Health for Animals
global animal medicines association

ANIMAL MEDICINES AND THE ENVIRONMENT

Principles and Practices

Contents

This document was produced by HealthforAnimals, the global animal medicines association. HealthforAnimals represents the animal health sector: manufacturers of veterinary pharmaceuticals, vaccines and other animal health products throughout the world, as well as the associations that represent companies at national and regional levels. The terms 'Animal Health Industry,' 'Animal Health Sector,' and 'Animal Health Companies' in this document refer only to HealthforAnimals Members. HealthforAnimals does not speak for any companies outside our Membership, but encourages them to also follow the principles and practices outlined in this document. To learn more about HealthforAnimals, visit our website: ***www.HealthforAnimals.org***.

Introduction

Protecting our environment is essential for the long-term health of both people and animals. Many private and public actors are rightly paying more attention to the release of medicines into the environment. Managing emissions and limiting any potential environmental impacts will help achieve the Sustainable Development Goals (SDGs) focused on the environment – in particular Goals 6, 14 and 15: clean water and sanitation, life below water and on land.

Sustainable Development Goals

Animal health companies recognize that we have a fundamental role to play in environmental protection, alongside our mission to protect the health and welfare of animals.

The responsible use of vaccines, parasiticides, antibiotics and other products, coupled with good husbandry, biosecurity, and veterinary access can prevent and treat animal disease. This leads to more economically sustainable farms that contribute to food security, nutrition, food safety and economic growth, and healthy pets who can share our homes. It also continues progress towards SDGs such as no poverty, zero hunger and good health and well-being.

This cannot come at the expense of our environment. While animal medicine companies cannot take on this challenge alone, we are committed to collaboration with other stakeholders to better understand, measure and mitigate environmental impact.

Minimizing the impact of medicines on the environment requires action throughout the life cycle. Manufacturing plays a role, however, due to highly controlled conditions and processes, the potential for releases into the environment is generally very low in comparison to the use and disposal phases. Therefore, companies must work with and rely on others in the life cycle of a medicine to ensure responsible stewardship.

The following sections outline the four key considerations in the life-cycle of a medicine: Development and Authorization; Manufacturing; Use and Disposal; and Limiting Impact after Use.

Each section identifies how animal medicines companies are acting, while also highlighting areas where others can support better environmental protections. The final graphic, *Environmental Protection: A Collective Responsibility*, outlines this in clear detail.

Principles

Animal health companies adhere to the following principles throughout the life-cycle of medicines:

1. We take a holistic OneHealth approach, carefully considering human, animal and environmental health.
2. We lead on product stewardship, taking responsibility where we can, throughout the product life-cycle – development, manufacture and use. We take risk-based measures to minimize impacts on target/non-target organisms and to minimize potential negative impacts on the environment.
3. We support strong enforcement of rules/regulations and we operate in compliance with applicable laws, and in some cases go beyond. We measure our performance and strive to continuously improve.
4. We view the environment as a joint responsibility we have together with suppliers, distributors, animal owners, veterinarians, regulators and others. We work collaboratively with all to fill knowledge gaps.
5. We support transparency of relevant information throughout the product life-cycle.

Development and authorization

The first phase in a product life-cycle is discovery, development and authorization.

Product development is a complex process that includes the need to balance different demands. Effective products must offer conveniences to the animal and the animal owner. Researchers must consider safety, efficacy, dosage and duration as well as animal handling. If there are multiple strong candidates in terms of efficacy, companies will select the one with best safety profile, which includes environmental safety.

During the **authorization process**, government regulators assess a product on three aspects – efficacy, safety and quality. Environmental safety is part of this process, which in many regions includes a mandatory environment risk assessment. The assessment conducted for veterinary medicines used in livestock and aquaculture includes predicting environmental concentrations and assessing potential impacts on indicator species in the environment, including effects on beneficial organisms. In addition, information on potential environmental impacts are also considered in pharmacovigilance systems.

Most animal medicines are found to be safe, but if regulators determine environmental or other risks outweigh the benefits, a product will not be authorized.

