Veterinary medicines: new EU rules to enhance availability and fight against antimicrobial resistance

Press contacts

Maria Daniela Lenzu
Press officer
+32 2 281 21 46
+32 470 88 04 02

What is AMR and how the new rules on veterinary medicines can contribute to the fight against it.

On 13 June 2018 EU ambassadors meeting in the Committee of Permanent Representatives (**Coreper**) **confirmed an agreement** reached on 5 June between the Bulgarian Presidency of the Council and European Parliament representatives on a regulation on **veterinary medicines**.

The agreement paves the way for a new system of rules that will improve the **availability of** these **medicines**, enhance **competitiveness and innovation in the veterinary pharmaceutical sector and** contribute to the **fight against antimicrobial resistance** (AMR) – the ability of bacteria to render the antibiotics used to treat infections ineffective.

> Today is a good day for both animal and public health. New smart EU rules will give us robust tools to prevent the abuse of antibiotics and limit the risk of the development of antimicrobial resistance. At the same time it will stimulate innovation and will lead to increased availability and easier access to veterinary medicines for veterinarians, farmers and pet owners that really need medicines to treat and prevent animal diseases.
>
> *Rumen Porodzanov, minister of agriculture, food and forestry of the Republic of Bulgaria and president of the Council*

The current legal framework for the marketing authorisation, distribution and use of veterinary medicines is set out in directive 2001/82/EC and regulation 726/2004.
Over time operators have underlined the limitations of these rules especially in relation to **availability of medicines** for limited markets (e.g. for bees) and the **lack of innovation** connected to the heavy **administrative burden** linked to the authorisation procedure. At the same time awareness of the risks associated with **antimicrobial resistance** has grown and the efforts to combat it have been stepped up.

The decision on a new framework comes after four years of intense technical work carried out by the three EU institutions to make sure that the new rules meet the needs of the market, and are legally watertight. Some of their main elements are:

Simplification and **innovation**: the new regulation clarifies and simplifies the procedures through which a marketing authorisation can be granted to new medicines, thereby reducing the administrative burden for companies, especially small ones. It also **increases the protection** for the initial marketing authorisation **for limited markets (including for minor species)**, so as to incentivise research and innovation and increase the availability of effective medicines on the market.

AMR: the new rules better frame the use of antimicrobials in animals by **limiting the use of antibiotics** for animals that are not yet sick but may run the risk of falling ill, both in the case of

- **prophylaxis**: the exceptional administration of antibiotics to an individual animal only, where the risk of a disease is very high and when its consequences are likely to be severe – e.g. after surgery; and
- **metaphylaxis**: the administration of antibiotics to a group of animals – e.g. herds and flocks – where the risk of bacterial infection or disease is high and no other appropriate alternatives are available.

Moreover the new rules will provide for **certain critical antimicrobials to be set aside for the treatment of certain infections in humans** in order to preserve their effectiveness.

Imports: the new regulation improves the protection of the European consumers against the risk of the spreading of AMR through imports of products of animal origin. It also creates a level playing field between EU and **third country operators** insofar as the latter will have to respect the **ban on antibiotics for growth promotion**, as well as the restriction on antimicrobials reserved for **use in humans**.

Pharmacovigilance and **controls**: the process of detection and prevention of the adverse effects of veterinary medicines will be **strengthened** and **uniform controls across the EU** will be enforced.

Now that the agreement has been confirmed by EU ambassadors on behalf of the Council, the regulation will be submitted to the European Parliament for a vote at first reading, and will subsequently go back to the Council for adoption.

The new rules will apply at latest in 2022.