Animal medicines package

In September 2014, the European Commission put forward a package of three proposals to update the legislative framework for veterinary medicines. More stringent rules are intended to tackle antimicrobial resistance and to improve the availability of veterinary medicines in the EU. During its October II plenary session, the European Parliament is expected to vote on the texts agreed in trilogue negotiations.

Background

In the European Union, only veterinary medicines that have been granted a marketing authorisation can be placed on the market. The present proposals aim to tackle certain shortcomings in current legislation, such as medicines not being readily available for certain 'minor' animal species with small markets (such as bees), and the heavy administrative burden linked to the authorisation procedure, hampering innovation and the optimal functioning of the internal market for these products. Also, the needs and drivers for investment differ substantially from those of the human sector; prices for veterinary medicines are substantially lower and the size of the animal pharmaceutical industry only a small fraction of that for human medicines. Therefore, the regulatory framework should be tailored to address the characteristics of the veterinary sector.

European Commission proposal on veterinary medicinal products

The proposed regulation aims to make more medicines available in the EU to treat and prevent diseases in animals. At the same time, the objective is to improve the functioning of the Union market for these products, as well as to simplify the existing rules to enhance the development of suitable medicines for all animal species. Additionally, in order to fight antimicrobial resistance (AMR) and to help keep antibiotics effective in both animals and humans, the proposal introduces the possibility of restricting the use in animals of certain antimicrobials that should be reserved for treating life-threatening human infections. The procedures for granting marketing authorisations as well as for the monitoring of side effects (pharmacovigilance) of veterinary medicinal products would be simplified.

European Commission proposal on medicinal products for human and veterinary use

The proposed regulation amends Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA), to take account of the fact that the new regulation on veterinary medicines will separate the marketing authorisation for veterinary products from that for medicines for humans. The proposal also establishes principles applicable to fees payable to the EMA, and aligns powers conferred on the European Commission with the Lisbon Treaty (delegated and implementing acts).

European Commission proposal on the manufacture, placing on the market and use of medicated feed

Medicated feed is one of the methods of oral administration of veterinary medicines, and in this light the proposal is strongly inter-related with the legislation on veterinary medicinal products. The proposed regulation aims to update and harmonise outdated rules on the manufacture, placing on the market and use of medicated feed and lay them down in a regulation instead of a directive. It includes general manufacturing requirements, rules for the approval of feed business operators, specific labelling requirements, rules to ensure the homogenous incorporation of a veterinary medicinal product into the medicated feed, and requirements to avoid carry-over of active substances from medicated feed to other feed. It also proposes to extend the scope to cover medical feed used both in food-producing and in non-food producing animals (including pets).

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European Parliament position

In the Parliament, the proposal on medicated feed was referred to the Committee on Agriculture and Rural Development (AGRI), and the other two files to the Committee on Environment, Public Health and Food Safety (ENVI).

On 10 March 2016, the European Parliament adopted amendments to the proposal for a regulation on veterinary medicinal products and to the proposal amending Regulation (EC) No 726/2004. The plenary agreed to return the two dossiers to the ENVI committee to undertake interinstitutional negotiations.

The AGRI committee adopted its report on medicated feed on 15 March 2016, and also voted to open interinstitutional negotiations.

The Council began examining the main proposal, the proposal on veterinary medicines, in the second half of 2014. According to a progress report presented by the presidency in June 2017, almost all provisions of the proposal were redrafted at least twice. The Permanent Representatives Committee (Coreper) agreed on the Council position on 20 December 2017. Trilogues and technical meetings were held during the first half of 2018, leading to three provisional agreements, reached in February 2018 and June 2018.

The ENVI committee endorsed the provisional agreements on veterinary medicines and on the procedures for the authorisation of medicinal products on 20 June 2018. To fight against antimicrobial resistance, the new rules would limit the prophylactic (preventive) use of antibiotics to individual animals, and only when justified by a veterinarian (e.g. after surgery). Metaphylactic use (treating all animals in a group when only part of them show signs of illness) should only happen where the risk of disease spreading is high and no other appropriate alternatives are available. Certain critical antimicrobials would be reserved for the treatment of humans only. The European Parliament succeeded in making EU standards reciprocal for imported foodstuffs: trading partners will have to respect the ban on antibiotics for growth promotion, as well as the restriction on antimicrobials reserved for use in humans. To encourage research into new medicines, in particular antimicrobials and medicinal products for minor species, the new regulation would simplify procedures for granting marketing authorisation and prolong periods of protection for technical documentation for them. On the demand of the Parliament and the Council, the EMA's fee structure would be adopted under the ordinary legislative procedure.

The AGRI committee endorsed the provisional agreement on medicated feed on 10 July 2018. As with the veterinary medicines proposal, the new rules would prohibit the prophylactic use of antibiotics in medicated feed, and allow metaphylactic use only in case of high risk, which the committee had insisted on. It is furthermore reiterated that antibiotics should not be used to enhance the performance of animals. Maximum cross-contamination levels of normal feed with active substances from medicated feed would in future be specifically defined following a science-based assessment. Medicated feed imported from third countries should comply with the standards. The proposed regulation also includes rules applicable to non-food producing animals (including pets).

The agreements have been confirmed by Permanent Representatives Committee on behalf of the Council. The final compromise texts are submitted to the European Parliament for a vote at first reading (scheduled for the October II plenary session), and will subsequently go back to the Council for adoption (expected before the end of the year). The new rules would then apply at the latest in 2022.

First-reading reports:

Committee responsible: ENVI; 2014/0257(COD), Rapporteur: Françoise Grosstête (EPP, France); 2014/0256(COD), Rapporteur: Claudiu Tănăsescu (S&D, Romania);

Committee responsible: AGRI; 2014/0255(COD); Rapporteur: Clara Eugenia Aguilera García (S&D, Spain).

See our 'EU Legislation in Progress' briefing on medicated feed.