Animal health industry practices during development and authorization

1. Early in the development phase, animal health companies **characterize relevant environmental properties** of new potential products. This allows for selection of those substances and products that have lower potential impact on the environment.
2. Animal health companies comply with **the stringent legal standards/requirements** set by national and international health, animal and environmental regulatory agencies. As part of the authorization dossier, an environmental assessment that includes potential environmental impact, must be included in many constituencies.
3. Animal health companies' **product labelling and information leaflets carry information** on relevant environmental properties, which include proper use/disposal instructions warnings against improper use.
4. Animal health companies **support transparency of environmental study end points** by results being made publicly available by Authorities in the documents they publish setting out the basis for their decisions.
5. Animal health companies **promote and contribute to international cooperation**. The sector has worked for over 25 years together with leading regulators to establish VICH guidelines. The guidelines include consideration of environmental impacts.
6. Animal health companies are **developing and funding a broader range of products/solutions**, such as vaccines, digital tools, diagnostics, etc. leading to more targeted use of their products.

Manufacturing

The manufacturing of approved animal health products involves a complex global supply chain. In many cases, animal health companies have their own facilities where products are manufactured from start to finish. Products and/or active ingredients for products are also manufactured under contract by other companies, often called 'third parties.' For the animal health sector, this often happens in the same facilities where human health products are manufactured.

Third party production facilities, where animal health companies do not have direct operational control, must comply with detailed procedures and rules set out in legislation and regulation. These relate to worker safety, water and air use, waste disposal, etc. In most countries these facilities are carefully and regularly inspected by authorities and by the companies whose products are made there.

Significant manufacturing of active pharmaceutical ingredients (APIs) takes place in the Asia-Pacific region as well as in Central and South America. In some cases, there are reports on emissions of APIs in the effluents of some API manufacturing plants and adjacent rivers at unacceptably high concentrations. Efforts have been made, and continue to be made, to improve emission control at manufacturing facilities. Industry is minimizing residues of APIs in effluents emitted from their own manufacturing facilities using the most appropriate techniques, and expect their suppliers do the same. In many countries there is legislation in place which deals with industrial emissions. It is important that these facilities are compliant with strict environmental controls. Governments have the authority and responsibility to examine applications and issue or refuse permits for manufacturing sites that are not compliant.

Animal health industry practices related to manufacturing

1. Animal health companies comply with stringent legal standards and requirements, including national and international laws regarding pollution and disposal.
2. Animal health companies ensure that protection of the environment in their supply chain is a priority. Examples include: embedding (longer-term) emission control expectations into supplier contracts; imposing supplier codes of conduct; including emission controls reviews into supplier audits; and providing training and assistance to suppliers.
3. Animal health companies partner and educate to enforce. Many companies are actively involved in joint initiatives to increase leverage, for example the Pharmaceutical Supply Chain Initiative (PCSI) group of pharmaceutical companies who have joined forces to promote responsible supply chain management and better business conditions across the industry.

Use and disposal

Although very limited, there are different pathways for animal medicines to enter the environment. This depends on the product, the target species and the use of the product. The use phase is the largest potential contributor to emissions into the environment, most notably through excretion.

Companies perform environmental risk assessments which focus on the use phase and consider the latest scientific guidance and knowledge. These risk assessments establish whether there is a need for additional label warnings or controls.

In terms of the usage of antiparasitic products, there are concerns about impact on beneficial organisms like dung beetles. Regarding antibiotics there are questions about the potential spread of resistant bacteria through the environment. There are many gaps in our understanding of the role that the environment plays in AMR transmission and it is currently unclear whether manure from animals treated with antibiotics has any impact on public health or the environment.

Nonetheless, in both cases, there have been significant **improvements in agricultural practice around the world that have led to positive impacts**. These include controlling application of manure, more selective and targeted use of products and more responsible use.

Residues of various types of medicinal products have been detected in the environment in water, soil, air, and biota. However, the European Commission has stated, *"No clear link has been established between pharmaceuticals present in the environment and direct impact on human health"*[1]. The WHO has also said that *"adverse health impacts to humans are very unlikely from exposure to the trace concentrations of pharmaceuticals that could potentially be found in drinking water"*[2].

Although different countries have different systems, **disposal of unused products is not a major issue in animal health sector**. Companies strongly encourage compliance with national requirements and instructions for correct disposal are provided with all products.

