. The Committee adopted recommendations for changes to the summary of product characteristics for **Neptra** and **Nobivac Myxo-RHD Plus** as outcome of signal detection activities.

Latest news on animal health

EMA has published its opinion on the designation of antimicrobials for the treatment of certain infections in humans

On 16 February, the European Medicines Agency (EMA) published its opinion on **the designation of antimicrobials or groups of antimicrobials reserved for the treatment of certain infections in humans**, in accordance with the requirements of Regulation 2019/6 on veterinary medicines.

This publication, which is highly expected, is a necessary step in the finalisation of the **delegated act aimed at establishing control measures on antibiotics for growth promoters** (as indicated in Article 118 of the Regulation which concerns animals or products of animal origin imported into the Union), and presented by the French Presidency of the Council (PFUE) as the first potential mirror clause in trade exchanges. This list was then submitted to and adopted by the Member States' experts in the Committee for Veterinary Medicinal Products (CVMP).

It should be noted that the French government has decided to anticipate European legislation on control measures for antibiotics for growth promoters by adopting a ministerial decree.

This scientific assessment was welcomed by the Federation of Veterinarians of Europe (FVE), which considers that this opinion "*fully implements the One Health approach*" and "*confirms that the EU remains strongly anchored to an evidence-based to ensure the health and welfare of humans and animals in Europe*" by ensuring "*the availability of all important substances for veterinary medicine, including 3rd and 4th generation **cephalosporins**, **polymyxins** and **colistin, macrolides** and **fluoroquinolones***".

Setting up transitional rules for the packaging and labelling of veterinary medicines

On 2nd March, the European Commission published a proposal for a regulation to establish **transitional rules for the packaging and labelling of authorised veterinary medicinal products** in accordance with Directive 2001/82/EC (on veterinary medicinal products) and Regulation 726/2004 (establishing Community procedures for the authorisation and supervision of medicinal products for human and veterinary use).

The objective of this proposal is to address the concerns expressed by Member States' competent authorities and stakeholders regarding the practical application of Regulation 2019/6 (on veterinary medicinal products) which enters into force on 28 January 2022, and the need to ensure the continuity of supply of veterinary medicinal products authorised under the previous legislation on the EU market.

Indeed, according to the European Commission, it is necessary to take urgent steps to address the interpretation problems raised, to remove any legal uncertainty and to avoid possible disruptions in the supply of veterinary medicines.

The proposal therefore provides for transitional rules until 29 January 2027 allowing marketing authorisation holders to market veterinary medicinal products that comply with the packaging and labelling requirements, even if these products do not comply with the requirements of Regulation 2019/6.

Adoption and enforcement of two EU implementing regulations on animal health

In February, two implementing regulations were officially published in the Official Journal of the European Union in the field of animal health. These include :

- Regulation 2022/160 - published on 4 February - aimed at establishing **uniform minimum frequencies in the performance of certain official controls, in order to ensure compliance with the Union's animal health requirements**. This provision establishes the frequencies of inspections (relating to identification and registration) for germinal products as well as for bovine, ovine and caprine animals.
- Regulation 2022/209 - dated 16 February - setting out **the format of the data to be collected and reported to determine the volume of sales and use of antimicrobial medicines in animals**. The data communicated by the Member States to the European Medicines Agency (EMA) must now take into account the species and categories of animals and the stages of their production.

Avian Influenza outbreak: European Commission rejects request by 12 Member States to support free-range poultry farming

At the Agriculture Council on 21 February, the European Commission indicated that it would **not accept a relaxation of the current rules on the marketing of free-range eggs during this current avian influenza situation**, despite a request from the Netherlands, supported by several countries.

Indeed, a joint note dated 16 February, initiated by the Dutch delegation and co-signed by 11 other Member States (Austria, Bulgaria, Cyprus, Denmark, Estonia, Ireland, Italy, Luxembourg, Malta, Portugal and Romania) aimed to underline the concerns of these states regarding the negative impact of the avian influenza epidemic on the sector. The Member states said that "*eggs from free-range poultry farms may no longer be commercialised*" as such if the poultry are kept for more than 16 weeks. Pointing to the risk of "*huge financial consequences*" for the sector, they had **asked the European Commission to provide an exemption to the 16-weeks rule** "*until a risk analysis shows that sheltering can be lifted*".

In response, EU Commissioner for Agriculture Janusz WOJCIECHOWSKI said that the European Commission was examining the issue as part of the ongoing review of marketing standards, but for the time being "*it is not possible to lift the legal requirements*". However, the European Commissioner also added at the press conference that the European Commission was not excluding short-term measures.

Reduction of veterinary drug residues in animals and food of animal origin in the European Union

According to the latest data collected by the European Food Safety Authority (EFSA), residues of veterinary medicines and other substances in animals and food of animal origin **continue to decrease in the European Union.**

According to EFSA, the percentage of samples in 2020 that contained maximum residue levels above the legally permitted limits is **the lowest figure observed in the last 11 years**. This is 0.19% compared to non-compliance rates that ranged from 0.25% to 0.37% during the mentioned period.

