EU NEWS

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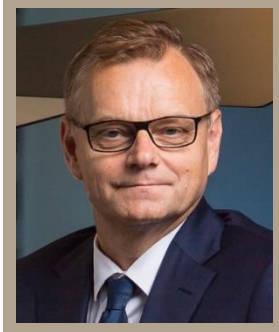
UEVP

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



In mid-July, the European Commission finally adopted the list of antimicrobials or groups of antimicrobials reserved for the treatment of certain infections in humans.

In practice, this list, which will come into force in February 2023, represents an important step for our profession, as the products on this list will consequently be banned for use in animals and withdrawn from European marketing authorisations.

In parallel, in order to act as quickly as possible to reduce the spread of epidemics (such as avian influenza and African swine fever), the European Commission has extended its "Stop African Swine Fever" outreach campaign and continues to work on draft legislation to allow Member States to use animal vaccination in the case of major epidemics.

Finally, Member States have recently mobilised to obtain new measures in favour of animal welfare during transport, which remains a key issue at European level. Regarding scientific testing on animals, several publications and statistical reports have recently been published, aiming to identify weaknesses in this area, and thus better ensure the protection of animal welfare.

Piotr KWIECIŃSKI, UEVP President

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PRIORITY ISSUES

Latest EU institutional news

Latest developments on the CAP reform

Following the reform of the Common Agricultural Policy (CAP), which comes into force on 1st January 2023, the EU Member States are finalising their national strategic plans (NSP).

On 18 July, the European Commission indicated that it had finalised discussions with five countries on the drafting of NSP. These five countries are: Portugal, Poland, Spain, Denmark and France.

The approval procedure has therefore been launched by the European Commission. The process takes about six weeks. The first adoption decisions are expected to be taken in early September.

The European Commission estimates that up to 10 Member States could submit a new version of their NSP before the end of the summer break. As a reminder, the adoption of all NSP must be done by the end of 2022 at the latest, in order to ensure the effective application of the CAP on 1st January 2023.

Furthermore, on 8th July, the European Commission published its delegated act and its related implementing act on the assessment of National Strategy Plans (NSPs). These texts specify the principles and information to be transmitted each year to the European Commission in order to monitor the implementation of the NSPs in the Member States. The Member States have all the secondary legislation necessary to apply the new CAP.

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 12 to 14 July 2022.

The Committee adopted a positive opinion for a marketing authorisation application for **Lotilaner Elanco**, a new antiparasitic product intended for use in dogs and cats.

The Committee adopted two positive opinions for variation requiring assessment for **Purevax RCPCh** and **Purevax RCPCh FeLV** to align the product information with the latest version (9.0) of the QRD template.

The Committee adopted three positive opinions for variations requiring assessment concerning quality-related changes for **Letifend, Nexgard** and **Prevomax**, as well as a positive opinions for a type II variation concerning quality-related changes for **ProZinc**.

The Committee adopted an opinion concluding that the marketing authorisations for veterinary medicinal products containing **toltrazuril** for oral administration to chickens should be varied to update the product information accordingly. Indeed, this matter was referred to the Committee by the Netherlands, in accordance with Directive 2001/82/EC, due to concerns relating the appropriateness of the restriction periods between the administration and the start of the laying period. The Committee agreed that the restriction period before the onset of lay should be amended to ensure consumer safety and concluded the referral procedure.

Following four request for limited market classification and eligibility, the Committee classified :

- an immunological product for sea bass as intended for limited market but not eligible for authorisation
- an immunological product for cattle, sheep and goats as intended for limited market and eligible for authorisation

- the decision on the requests for an immunological product for turkeys and an alimentary tract and metabolism for dogs were postponed to the September 2022 meeting.

During this meeting, the Committee reelected its Vice-Chair of the scientific advice working party, Mrs Sylvie LOUET, for a further 3-year mandate. The Committee also appointed Dr Carina BERGMAN for a 3-year mandate, as a fifth CVMP co-opted member with the relevant scientific competence in toxicology and residues.

Latest news on antibiotics at EU Level

Adoption of the implementing act of the European Commission concerning antimicrobials or groups of antimicrobials reserved for the treatment of certain infections in humans

In the framework of the control of antibiotic resistance, the European Commission adopted on 19 July its implementing act listing **the antimicrobials or groups of antimicrobials reserved for the treatment of certain infections in humans.**

As a reminder, this adoption follows the rejection of the objection in the plenary session of the European Parliament, which took place on 23rd June, allowing the initial proposal of the European Commission to be maintained. This decision was taken in accordance with Regulation 2019/6, which aims to contribute to the European 'One Health' Action Plan against antimicrobial resistance (AMR) and the Farm to Fork strategy of the European Commission.

In practice, it will now be prohibited to deliver European marketing authorisations (MAs) in veterinary medicine for products on this list, banned for use in animals "*under any circumstances, including as part of the therapeutic cascade in the absence of authorised medicines*", as well as in animal feed. It will also be strictly forbidden to import into European Union animals or their products that have received antimicrobials included in this list.

