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In mid-September, the President of the European Commission, Ursula VON DER LEYEN, presented her proposal for the future College of EU Commissioners and the allocation of portfolios. On this occasion, she proposed the appointment of Hungarian Olivér VÁRHELYI as European Commissioner for Health and Animal Welfare, pending his approval by the European Parliament during the hearing scheduled in the coming weeks. This portfolio, long requested by many EU actors – including MEPs, NGOs and stakeholders – represents a significant step forward in recognizing animal welfare as a full responsibility within the Commission.

This same month, several measures were taken in the field of animal health. Notably, new progress was made in the fight against antimicrobial resistance, with the European Commission acknowledging the importance of the United Nations' political declaration on this issue, reaffirming that it remains a priority – which is also the case for our profession.

Furthermore, the Commission has launched several works aimed at revising the minimum training requirements for veterinarians and implementing certain provisions of the veterinary legislative package. Additionally, the Commission's efforts have once again focused on Avian influenza, African swine fever, and Goat plague, diseases that continue to spread in certain Member States. As a result, new restriction and surveillance measures have been adopted to curb their spread. Finally, Member States and MEPs have called on the Commission to take further measures to prevent the spread of Bluetongue.

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 <u>meeting</u> from 10th to 12th September 2024.

The Committee adopted a positive opinion for marketing authorisation for **ArthriCox** (*firocoxib*), a new product for the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs and for the relief of pain and inflammation associated with osteoarthritis in dogs.

The Committee adopted a positive opinion for a marketing authorisation **Cirbloc M Hyo**, a new vaccine for the active immunisation of pigs.

The Committee adopted a positive opinion for a variation requiring assessment for **NexGard Combo** to implement changes in the product information to further clarify the method of administration.

The Committee adopted a positive opinion for variations requiring assessment for **Yurvac RHD** to add a new therapeutic indication for passive immunisation against RHDV2 (not demonstrated against highly virulent strains) of the offspring of the vaccinated does for at least 30 days.

The Committee adopted by positive opinions for variations requiring assessment concerning quality-related changes for: Cerenia, Locatim, Mhyosphere PCV ID, Panacur AquaSol, Profender, Respiporc FLU3, Cimparica, Simparica Trio, Solensia, Strangvac, Suvaxyn PRRS MLV and Zenalpha.

The Committee adopted by positive opinions for variations requiring assessment to align the product information with version 9.0 of the QRD template for: **Cimalgex**, **Equilis West Nile**, **Felpreva**, **Inflacam**, **Letifend**, **Metacam**, **Purevax FeLV**, **Respiporc FLU3**, **Rheumocam**, **Novem**.

The Committee was informed of the formal notification from Intervet International B.V. of their decision to withdraw the application for an initial marketing authorisation for **Equilis EHV 1+4** and the Committee was also informed of the formal notification from Elanco GmbH of their decision to withdraw the application for a variation requiring assessment concerning quality-related changes for **Neptra**.

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

The CVMP classified an immunological product for honey bees as intended for a limited market and eligible for authorisation under the <u>2019/6 Regulation</u>. It also classified an immunological product for sea bass as intended for a limited market and eligible for authorisation under the <u>2019/6 Regulation</u> as well as an immunological product for dogs as intended for a limited market and eligible for authorisation under the <u>2019/6 Regulation</u> as well as an immunological product for dogs as intended for a limited market and eligible for authorisation under the <u>2019/6 Regulation</u>.

The Committee classified a product for cats under the alimentary tract and metabolism classification, as intended for a limited and eligible for authorisation under the <u>2019/6 Regulation</u>. The classification for a product for exotic animals was deferred.

The Committee opened a 4-month consultation for a <u>guideline</u> on risk management requirements for elemental impurities in veterinary medicinal products. It provides recommendations on how the risk management may be conducted for elemental impurities for veterinary medicinal products authorised or to be authorised in the European Union.

