

# **Global Antimicrobial**

# Policy

### **Our Purpose**

As a company dedicated to animal health, Elanco recognizes our ethical obligation to help veterinarians and farmers responsibly use antimicrobials — including antibiotics — when treating animals. Our purpose is to protect the health of both humans and animals, while also guarding the safety of food.

We understand that consumers, along with people who raise and prepare food, often have questions about how and why antibiotics are used to protect animal health and welfare. We take these questions seriously, which is why Elanco has instituted a company-wide antimicrobial policy to guide our work throughout the world.

# What is responsible use?

Responsible use means providing the right dose at the right time to the right animal.

Our global policy is designed to enable continued, responsible antimicrobial use while protecting the long-term viability of antimicrobial products for human and animal health.

The policy also guides business decisions as we dedicate resources to identifying, developing and promoting new animal-health innovations. And, it provides direction for how we will support market access for meat and dairy products derived from animals treated with antibiotics, ultimately enabling free trade and food security for a growing world.

## **Our Guiding Principles**

- Elanco supports the responsible use of antibiotics in farm animals to protect human health and food safety, and to ensure animal health and welfare.
- Elanco advocates for the development and use of animal-only antibiotics, which are developed specifically to promote animal health without impacting the effectiveness of human medicines.
- Elanco will voluntarily narrow the approved uses of Elanco's shared-class antibiotics (those used in both human and animal medicine) to therapeutic-only uses in animals.
- Elanco will not promote the use of shared-class antibiotics for animal growth, animal performance or productivity enhancement.
- Elanco will transition current label indications for shared-class antibiotics to therapeutic-only determined by regulatory-review and -approval processes globally.
- Elanco supports veterinary oversight of shared-class antibiotics for therapeutic purposes in animals.
- Elanco supports the development of enhanced tools that will allow veterinarians and farmers to verify and validate their responsible use of antibiotics.
- Elanco has the responsibility to share accurate information about why antibiotics are used in animals so consumers, supermarkets, veterinarians and farmers can make informed decisions about antibiotic use.



## Our Role

#### Lead. We will:

- Provide leadership on the topic of antibiotic use to our customers, farmers, veterinarians and other farming stakeholders, including the food chain, government policy makers and non-governmental organizations (NGOs)
- Voluntarily narrow the approved uses of Elanco's shared-class antibiotics to therapeutic-only use in animals
- Globally advocate for and actively support professional oversight of antibiotic use and responsible-use programs

#### Engage. We will:

- Seek to understand and address questions about how animals are raised to build confidence in the responsible use of antibiotics for animal health and welfare
- Consider it the responsibility of everyone involved in raising animals to provide clear, honest answers about why antibiotics are used
- Use market research and other insights to help those in the food chain respond to questions, reassuring consumers they can trust in the responsible use of antibiotics to protect animal health

#### Collaborate. We will:

- Understand that farming stakeholders, consumers and our customers will ask questions about how to best use antibiotics for animal health, and we will collaborate with them to use antibiotics responsibly
- Work with farming stakeholders, customers and consumers to enable the responsible use of antimicrobials in animals, protecting the long-term viability of antibiotics for human and animal health



## **Our Rules of Engagement**

The following guidance will help us be good stewards of Elanco's antimicrobial products:

**About Elanco's internal governance:** The Elanco Antimicrobials Lead Team (ALT) will govern the company's antimicrobial policy, and guide company teams as they develop and market antimicrobial products for food animals.

**About product registrations:** Elanco will continue to seek regulatory approvals for therapeutic uses of antibiotics in all antimicrobial classes. We also will continue marketing current antimicrobial products and research new ways to use them, while actively seeking innovative alternatives for animal care. Specifically:

- Elanco will actively and publicly differentiate between animal-only and shared-class antibiotics
- Elanco will not pursue new performance-based regulatory approvals (gain, efficiency of gain, growth promotion) for shared-class antibiotics
- Elanco will research new performance indications for animal-only antibiotic classes
- Elanco will pursue therapeutic-only approvals and not performance claims for new antibiotic alternatives that demonstrate antimicrobial activity with significance for human medicine

**About new product development:** Research-and-development (R&D) teams will actively work to commercialize products that support healthy animals and their productivity, providing comprehensive animal-health solutions to benefit the entire food chain — from the farm through harvest, processing and distribution. We will continue to seek new antimicrobial alternatives.

**About professional oversight:** Elanco supports oversight of antibiotic use by trained professionals, including veterinarians and other experts in animal care. Where an appropriate veterinary infrastructure — including legislative, professional and educational support — is lacking, Elanco will identify opportunities to support and invest in developing a veterinary infrastructure to enable responsible oversight of antibiotic use in farm animals throughout the world.

**About risk-based assessment of antibiotic classes:** Since antimicrobials are not all alike, policies and regulations should reflect that all antimicrobials do not offer the same societal risk for resistance. That is why Elanco supports risk-based assessment and regulatory review of products, resistance-monitoring programs, and appropriate sales-data and surveillance programs — all based on sound scientific research.

**About partnerships:** Elanco will work with animal-health associations, animal-agriculture organizations, key opinion leaders, academic institutions, food chain stakeholders, governments and regulatory bodies, NGOs and others to proactively advance shared initiatives that protect the health of both humans and animals, while also guarding the safety of food.

#### **Our Business**

Elanco supports the responsible use of antimicrobials under veterinary oversight for therapeutic purposes, which include treatment of disease, as well as strategic, targeted use of antimicrobials when animals are exposed to disease or are likely to become sick. We will collaborate with other stakeholders to ensure antibiotics, especially shared-class antibiotics, are used responsibly to treat and prevent animal diseases.

Furthermore, Elanco will pursue new advancements to broaden our approach to keeping animals healthy. We will invest in R&D and technical support while also supporting legislation, professional development and education that give farmers access to the best information and resources regarding animal welfare and food safety.



# **Global Market Access**

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