Note that this regulation will come into force **on 9 February 2023**, six months after the adoption of the implementing regulation and its publication in the *Official Journal of the European Union*.

Latest news on animal health

Five European countries present their recommendations for updating animal transport legislation

During the Agriculture Council on 18 July, Germany, Belgium, the Netherlands, Denmark and Sweden presented a joint document containing their recommendations for revising the legislation on animal transport within the European Union and to third countries.

In particular, the delegations advocate an 8-hour limit for the transport of all animals to the slaughterhouse. The report also addresses other issues such as rules for exports of live animals to third countries, the dimensions of animal transport vehicles, requirements for feed intervals and digital tools for controls.

Although the ministers of the member countries are unanimously in favour of a review of the regulations, there is still some reticence on key provisions. For example, on the issue of limiting transport times, Poland, Hungary and Romania are opposed to this limit, as some Member States do not have slaughterhouses close to their livestock farms.

The European Commission is expected to present its proposal on animal welfare in 2023, revising the Regulation on the protection of animals during transport (established in 2004). In the meantime, the European Food Safety

Authority (EFSA) will carry out a series of assessments and provide scientific opinions on animal transport by September, which will serve as a reference for the European Commission.

Delegated act on the use of veterinary medicinal products: European Commission answer to a parliamentary question on vaccination against highly pathogenic avian influenza

Following the parliamentary question of MEP Aditdzhe ALIEVA-VELI (RE, Bulgaria) in May 2022 concerning the potential removal of EU trade restrictions on poultry products following a vaccination against highly pathogenic avian influenza, the European Commission replied on 7 July 2022.

For the European Commission, under current EU animal health legislation, "*Member States may take measures concerning the use of veterinary medicinal products (including vaccines) to ensure the most effective prevention and control of listed diseases, including highly pathogenic avian influenza (HPAI), provided that such measures are appropriate and necessary*".

The European Commission added that a delegated act on the use of veterinary medicinal products to facilitate vaccination against major animal diseases is being drafted, and is expected in the **2nd half of 2022**. One of the objectives of this legal act will be to provide a framework for vaccination so that the use of different vaccination strategies (against HPAI) can be combined, while respecting biosecurity and other existing disease prevention and control measures, in order to ensure a "*responsible*" poultry trade.

EFSA extends 'Stop African Swine Fever' public campaign

The European Food Safety Authority (EFSA) announced on 20th July the prolongation of the outreach campaign to raise awareness among farmers, veterinarians and hunters against the spread of African swine fever, for the third consecutive year.

The "**Stop African Swine Fever**" campaign is carried out in collaboration with local authorities in the following 18 countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Greece, Hungary, Kosovo, Latvia, Lithuania, Montenegro, North Macedonia, Poland, Romania, Serbia, Slovakia and Slovenia.

The spread of African swine fever continues at an alarming rate, with recent outbreaks in Italy and two sporadic outbreaks in Germany, near the borders with France and the Netherlands respectively," underlined the Director of EFSA, Bernhard URL.

In this context, the management of wild pig populations will be on the agenda during the 'high level ministerial' meeting organised by the European Commission on 27 September, in the presence of the Czech Republic's Presidency of the Council of the European Union.

OTHER ISSUES

Latest news on animal welfare

Drafting of the report on the implementation of the European Directive on the protection of animals used for scientific purposes

In accordance with the European Directive on the protection of animals used for scientific purposes, Member States are required to submit information on the implementation of the Directive to the European Commission every five years. The aim is to identify and address persistent weaknesses, such as incomplete and incorrect data sharing.

In anticipation of the next official report covering the period 2018-2022, due to be published on 10 November 2023, the European association for animal welfare, Eurogroup for animals, has published summary reports for the 14 Member States that use the highest number of animals for scientific purposes, as well as a general summary report for the rest of the Member States to assist Member States in drafting their next reports.

In addition, on 15 July, the European Commission published its latest annual statistical report, covering the year 2019, on the use of animals for scientific purposes in the EU Member States. The report indicates that 10.74 million animals were used in research, testing and education in 2019 (a decrease of 1.5% compared to 2018), of which 1.2 million animals were used for the creation and maintenance of groups of genetically altered animal. Overall, the report reveals that 9% of all animals used were inflicted severe suffering.

Publication of the Joint Research Centre (JRC) of the European Commission on alternative biomedical research models to animal testing

On 22 July, the Joint Research Centre (JRC) of the European Commission published a review of the state of the art of the 88 identified non-animal biomedical research models.

Advanced therapy medicinal products (ATMPs) are a category of innovative biological products (including somatic cell therapy, gene therapy, tissue engineering) aimed at developing new treatments for rare diseases and establishing more personalised medicine.

While ATMPs are expanding rapidly, several obstacles still hinder the fast development and wider clinical use of these alternatives to animal experimentation, such as limited amounts of measurement information.

This review therefore highlights a pressing need to develop more sophisticated and innovative non-animal approaches in this field, which will allow more systematic use of this method.

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