Latest EU institutional news

Announcement of the proposal from the future College of Commissioners: Animal welfare at the core of the new European Commission

Long requested by MEPs, NGOs and European citizens' initiatives, animal welfare is now a clearly defined responsibility in a Commissioner's portfolio.

On 17th September, European Commission President Ursula VON DER LEYEN unveiled her proposal for the future College of Commissioners and the allocation of portfolios. Hungary's Olivér VÁRHELYI has been nominated for the post of Commissioner for Animal Health and Welfare, subject to his approval at the European Parliament hearing in the coming weeks.

In his mission letter, he is called upon to ensure the implementation of the revision (already promised during the last mandate) of European legislation on animal welfare, and to continue work on antimicrobial resistance (AMR), considered "one of the main threats to public health".

The work of the new Commissioner for Animal Welfare will also be closely linked to that of other Commissioners, notably the Commissioner-designate for Agriculture and Food Christophe HANSEN, who is expected to "bring to life the report and recommendations of the strategic dialogue on the future of European agriculture". As a reminder, this report explicitly recommends a revision of animal welfare legislation by 2026, as well as a transition to cage-free farming systems.

Olivér VÁRHELYI will also be working with the Commissioners responsible for fisheries, trade and the environment, among others, to ensure ambitious European legislation aimed at securing high animal welfare standards in all relevant areas.

It should be noted, however, that the appointment of Olivér VÁRHELYI - close to Victor ORBAN and member of the Patriots for Europe (PfE) group in the European Parliament - will first have to be validated by the European Parliament. His confirmation could presage a complicated hearing before the ENVI parliamentary committee. Indeed, S&D, Renew and EPP MEPs have not yet decided what to do, and may be considering opposing him, given his proximity to the Hungarian government and his background.

Nevertheless, VÁRHELYI is not an unknown to the European scene, having previously held the position of Commissioner for Neighborhood Policy and Enlargement, and has been a specialist in European affairs for many years (Hungary's Permanent Representative to the European Union, Head of Unit at the European Commission, etc). For this reason, the Hungarian government's reaction to a negative assessment prompts caution. Some observers fear that Viktor ORBAN will take time to appoint a replacement, thereby disrupting the confirmation process. Others fear an alternative that "could be even worse".

Next steps:

The Commissioners-designate will now have to undergo hearings before the relevant parliamentary committees of the European Parliament, before a validation vote at a plenary session of the College as a whole.

The timetable is likely to change, but to date, the next steps are as follows:

- Week of 4th November: Hearings of all candidate Commissioners before the relevant European Parliament committees.
- From November 4th to 12th : The vote to confirm the College of Commissioners at the plenary session of the European Parliament should take place on one of these two dates.
- 31st October: End of the current European Commission's term of office.

1st November (*optimistic scenario*) or 1st December (*at the latest*): The new European Commission takes office.

Latest news on antimicrobial resistance

European Commission welcomes adoption of international declaration on combating antimicrobial resistance

The European Commission welcomed the adoption at the UN General Assembly on 9th September 2024, of concrete steps to combat antimicrobial resistance (AMR) in all sectors, alongside UN member countries and EU member states.

Political leaders have committed to a series of measures:

- The introduction by all countries of national action plans to combat AMR;
- The establishment of an independent expert panel to support evidence-based action against AMR (the EU will contribute 2.5 million euros to this panel in 2025);
- The goal of reducing the number of deaths worldwide due to bacterial AMR by 10% by 2030;
- The commitment to significantly reduce the use of antibiotics in the agri-food sector by 2030;
- The promotion of sustainable financing, with particular emphasis on low- and middle-income countries, and an inventory of funds available for AMR.

