



# The U.S. and EU Animal Pharmaceutical Industries in the Age of Antibiotic Resistance

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## What Is the Issue?

Antibiotic drugs are a lifesaving technology widely used in human and veterinary medicine. However, the use of antibiotic drugs also creates selective evolutionary pressures that can spawn microbes and genes resistant to the drugs. Antimicrobial resistance has become an important global human health concern, with widespread public and private initiatives aimed at managing resistance.

The animal pharmaceutical industry (or “animal pharma”), a research-intensive business, is the source of antimicrobial drugs, biological products (like vaccines), pharmaceuticals other than antibiotics, and other health products for animals. It develops and markets products not only for livestock but also for companion animals like dogs and cats.

Animal pharma has been pivotal in driving agricultural productivity growth worldwide. However, the industry faces new challenges with the growth of concern over antimicrobial resistance. The demand for animal pharma products, the development of new products, and the regulatory environment are all affected by antimicrobial resistance concerns.

On the one hand, growing concern has led to more rigorous regulations on the use of antibiotics in food-animal production, rising demand for food products raised without antibiotics, and wider adoption of disease-reduction methods. These developments, in turn, may have the effect of decreasing sales of antibiotic products, lowering incentives to invest in new livestock antibiotics, and raising incentives to invest in non-antibiotic products. On the other hand, growing export demand for meat from the United States and the European Union (EU), rising animal disease pressures brought about by increasing globalization, and antibiotic resistance in animals may accelerate demand for antibiotics use and continue to provide incentives to develop new veterinary antibiotics.

Integrating data from many sources, this report analyzes the trends in sales of veterinary antibiotics and new product development by the U.S. and EU animal pharma industries. U.S. and EU regulatory processes are the focus because the United States and EU comprise approximately 60 percent of the animal pharma market and host the headquarters of all of the leading animal pharma firms. Furthermore, because many products are initially aimed at U.S. and EU markets, they are generally subject to approval through U.S. or EU regulatory processes.

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## What Did the Study Find?

### Sales of Antibiotics for Food-Animal Production

Between 2015 and 2017, total U.S. sales of antibiotics for food-animal production declined 30 percent (by weight), after annual increases in each year between 2009 and 2015. From 2010 to 2015, in 17 EU countries, antibiotics sales for production dropped 31 percent. The following factors have influenced these sales:

- U.S. consumer demand for products raised without any antibiotics has risen, particularly for poultry. In 2017, approximately 44 percent of U.S. broilers were raised without antibiotics, up from 2.7 percent in 2012.
- The steady increase in U.S. and EU production of meat over the past two decades—largely due to rising export demand, particularly from Asia—is raising demand for antibiotics sales in the United States and EU.
- U.S. restrictions on use of growth-promoting antibiotics enacted in 2017 appear to have contributed to declines in antibiotics sales, and similar European regulations are generally correlated with declines in overall antibiotics sales.

### Development and Approval of New Animal Pharmaceutical Products

- Although research and development (R&D) dollars spent in the animal pharma industry have increased, the number of new animal drugs approved in the United States has declined, leading to an increase in R&D dollars spent per newly approved drug.
- Besides declining in number, new drug approvals have also changed in type: companion-animal products constitute an increasing share of new animal drug approvals in the United States. Because most drugs are not approved for both food and companion-animal use, this finding suggests the increasing share of animal pharma R&D devoted to companion-animal pharmaceuticals comes at the expense of food-animal pharmaceuticals.
- Approvals of food-animal antibiotics have declined both in number and as a share of approvals of all food-animal pharmaceuticals. Since 1992, most new antibiotic approvals for use in food animals have been generic drugs that are also used in human medicine.
- Since the inception of generic drugs in the United States in 1992, these drugs account for approximately half of new U.S.-approved veterinary drugs. Drug categories with the most generic competition also tend to have fewer drugs with novel active ingredients, suggesting that generic competition may tend to suppress R&D in these categories.
- A 2003 regulation increasing requirements for new antibiotics approved for food-animal use did not affect the number or types of antibiotics brought through regulatory approval.

## How Was the Study Conducted?

This report compiles and analyzes data from a variety of sources, including meat production and export data from multiple countries, antibiotics sales data from both the U.S. Food and Drug Administration's Center for Veterinary Medicine and the European Medicines Agency, animal pharmaceutical industry data from firm annual reports and industry trade groups, and license data for U.S. veterinary biologics from USDA's Center for Veterinary Biologics. Trends in antibiotics sales and development for food-animal use are analyzed using a newly generated dataset of animal pharmaceutical product approvals. An econometric model is used to analyze whether drug development was affected by the introduction of a 2003 regulation requiring more robust testing for approval of new food-animal antibiotics.