In addition, if a product is administered by a veterinary professional, unused medicines can also be taken back, used on other farms or disposed of responsibly. For companion animals, most medicines are administered at the veterinary clinic, but for the small fraction administered at home, veterinarians and product labels provide proper disposal instructions.

Animal health industry practices related to consumption and disposal

1. Animal health companies **provide veterinary products with explicit details on their use and disposal**. Such details are included on the packaging and disposal instructions vary per country depending on national regulations.
2. Animal health companies **monitor any reported environmental incidents involving their products** through pharmacovigilance systems, and take appropriate action.
3. Going beyond statutory requirements, companies **proactively work to increase knowledge of the appropriate disposal** of unused medicines in markets where this is not well organized.
4. Animal health companies **undertake a range of activities related to antibiotics**, such as promoting responsible use, joining food-chain coalitions undertaking specific reduction measures, informational activities and investment in the development of new products (vaccines, nutritional products, etc). As a result, the need for veterinary antibiotics is decreasing in major markets. Specific activities being undertaken by the animal health sector can be seen in the "*Roadmap to Reducing the Need for Antibiotics*" available at www.HealthforAnimals.org/Roadmap
5. Animal health companies undertake a **range of activities related to antiparasitic products**. These include responsible use guidance, encouragement of more targeted use of products, training of livestock and pet owners in correct use and product administration.

[1] European Union Strategic Approach to Pharmaceuticals in the Environment, European Commission, 11 March 2019, https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

[2] Pharmaceuticals in drinking-water, World Health Organisation, https://apps.who.int/iris/bitstream/handle/10665/44630/9789241502085_eng.pdf?sequence=1

Limiting impact after use

While proper disposal largely prevents unused medicines from reaching the environment, animal excretion is an unavoidable pathway.

However, this can be well managed, which helps limit environmental impacts. Livestock manure, especially on large scale farms, is often collected on-farm, stored and/or treated (e.g. composting, allowing it to dry in the sun, or using it in biogas installations), and then used/sold as a crop fertilizer, while animals kept on pasture may excrete directly onto the soil.

Medicine residues still in the manure may leach into the soil over time and/or transfer into waterways. Throughout this slow and lengthy migration, different processes of chemical and biological degradation may occur that break down the medicine, which reduces their potential environmental impact.

The environmental risk assessment for livestock veterinary medicines undertaken by companies considers this pathway and potential harm to the environment. Additional label instructions or control can be specified by regulators and only animal medicines determined to be safe for the environment are approved.

Environmental Protection: A Collective Responsibility

Protecting the environment requires action throughout a medicine's life cycle. Authorities, users, suppliers, veterinary professionals, farms, and retailers must be aware of their respective roles.

Development and authorization

Authorities:
Assess applications, including the environmental impact

Authorities:
Apply risk mitigation measures

Authorities:
Set and enforce stringent legal standards

Authorities:
Publish decisions and the basis for these (including end points)

Actions that can be taken by Animal Health companies

Characterize relevant environmental properties

Evaluate substances with lower environmental impact

Comply with stringent legal standards/ requirements

Assess potential environmental impacts and review in dossier

Create guidelines for responsible use

Generate relevant end point data

Manufacturing

Authorities:
Set and enforce stringent legal standards

3rd party suppliers:
Comply with legal standards

3rd party suppliers:
Continuously improve environmental emissions standards

3rd party suppliers:
Strictly comply with client codes of conduct

Actions that can be taken by other stakeholders

Comply with stringent legal standards and Good Manufacturing Practice standards

Regular audits of active ingredient suppliers

Create strict supplier codes of conduct, including emission control expectations

Train suppliers on compliance and responsible manufacturing

Use and disposal

Authorities:
Create systems for proper disposal

Retailers:
Distribute authorized products with advice on usage

Veterinary:
Prescribe most appropriate products/dosage

Veterinary:
Collect unused products or help educate user on proper disposal

User:
Proper use and disposal according to label

Farm:
Create and implement manure management plans

All:
Report adverse incidents into pharmacovigilance systems

Provide guidelines and education for responsible use and disposal

Monitor incidents through pharmacovigilance systems

Partner with veterinary, farmer, and other value chain groups for improved use and disposal

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