These recommendations underline the importance of responsible use of veterinary medicines, based in particular on the positions of European stakeholders calling for support for a sustainable reduction in the use of antibiotics. As part of this political declaration, veterinary medicine companies worldwide have set measurable objectives, including the marketing of new preventive and diagnostic tools. In addition, countries have reaffirmed their commitment to collecting data on antibiotic use over several decades, which they share with organizations such as the European Medicines Agency and the World Organization for Animal Health, thus contributing to a better global understanding of their use

This political <u>declaration</u> thus reaffirms strong support for disease prevention and access to animal health tools, with the aim of "*a supply of essential, high-quality and affordable veterinary medicines, vaccines and diagnostics*". Emphasis is also placed on the need to improve diagnostics and increase the number of veterinarians and para-professionals worldwide, while promoting science-based solutions.

This political statement was also welcomed by several European animal protection organisations, including <u>Animal Health</u>.

Publication of an implementing regulation establishing the list of third countries or regions authorized to introduce into the Union certain animals and products of animal origin

On 4th October, the European Commission published <u>an implementing regulation</u> establishing a list of third countries and regions of third countries authorized to introduce into the Union animals and products of animal origin intended for human consumption, in compliance with the ban on the use of certain antimicrobial products.

In particular, this <u>text</u> distinguishes third countries or regions of third countries in which, as regards animals and products of animal origin intended for export to the Union, the requirements set out in Article 3 of <u>Delegated Regulation 2023/905</u> are fulfilled, and those which, for the production of products intended for export to the Union, intend to process only animals or products of animal origin from either Member States or other third countries.

Thus, for the following countries or regions, the entry into the Union of consignments of certain animals and products of animal origin intended for human consumption is authorized with regard to the application of the ban on the use of certain antimicrobial medicinal products, provided for in <u>Regulation 2019/6</u>: Andorra, Albania, Argentina, Australia, Azerbaijan, Bosnia and Herzegovina, Bangladesh, Brazil, Botswana, Belarus, Canada, Switzerland, Chile, Cameroon, China, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Egypt, Ethiopia, Falkland Islands, Faroes, United Kingdom, Georgia, Greenland, Guatemala, Hong Kong, Honduras, Israel, Isle of Man, Jersey, Japan, South Korea, Lebanon, Morocco, Moldova, Montenegro, Madagascar, North Macedonia, Myanmar/Burma, Mongolia, Mexico, Malaysia, Namibia, New Caledonia, Nicaragua, New Zealand, Peru, Philippines, Pakistan, Saint Pierre and Miquelon, Paraguay, Russia, Rwanda, Saudi Arabia, Singapore, San Marino, El Salvador, Togo, Thailand, Türkiye, Taiwan, Ukraine, United States, Uruguay, Venezuela, Viet Nam, Kosovo, South Africa and Zambia.

These provisions will come into force **24 months** after the date of application of Commission Implementing <u>Regulation 2024/399</u>. Therefore, this Regulation should apply from 3rd September 2026.

Latest news on professional qualifications for veterinary surgeons

Open public consultation on the draft delegated act updating the minimum training conditions for veterinary surgeons

The European Commission has launched a <u>public consultation</u> on a <u>draft delegated act</u> aimed **at updating the minimum training conditions for veterinary surgeons**, in accordance with the <u>Directive</u> on the automatic recognition of professional qualifications for the cross-border access to regulated professions in the European Union. The contribution period is open for 4 weeks, **until 21**st **October 2024**.

According to the text proposed by the European Commission - which also amends Annex V - of the directive, veterinary training must guarantee that the professional concerned has acquired the following knowledge and skills:

- Knowledge of the sciences on which the activities of a veterinary surgeon are based and of the EU law relating to those activities;
- Adequate knowledge of the structure, functions, behaviour and physiological needs of animals, as well as the skills and competences needed for their husbandry, feeding, welfare, reproduction and hygiene in general;
- The clinical, epidemiological and analytical skills and competences required for the prevention, diagnosis and treatment of the diseases of animals, as well as to assess and manage pain, safely perform aseptic surgery, sedation, anaesthesia and euthanasia, whether considered individually or in groups, including specific knowledge of the diseases which may be transmitted to humans;

