

Antibiotic Stewardship Executive Summary

A Summary of Progress

8-POINT ANTIBIOTIC STEWARDSHIP PLAN



Act with Responsibility Globally

Elanco has worked with more than 10,000 producers, veterinarians and food chain partners globally to help improve responsible use of antibiotics, including:

- Creating awareness of pending regulatory changes
- Providing counsel on policy creation and resulting practice changes
- Offering analysis of supply chain implications from potential policy changes
- Sharing research into consumer perceptions and how to address consumer questions about antibiotics
- Delivering health monitoring and tracking data to producers to help them to them make more informed animal health and care decisions to potentially reduce the need for antibiotic treatment

Data and the counsel of the Elanco team has helped shape antibiotic policy to establish or enhance responsible use of antibiotics for dozens of protein value chain partners across the globe, as well as helping to ensure the products and tools regulators prefer are used in the food system.



Cease Marketing of Growth Promotion Uses for Shared-Class Antibiotics

Elanco stopped all marketing of growth promotion uses of shared-class antibiotics around the world by August of 2016. The company has also completed 97 label change submissions to remove growth promotion claims around the world for four shared-class molecules.



Eliminate Continuous Use of Shared-Class Antibiotics for Therapy Where Alternatives Exist

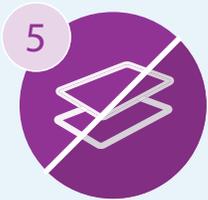
Elanco is pioneering new research to better understand liver abscesses in cattle, a disease condition that requires continuous use without viable alternative options. Elanco's research includes efforts to better understand the disease model, exploring alternative dosing programs, vaccine combinations and alternatives to shared-class antibiotics.

Under U.S. Food and Drug Administration's (FDA) Guidance 209 and 213, the current label for liver abscesses remains as a therapeutic use, but Elanco has submitted label changes to require veterinary oversight via a Veterinary Feed Directive (VFD). We've accelerated our efforts to identify alternatives, but until a solution is found, it's incredibly important that policies don't get ahead of the science, which could jeopardize animal welfare or food safety.



Eliminate Over-The-Counter Sales of Shared-Class Antibiotics, Where Oversight Exists

Elanco has completed submission of 67 labels for five shared-class molecules to move products from over-the-counter use to be under the oversight of a veterinarian in the United States, Canada and Brazil, the countries where over the counter uses remained and veterinary infrastructure exists. Building greater veterinary capacity is a critical need in many countries.



Eliminate Concurrent Use of Shared-Class Antibiotics to Treat the Same Disease

Elanco does not support concurrent use of shared-class antibiotics to the same disease where there is no co-formulation approved.



Support Veterinary Oversight

Elanco convened industry leaders at a One Health Antibiotic Stewardship Summit to identify actions to build veterinary training and capacity where gaps exist globally. A committee formed from that meeting is working to:

- Identify a self-sustainable model for providing veterinary services in a way that meets the needs of varying sizes and levels of operations plus assuring appropriate antibiotic use
- Create recommendations that elevate global veterinary standards through curriculum and certification
- Identify gaps in global animal health care including pharmacovigilance and discuss pathways to expand veterinary and para-veterinary capacity and responsibility to meet those needs



Develop New Animal-Only Antibiotics

Antibiotics classes used exclusively in animals pose virtually no risk of contributing to human bacterial resistance and can help reduce the need for shared-class antibiotics. In 2016, Elanco gained U.S. approval for two new animal-only antibiotics in pork and poultry, giving producers new alternatives to protect animal health and well-being without affecting antibiotic treatment outcomes for people. The products:

- Prevent mortality caused by necrotic enteritis in poultry
- Reduce the incidence and severity of diarrhea caused by pathogenic E.coli in weaned pigs



Create Alternatives

Elanco has identified nearly 50 new development ideas for assessment, with 17 new candidates entered into Elanco's pipeline and 12 additional candidates completing proof-of-concept studies within the next year. Elanco's research efforts have focused on the greatest areas of unmet need for livestock producers, where shared-class antibiotics are the primary option today. New candidates include solutions for swine and bovine respiratory disease that causes pneumonia, and enteric or intestinal diseases in pigs, which cause a number of health challenges including diarrhea.

In 2016, Elanco launched or expanded geographic availability of four antibiotic alternatives including vaccines, enzymes and a protein. The first-of-its-kind protein helps support the natural function of a dairy cow's immune system, reducing the incidence of clinical mastitis in the first 30 days of after calving.

Species	Target Diseases	Pipeline Entry	2016 New Approvals	Ongoing Assessment
 Beef	Bovine Respiratory Disease	✓		✓
 Beef	Liver Abscess			✓
 Dairy	Mastitis		✓	✓
 Poultry	Coccidiosis			✓
 Poultry	Necrotic Enteritis		✓	✓
 Swine	Enteric	✓	✓	✓
 Swine	Porcine Respiratory Disease Complex	✓		✓

NEW COMMITMENTS



Developing New Alternatives

By 2020, we believe we can provide solutions that address five of the most critical unmet livestock disease challenges in a fundamentally new way. Other new commitments include:

- Opening of the Elanco Vaccines Innovation Center in June of 2016. This state-of-the-art laboratory has space for up to 100 scientists, and near-term projects include vaccines for salmonella and Bovine Respiratory Disease
- Partnership with EnBiotix to explore application of engineered phage technology for bacterial infections as an alternative to traditional antibiotics
- Partnership with Kansas State University to explore discovery and development of a liver abscess vaccine
- Creation of the Elanco Alternatives to Animal Antibiotics Grand Challenge awarding more than \$2 million to support identification of new and novel ways to treat liver abscesses in cattle, necrotic enteritis and coccidiosis in poultry and lawsonia and strep suis in pigs without antibiotics



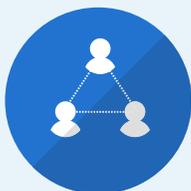
Building Nutritional Health Capability

Using the most advanced science, Elanco's newly-formed Nutritional Health organization will develop, manufacture, and market products that fit and shape consumer preferences across all production systems. Our focus includes a range of products which will improve the health of animals through nutrition while providing value to our customers. These products could include prebiotics, probiotics, and enzymes, among additional technologies which improve the gut health of animals and reduce the use of conventional antibiotics. In addition to Elanco's current products in this space, the new business is anticipated to deliver two new products to customers annually between 2017 and 2020.



Prevention 360: Creating Value by Aggregating Information, Interventions and Innovation

In an effort to reduce the need for antibiotics to treat animal illness, the industry is increasingly focused on disease prevention and early disease detection. Elanco is helping prevention and detection efforts globally by linking diagnostics and production outcomes with integrated analytics to predict disease risk and design sustainable solutions. With expanded access to data, a growing product portfolio, and precision application, antibiotic alternatives such as vaccines, enzymes, and probiotics will become more reliable and more effective. Our vision is not just to move from treatment to prevention, but to develop technologies that promote health even before an animal is born—this can reduce the need for antibiotic use while maintaining animal welfare and improving food security.



Facilitate Greater Collaboration

Elanco convened more than 200 global animal protein industry leaders during 2016's One Health Summit, including more than 50 CEOs and owners, intergovernmental organizations, NGOs and experts. As an outcome of the Summit, those participants have formed three technical work streams to address critical challenges such as:

- Increasing global veterinary training and capacity
- Enhancing metrics and monitoring of responsible use globally
- Increasing incentives for innovation and working to enhance predictability of regulatory pathways