Part A: Direct Translation

New legislation for veterinary medicines

European Medicines Agency welcomes European Commission proposal to increase availability of medicines across Europe

New rules have been proposed by the European Commission to improve the health and wellbeing of animals by stimulating the development and availability of veterinary medicines.

The legislative proposal also tackles the growing concerns over antimicrobial resistance by proposing a series of tools to minimise the risks that may arise from the use of antibiotics in veterinary medicine.
The proposal represents a major evolution of the legal framework for the authorisation of veterinary medicines in the European Union (EU).

The document has been published on the Commission's website together with questions and answers under Revision of the legal framework for veterinary medicinal products.

The revision aims to:

- simplify the regulatory environment and reduce administrative burden for companies developing veterinary medicines through streamlined marketing-authorisation procedures and simplified pharmacovigilance rules;
- stimulate the development of new veterinary medicines, including products for small markets (minor use and minor species), with the introduction of special rules in certain areas such as apiculture and aquaculture and better mechanisms to reward companies' investments in the development of innovative medicines;
- facilitate the circulation of veterinary medicines across the EU, through streamlined procedures and clear rules for internet retailing of veterinary medicines within the EU;
- fight the development of antimicrobial resistance through specific measures such as a restriction of the use in animals of certain antimicrobials that are reserved for the treatment of infections in people.

The European Medicines Agency welcomes the publication of this proposal as the availability of veterinary medicines and the fight against antimicrobial resistance are two major priorities for the Agency, as reflected in its work programme.

Today, the Commission has also adopted a proposal for a revision of the EU legislation on food for animals containing medication. The aim is to ensure that medicated feed is only produced by approved manufacturers using authorised veterinary medicines.

Other EU institutions, including the European Parliament and the Council, will now consider the Commission's proposals and will adopt their positions in due course, in accordance with the co-decision procedure.

Commission adopts proposals to improve animal and human health

Today, the Commission adopted proposals on veterinary medicinal products and medicated feed, to improve the health and wellbeing of animals, to tackle antimicrobial resistance (hereinafter, AMR) in the EU and to foster innovation.

- The proposal on veterinary medicinal products aims in particular to make more medicines available in the EU to treat and prevent diseases in animals.
- The proposal on the modernisation of medicated feed legislation now includes feed for pets in its scope. The idea is to ensure the appropriate standard of product quality and safety in the EU, whilst simultaneously paving the way for better treatments for diseased animals.

The proposed rules will benefit animals – including aquatic species, their holders, pet owners, veterinarians and businesses - including the pharmaceutical and feed industries, in the EU.

Tonio Borg, European Commissioner for Health, said: "*These proposals both have animal health and welfare at their heart. However, they also represent a major step forward for public health as they introduce measures that contribute towards combating the growing threat of AMR, keeping antibiotics effective for people and animals alike."*

Proposal on veterinary medicinal products

With its proposal, the Commission aims to tailor legislation on veterinary medicines to the needs of the veterinary sector whilst continuing to ensure a high level of public and animal health and a safe environment.

The proposed Regulation builds upon existing EU rules for veterinary medicines which ensure that only medicines that have been granted a marketing authorisation can be placed on the market. However, rules are simplified to ensure the development of suitable medicines for animals in the EU. This reduction in red tape will concern both the marketing authorisation procedure and the monitoring of side effects (pharmacovigilance).

The proposed rules are particularly timely for minor species such as bees, goats, turkeys, horses etc. for whom available medicines are currently lacking.

To combat AMR and to help keep antibiotics effective in humans and animals, the proposal introduces the possibility of restricting the authorisation and use in animals of certain antimicrobials that are reserved to treat human infections.

Proposal on medicated feed

The proposed Regulation will repeal and substitute the outdated Directive (90/167/EEC) on the manufacture, placing on the market and use of medicated feed.

After veterinary prescriptions, medicated feed is an important route for administering veterinary medicines to animals. Its aim is to harmonise the production standards and marketing of medicated feed in the EU at an appropriate safety level, and to reflect technical and scientific progress in this area.

The proposed rules will ensure that medicated feed can only be manufactured from specifically authorised veterinary medicines and by approved manufacturers. AMR will be tackled through measures such as a ban on medicated feed being used preventively or as growth promoters. Additionally, EU wide residue limits for veterinary medicines in ordinary feed are established at a limit to avoid the development of AMR.

The scope of the proposal explicitly includes medicated feed for pets, so that pets – especially those with chronic diseases, can be treated more easily with innovative medicated pet food.

Next steps

Other EU institutions, including the European Parliament and the Council, will consider the Commission's proposals and will adopt their positions in due course, in accordance with the co-decision procedure.