- Adequate knowledge, skills and competences for preventive medicine, including competences relating to inquiries and certification;
- Adequate knowledge of the hygiene and technology involved in the production, manufacture and putting into circulation of animal feedstuffs or foodstuffs of animal origin intended for human consumption, including the skills and competences required to understand and explain good practice in this regard;
- The knowledge, skills and competences required for the responsible and sensible use of veterinary medicinal products, in order to treat animals and to ensure the safety of the food chain and the protection of the environment;
- Adequate knowledge and understanding of the One Health concept, including skills and competences for its application and integration in veterinary public health;
- Knowledge of the organisation and management related to a veterinary business, including practice management and animal health economics; adequate knowledge, skills and competences on interpersonal and interprofessional interaction, communication, teamworking and multidisciplinary collaboration;
- Adequate knowledge of information technology and digital technologies, and the skills and competences necessary for their practical application in the veterinary domain.

Based on the results of the consultations, the European Commission may amend the draft act, which will then be subject to a 2-month examination period during which the Member States and the European Parliament may formulate objections to the text. If the comitology procedure is conclusive, the text will then be published in the *Official Journal of the European Union* and enter into force. Publication is scheduled for the **4th quarter of 2024**.

Latest news on veterinary package

Publication of public consultations by the European Commission on delegated acts in the veterinary package (veterinary medicinal products and vaccines)

The European Commission has announced that two public consultations on implementing acts relating to veterinary medicinal products and vaccines will be launched shortly:

- The <u>first consultation</u> will focus on **veterinary medicinal products** and the rules governing good manufacturing practice for active substances used as starting materials. The aim of this initiative is to ensure that good manufacturing practice for these active substances is applied consistently throughout the EU.
- The <u>second consultation</u> will concern uniform rules on good manufacturing practice for **inactivated autogenous veterinary vaccines**.

The European Commission is due to publish these two initiatives in the 1st quarter of 2025.

Latest news on animal health at EU level

Member States and MEPs call on the European Commission to take new measures to prevent the spread of Bluetongue

The Member States called for a European vaccination campaign against serotype 3 Bluetongue (BTV-3) during the Agriculture Council, held on 23rd September.

Led by <u>Belgium</u>, this request was supported by several countries, which highlighted the challenges of "*ensuring a sufficient supply of safe vaccines*" and called for "European-level reflection to anticipate threats and work with laboratories on the availability of products." Austria, in particular, advocated for the "*implementation of the necessary regulations to authorize vaccines and harmonize procedures*".

Additionally, Spain, Portugal, and Malta stressed the need to increase investment in animal health. Belgium, for its part, <u>urged</u> the European Commission to assess "the feasibility of activating the CAP crisis reserve" and announced that it would submit an official request to this effect. More globally, Greece, which was affected this summer by an epizootic of goat plague (also called "peste des petits ruminants") that is now "in decline", also took the opportunity to <u>request</u> "adequate financial resources" to "support central and local authorities" as well as farmers impacted by the restrictive measures taken to curb the disease, asking for "additional provisions" to restock herds.

Finally, Sweden, which considers it has eradicated African swine fever from its territory, <u>expressed</u> the view for "*restricted zones*" to be lifted as of 1st October 2024.

The issue of new measures to prevent the spread of bluetongue had already been raised in the European Parliament. Indeed, about forty MEPs from the EPP, S&D, and Renew groups co-signed a question addressed to European Health Commissioner Stella Kyriakides on 12th September, asking: "*Does the European Commission plan to launch a European vaccination campaign*?"

The MEPs regretted "the lack of coordination at the European level in managing" this disease, which particularly affects Belgium, the Netherlands, France, Luxembourg, Germany, and the Czech Republic. They also voiced concerns about "the Commission's lack of vigilance regarding barriers to intra-EU trade", stressing that "animals tested as free of disease and treated with insecticides should be able to move freely across the EU".