However, compared to the figures for the previous three years (2017 to 2019), the 2020 compliance rates have increased for **antithyroid agents, steroids** and **resorcylic acid lactones**. Increases were also seen for **anthelmintics, organochlorine compounds, organophosphorus compounds, dyes** and some substances classified as "***other substances***".

Member States approve new innovative feed additive for dairy cows

At the meeting of the EU Standing Committee on Plants, Animals, Food and Feed (Scopaff) on 23 February, Member State representatives approved a proposal from the European Commission for **an "innovative" feed additive for dairy cows**.

This additive is composed of 3NP (3-nitrooxypropanol) - an inhibitor of the enzyme methyl coenzyme M reductase (MCR) - which catalyses the last stage of methanogenesis, and which could then reduce methane emissions by 20 to 35%.

This proposal was based on a scientific opinion of the European Food Safety Authority (EFSA) published on 19 November 2021 establishing the efficacy of this additive.

The decision of the European Commission formalising this marketing authorisation, through the adoption of an implementing act, is expected in the coming months.

Reciprocity of European standards: European Commission invites stakeholders to respond to its public consultation

In mid-February, the European Commission opened a public consultation on its report regarding the **application of EU health and environmental standards to imported agricultural and food products.**

This study (not legally binding) is co-led by the Directorates-General for Health and Food Safety (DG SANTE), Agriculture and Rural Development (DG AGRI), Trade (DG TRADE) and Environment (DG ENVI). The European Commission plans to publish this report in the **2nd quarter of 2022**.

The objective of this report is to **identify initiatives that could make the application of EU health and environmental standards to imported agricultural and food product,** in line with World Trade Organisation (WTO) rules. Several policies are expected to be covered by the report, including **animal welfare standards and production processes and methods** (such as the ban on the use of antibiotics for human use only).

It should be noted that the forthcoming report will not contain any new policy initiative or commitment, but according to the European Commission, it will serve as a basis for future agricultural and food trade policy in terms of safety and sustainability standards, in the context of the European Green Deal, the Farm to Fork strategy and the Trade Policy Review.

OTHER ISSUES

Latest news on animal welfare

The European Parliament has adopted its report on animal welfare on farms

On 16 February, the European Parliament voted and adopted its **report on animal welfare on farms** with a large majority - 496 in favour, 140 against and 51 abstentions.

Based on the resolution, for which Jérémy DECERLE (RE, France) was designated rapporteur, the final text stresses **the need to harmonise the implementation of animal welfare legislation in the European Union**. MEPs believe that the current legislation is not applied consistently, is not in line with scientific progress and does not cover all species. The report therefore calls for its rules to be updated - based on scientific data -, for impact assessments to be carried out, for a species-by-species approach to be developed and for its implementation to be standardised

With regard to **European animal welfare labelling**, the European Parliament supported a "*harmonised and binding EU framework with common requirements for voluntary animal welfare labelling*".

The European Parliament also asked the European Commission to negotiate, at multilateral level and in the framework of bilateral agreements, "***reciprocity clauses** on compliance with animal welfare rules for imported products*".

Only one amendment tabled by the Greens/EFA group was approved in plenary, **against the use of Common Agricultural Policy (CAP) funds for bull-fighting.** The other amendments were rejected, notably the one on the ban on the crushing of male chicks and the one calling for a ban on the fattening of geese and ducks for the production of foie gras.

In reaction, MEP Francisco GUERREIRO (Greens/EFA, Portugal) - shadow rapporteur on this file - denounced a "*missed opportunity*" and regretted that the text focuses on "farmers, the competitiveness of the sector and the economic consequences" of animal welfare standards. Conversely, this vote was welcomed by Copa-Cogeca.

EFSA launches its public consultation to establish a common methodology for upcoming animal welfare studies

In the context of the review of animal welfare legislation, the European Commission has mandated the European Food Safety Authority (EFSA) to conduct a series of animal welfare studies on calves, laying hens, broilers, pigs, ducks, geese and quail, and dairy cows.

If their publications are expected **between June 2022 and March 2023**, EFSA launched a public consultation in mid-February to **establish guidelines and a common methodology for the studies to be undertaken**. In this regard, EFSA proposed to compare the conditions of breeding and transport in relation to an "*optimal*" state to establish quantitative indicators of animal welfare. The consultation will close on **28th March**.

European Council to discuss possible EU legislation on the trade and sale of dogs

At the last Agriculture Council on 21st February, Danish Agriculture Minister Rasmus PREHN officially supported **EU legislation on the trade and sale of dogs**.

This position was also supported by the German delegation, which also highlighted concerns about the welfare of dogs in trade with third countries, confirming the necessity of "*a European solution*". Lithuania, Sweden, Belgium, Bulgaria and the Czech Republic expressed their agreement with the Danish request.

In response, the European Commissioner for Health and Food Safety, Stella KYRIAKIDES, pointed out the existing rules on the registration of dogs for animal health purposes and announced that the European Commission will check "*whether there is a need for action at EU level in the context of the revision of animal welfare legislation*".

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