Green light for new rules on veterinary medicines and medicated feed

The EU is introducing new and improved rules to step up the fight against antimicrobial resistance and improve the availability and safety of veterinary medicines and medicated feed. This will be of benefit to animal health and help boost the competitiveness of the EU veterinary pharmaceutical sector.

The Council today adopted the animal medicines package including two new regulations on:

1. veterinary medicinal products
2. the manufacture, placing on the market and use of medicated feed

and changes to the existing rules laying down procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

This package is a major milestone in the fight against antimicrobial resistance: on the one hand antimicrobials and antibiotics will have to be used much more prudently than is the case now, and on the other hand we encourage the development of better medicines and medicated feed. It is a win-win for public health and the competitiveness of the EU pharmaceutical industry.

Elisabeth Köstinger, Austrian Federal Minister for Sustainability and Tourism and President of the Council

The new rules on veterinary medicinal products:

- clarify and simplify the procedures through which a marketing authorisation can be granted to new medicines, thereby reducing the administrative burden for companies, especially small ones
- better frame the use of antimicrobials in animals by further limiting their use for animals that are not yet sick but may run the risk of falling ill, both in the case of prophylaxis and metaphylaxis
- provide for certain critical antimicrobials to be set aside for the treatment of certain infections in humans in order to preserve their effectiveness
- improve the protection of the European consumers against the risk of the spreading of AMR through imports of animals and products of animal origin
- strengthen pharmacovigilance and controls

The new rules on medicated feed:

- set out criteria for the approval of feed business operators and their obligations when manufacturing medicated feed
- lay down harmonised requirements in order to avoid cross contamination of a non target feed with active substances
- clarify the prescription and use of medicated feed containing antimicrobials in food-producing animals
- prohibit the use of medicated feed for prophylaxis

In addition, regulation 726/2004 that establishes the European Medicines Agency and the centralised procedure for the authorisation and supervision of medicinal products is adapted in order to avoid any overlap with the procedures laid down in the new regulation on veterinary medicinal products.

Next steps

The Council and the European Parliament now need to sign the adopted regulations. The signed texts will then be published in the EU Official Journal and will enter into force 20 days later. However, the new rules will only be fully operational as of end of 2021.

Background

The animal medicines package is a package of three proposals for regulations updating the existing legislative framework for
veterinary medicines and medicated feed by further tailoring it to the specificities of the animal health sector. While continuing to safeguard public and animal health, animal welfare, food safety and the environment, the package is aimed in particular at increasing the availability of veterinary medicines in the EU, improving the functioning of the EU market, reducing administrative burdens and fostering innovation.

- Background: Animal medicines package
- Veterinary medicines: new EU rules to enhance availability and fight against antimicrobial resistance (press release, 13/06/2018)
- Medicated feed: Council's green light wraps up the animal medicines package (press release, 27/06/2018)