Publication of several implementing acts by the European Commission on new outbreaks of African swine fever

On the 9th, <u>16th</u> and <u>23rd</u> September and on the <u>4th</u> of October the European Commission published several implementing acts about new outbreaks of African swine fever in Europe.

The regions affected by new protection, surveillance and restriction rules include:

- Greece in the regions of Macedonia and Thrace ;
- Italy in the regions of Lombardy and Piedmont ;
- Poland in the regions of Pomorskie, Western Pomerania and Zachodniopomorskie;
- Germany in the states of Mecklenburg-Vorpommern and Hesse ;
- Lithuania in the county of Alytaus.

Also, on the basis of information provided by Germany, for African swine fever, certain areas of the German federal state of Saxony, currently listed as restricted zone II (in Annex I to the <u>implementing regulation</u>), should now be listed as restricted zone I in that annex, due to the absence of outbreaks of African swine fever in kept and feral pigs in the last 12 months.

Publication of several implementing acts by the European Commission on new outbreaks of goat plague in Greece and Romania

On <u>19th</u> and <u>23th</u> September, the European Commission published several implementing decisions about new outbreaks of Goat plague (also called "*peste des petits ruminants*") in **Greece** and **Romania**.

Goat plague is an infectious disease which has been seriously affecting goats and sheep in Greece and Romania for the past few months.

Greece is affected by several outbreaks of the disease in its territory, including:

- In the regional unit of Aetolia-Acarnania;
- In the regional unit of Rodopi;
- In the regional unit of Ilia;
- In the region of **Corinthian**;
- In the Larisa regional unit.

In Romania, regions affected by new outbreaks are listed as follows:

- In the county of **Tulcea**;
- In the county of **Constanta**;
- In the county of **Timis**;
- In the county of **lalomita**.

Regions affected by the disease will now be under surveillance, protection and restriction measures.

Publication of an implementing decision by the European Commission about new outbreaks of Avian influenza in Europe

On <u>12th and <u>23rd</u> September the European Commission published an implementing decision on outbreaks of highly pathogenic Avian influenza (HPAI) in certain Member States of the European Union.</u>

Following the notification by national authorities to the European Commission of outbreaks of the disease in their countries, the following regions are placed under protection and surveillance zones:

- France, in the departments of Finistère;
- Germany in the state of Saxony-Anhalt;
- Czech Republic in the region of Příbram;
- Denmark in the municipality of **Guldborgsund**.

Publication of several implementing acts by the European Commission on new outbreaks concerning of Goat pox

On <u>11th</u> and <u>19th</u> September, the European Commission published several implementing acts about new outbreaks of Goat pox in Europe.

The regions affected by new protection, surveillance and restriction rules include:

• Bulgaria in the region of **Yambol**;

• Greece in the regions of Evros and Kavala.

These regions should therefore set up a protection zone, a surveillance zone and, if necessary, other restricted zones around or in the immediate vicinity of the protection and surveillance zones.

Exchange of views within the Council's Special Committee on Agriculture on the impact of health constraints and animal diseases on the pig and poultry sectors

On 9th September, at the meeting of the <u>Council's Special Committee on Agriculture (SCA)</u> in Budapest (Hungary), EU member states highlighted **the impact of health constraints and animal diseases on the European pigmeat and poultry sectors**.

Following a presentation by the European Commission on the current state of these two markets, delegations were invited to express their concerns regarding animal health and welfare.

In particular, some delegations called for mandatory country-of-origin labelling and increased support for farmers. Emphasis was also placed on the need to invest in vaccine research, the development of new technologies, and the implementation of preventive and risk management measures.

In addition, some delegations regretted that certain third countries do not recognize "regionalization", which would make it possible to avoid global import bans in the event of an epidemic, even in disease-free regions.

Finally, a (non-public) note presented by the Hungarian Presidency of the Council recalled that, although the pig and poultry sectors were not eligible for coupled aid under the Common Agricultural Policy (CAP), they could benefit from investment support and measures linked, in particular, to animal health and welfare.

