

Risk analysis process: the scientific basis for the regulation of veterinary medicines

Issue

In the interests of public health, animal health and animal welfare veterinary medicines are regulated to ensure that only safe (for animals, users, consumers and the environment) and effective products of appropriate quality are placed on the market. This process must be achieved in a proportionate and balanced way to allow society to gain the benefits that these products bring.

Background

Animal health products are essential for animal welfare and make valuable contributions to society by protecting and preserving the health of animals and preventing the spread of disease and parasites that can pass between animals and people. Companion animals have come to play a more important role in people's everyday lives and veterinary medicines help to extend the length and quality of their lives. Veterinary medicines also play a key role in assisting food producers to provide safe and affordable food of animal origin (meat, eggs and milk) for a growing world population.

Before a veterinary medicine can be placed on the market it must undergo, among other things, a safety evaluation by the competent authority. This takes the form of a risk analysis, which includes a benefit-risk assessment: the benefits must be proven and the potential risks, such as adverse reactions, user-safety, consumer safety and environmental safety, must be investigated and characterised. The benefits must outweigh the risks, or the medicine will not be authorised. More information on these terms is provided in the box below.

If the outcome of the benefit-risk assessment is positive, the second step is to define risk management measures to minimise any potential risks (e.g. store out of the reach of children) to ensure that those responsible for the welfare of animals in their care can safely access the benefits of the product. Finally, ensuring the user is aware of any potential risks is an important part of risk communication, and this can be achieved through effective packaging, including an informative pack leaflet.

Once marketed the safety evaluation process of a medicinal product does not stop. Post-marketing surveillance procedures are required to capture any unexpected harmful effects of a product so that the benefit-risk profile of a veterinary medicinal product can be periodically reviewed.

Position

IFAH's mission is to promote a predictable, harmonised and science-based regulatory approval process that facilitates the availability of quality animal medicines, vaccines and other animal health products. A major attribute of the animal health industry is the requirement that any new veterinary medicinal product must be subjected to a stringent, scientific and objective review of a data dossier covering all aspects of the quality, safety and efficacy of the product. This marketing approval process is underpinned by an assessment of both the benefits and risks associated with the intended use of the product.

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A science-based risk analysis is the most effective method for judging the risks that might be associated with the use of animal health products and balancing them against the benefits that the products bring to the animals treated and to society as a whole. The use of benefit-risk assessment during the safety evaluation allows authorities to make informed and science-based decisions about the proper use of animal health products to treat and prevent diseases in animals. These decisions, and the basis for them, must then be effectively communicated to all stakeholders and interested parties to ensure the process is transparent and understood.

The animal health industry, through IFAH, strongly supports the use of science-based risk analysis as a basis for making public policy decisions about the approval and use of animal health products, and encourages its use by authorities that regulate veterinary medicinal products.

Summary

Licensed veterinary medicinal products have passed an independent scientific assessment of their quality, safety and efficacy. Risk analysis principles are used to ensure the products have an appropriate benefit-risk balance. Post-marketing surveillance procedures provide a mechanism to ensure that the benefit-risk profile of veterinary medicinal products in the market-place remain positive.

Additional Background Information

Risk Analysis terms in the context of the regulation of veterinary medicines

Risk analysis is a process consisting of three interconnected components, namely benefit-risk assessment, risk management and risk communication. This process makes the important differentiation between a 'hazard' (something that could be harmful) and a 'risk' (the likelihood of the hazard occurring).

Benefit-Risk assessment is a science-based process for a safety evaluation, to support appropriate decision-making, consisting of four steps: hazard identification, hazard characterisation, exposure assessment, and benefit and risk characterisation. In the context of veterinary medicines, it examines the specific use of the product to ensure the benefits outweigh any potential risks.

The benefit-risk balance will be different for each product, depending upon, for example, the severity of the disease being treated. The final benefit-risk balance will be affected by any risk management measures (see below) that could be imposed to minimise any potential risk.

Risk management is a process, undertaken by the authorities, of setting appropriate conditions of use for the medicine to reduce potential risk to an acceptable level. If this cannot be done then the risk management decision will be to refuse marketing authorisation for the product. The risk management measures should be proportionate to the level of risk identified in the risk assessment. The process may involve weighing different policy alternatives in consultation with interested parties. Risk management measures could include label warnings and label restrictions that limit the use of the product to defined situations or by trained professionals.

Risk communication is the exchange of information between the authorities, manufacturers, the public and other interested parties about the outcome of the risk analysis process. It should address the risk factors, risk management measures and risk perceptions. In any event, all stakeholders and interested parties must be in a position to fully understand the decision making process and the requirements that must be met to safely market and use the product. Risk communication must be pro-active, transparent and objective.