Briefing paper

Assessment and authorisation of animal medicines: protecting the environment

- **An independent and robust evaluation and authorisation process for animal medicines means that, before reaching the market, their quality, safety, and efficacy is assessed as part of a benefit-risk evaluation.**
- **This evaluation includes a thorough environmental risk assessment, whereby any medicines posing unacceptable risks are denied an authorisation for use and, as such, do not reach the market.**
- **AnimalhealthEurope's members comply with all relevant independent regulatory processes for authorising medicines. Protecting animals, people and the environment is a priority for our industry.**
- **AnimalhealthEurope works with EU decision makers to ensure both environmental protection and access to animal medicines.**

A robust regulatory evaluation precedes each marketing authorisation

Before reaching the market, animal medicinal products undergo a stringent authorisation process and are only approved in case of a positive benefit-risk assessment evaluation. The environmental risk assessment is a mandatory part of this evaluation by the European Medicines Agency (EMA) or the relevant competent national authority. This process was reinforced in 1993[1] and is conducted using independent, internationally adopted OECD[2] and VICH[3] guidelines and standards.

It is important to note that an authorisation can be denied by the regulator if the outcome of the environmental risk assessment identifies unacceptable risks, which are not outweighed by the therapeutic benefits of the product, and therefore, the medicine will not reach the market.

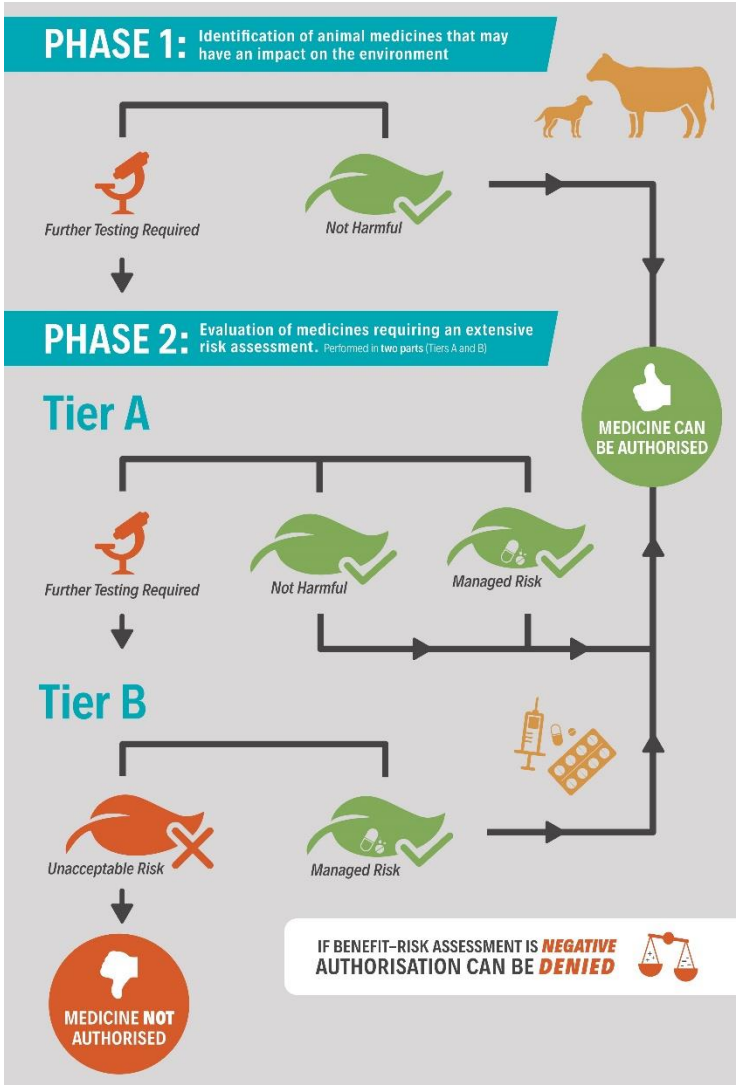
Environmental risk assessment explained

The environmental risk-assessment (ERA) process includes examining the potential impact of animal medicines on the environment, and evaluating possible risks.

In those cases where a potential risk is identified, this can be managed by risk mitigation measures, which are clearly stated on the product labels and should be respected. Thus, the ERA and label recommendation on use have a vital role to avoid a negative impact on the environment.

[1] Commission Directive 92/18/EC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the texting of veterinary medicinal products (enforced in 1993)
[2] Organisation of Economic Co-operation and Development
[3] International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

Environmental risk assessment of animal medicines



Responsible use of animal medicines

AnimalhealthEurope members take their responsibilities to protect the environment seriously and continuously throughout the lifecycle of medicines in accordance with legislation, and actively promote the responsible use of animal medicines. Used appropriately, and respecting the product's label and leaflet instructions, authorised animal medicines should not pose a significant risk to the environment.

Cooperation

AnimalhealthEurope is fully committed to working with EU decision makers to ensure both environmental protection and access to animal medicines, the paramount objective of our industry.

Healthy animals** mean **healthy people** and a **healthier planet