Publication by the European Commission of a report on the operation of official controls on animal health and welfare rules

On 11th September 2024, the European Commission published a <u>report</u> on the operation of official controls in 2022 in Member States aimed at ensuring compliance with feed legislation and rules on animal health and welfare, plant health and plant protection products.

The report shows that nearly 5 million checks revealed 1.2 million breaches, resulting in over 475,000 sanctions. The Commission also noted shortcomings in the control systems of certain member states.

The report also mentions the audits and controls carried out by the Commission on the welfare of calves at checkpoints during transport within the Union, as well as animal welfare on board livestock vessels.

Following these audits, the European Commission has made a number of recommendations:

- **Feed**: The audits highlighted the need to improve the assessment of operators' risk analysis systems, the implementation of appropriate sampling protocols, and official controls on labelling.
- Animal health:
 - African swine fever, controls revealed difficulties with early detection, biosecurity, as well as movement control in restricted zones.
 - With regard to avian influenza, improvements are recommended in contingency planning and epidemiological investigations.
 - o Checks on rabies eradication programs show general progress in line with objectives.
- Animal welfare: A summary report on quality management systems and the use of indicators highlighted the need to develop harmonized indicators for measuring and monitoring animal welfare on farms. With regard to animal transport, the Commission has initiated new projects on the longdistance transport of weaned calves and maritime transport to third countries.

OTHER ISSUES

Latest news on international trade

State of play of negotiations on the EU- MERCOSUR trade agreement

On 5th and 6th September, representatives of the European Commission and MERCOSUR member states met in Brasilia (Brazil) to continue negotiations on the EU-MERCOSUR trade agreement.

Several member states, including Spain, Germany, Portugal, Sweden, Denmark, Finland, the Czech Republic, Luxembourg, Croatia, Estonia and Latvia, called on the President of the European Commission, Ursula VON DER LEYEN, to finalise the agreement by the end of the year.

However, the European Commission responded to these requests by stating, through its spokesperson on 9th September, that it was "not ready to conclude the negotiations" at this stage. "The European Union continues to focus on resolving the outstanding issues, ensuring that the agreement achieves sustainability objectives while respecting sensitivities in the agricultural sector", he added.

Since 2nd September, several <u>European organisations</u>, including <u>FNSEA</u> and <u>Interbev</u>, have reaffirmed their opposition to the conclusion of this agreement, fearing that the agricultural sector will be considered "*an adjustment variable*".

Latest news on animal welfare at EU level

Renewal of the Animal Welfare and Conservation Intergroup

On 19th September 2024, the Animal Welfare and Conservation Intergroup <u>renewed</u> its Bureau as part of the European Parliament's new mandate. MEP Niels FUGLSANG (S&D, Denmark) was elected Chair, succeeding Tilly METZ (Greens/EFA, Luxembourg), former Chair, now appointed Honorary Chair alongside Anja HAZEKAMP (GUE/NGL, Netherlands).

MEPs Thomas WAITZ (Greens/EFA, Austria), Emil RADEV (EPP, Bulgaria), Sebastian EVERDING (GUE/NGL, Germany), Maria NOICHL (S&D, Germany), Manuela RIPA (EPP, Germany), Petras AUSTREVICIUS (Renew, Lithuania), Jadwiga WISNIEWSKA (ECR, Poland), Martin HOJSIK (Renew, Slovakia) and Michal WIEZIK (Renew, Slovakia) were elected Vice-Presidents of the Intergroup.

Created in 1983, the Intergroup on Animal Welfare and Conservation is one of the European Parliament's oldest informal working groups. Although it has no direct legislative powers, it plays an essential role in promoting initiatives to improve animal welfare within the European Union.

During the previous mandate, the intergroup was particularly active, notably in relation to the European Commission's promise to propose an "*animal welfare legislative package*". Indeed, its main mission is to ensure that animal welfare is taken into account in European policies, particularly in the fields of agriculture, the environment, trade and research.

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info@euralia.eu