

This document provides the collective answers of the six [HealthforAnimals Members](#) to the questions sent by the FAIRR Initiative in June/July 2022 as part of their ongoing 'engagement.' These answers have also been posted on the [HealthforAnimals website](#) so others may view our Members perspectives and commitment to responsible use of animal medicines.

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### **Introduction: Trends of antibiotic use in animals**

Global use of antibiotics in animals continues to decline according to the World Organisation for Animal Health (WOAH, formerly OIE). Its June 2022 '[Annual Report on Antimicrobial Agents Intended for Use in Animals](#)', indicates that the 'use of antimicrobials in animals across the world has shown an overall decrease of 27% between 2016 and 2018'. It noted these levels of declines across all its regions and greater levels of reduction in some antibiotic classes.

The latest United States FDA report: '[Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals](#)' noted a 38% reduction in the sales of medically important antibiotics for use in livestock since 2015.

The latest report from the European Union: '[European Surveillance of Veterinary Antimicrobial Consumption \(ESVAC\)](#)' published by EMA, shows that European countries have reduced the use of antimicrobials in animals from 2011 by 43%.

Data from other countries also indicate continued significant reductions in the need for antibiotics in animals in their countries, particularly those critically important to human health.

Furthermore, [global sales data from HealthforAnimals Members](#) demonstrates that antimicrobials are a shrinking segment of the wider product portfolio. Antimicrobials share of the product portfolio saw a 28% relative decline from 2013-2021, reflecting the global push for more preventative care. However, it is important to note that this data only includes HealthforAnimals Members; it is unclear whether smaller, national / local companies are achieving similar results.

However, it is essential to note that while significant reductions have been achieved – antimicrobials will always remain an important part of veterinary care. There is no alternative to antibiotics when an animal is sick with bacterial disease.

### **A.1. Demonstrating effective management of antimicrobial residues in manufacturing and production**

#### **1. How does the company's environmental risk management (ERM) strategy address antimicrobial residues in manufacturing effluent? For example, setting discharge limits for antimicrobial residues, and monitoring adherence through audits.**

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.

Each company adopts a strategy tailored to their supply chain that ensures environmental concerns are addressed at each stage of medicine production. However, no matter the approach, three principles underly this work:

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

Facility audits are an important part of ensuring compliance with these principles. It is why in the Animal Health sector's [Roadmap to Reducing the Need for Antibiotics](#), HealthforAnimals Members pledged to undertake at least 50 audits of active ingredient suppliers by 2025. The [2021 Roadmap Progress Report](#) found that Members had already conducted 206 audits – 4x more than initially pledged – between 2019-2021.

**2. How does the ERM strategy apply to (i) owned and/or operated manufacturing sites; (ii) third-party manufacturers and suppliers of antimicrobial APIs and finished products; and (iii) external waste treatment plants?**

The three principles outlined above apply no matter where a medicine is produced. Whether production is done 'in-house' through a company-owned facility or with an external / third-party contractor, animal health companies have processes to help ensure adherence to the necessary environmental standards.

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 regularly inspected by authorities.

Furthermore, HealthforAnimals Members work to minimize residues of APIs in effluents emitted from their own manufacturing facilities using the most appropriate techniques, and expect their suppliers do the same. Companies will conduct regular audits to ensure proper compliance and implement corrective measures, implement supplier codes of conduct, embed emission control expectations in contracts, and conduct on-site trainings.

**3. How does the company ensure compliance to the specifications for antimicrobials in the environment in its ERM strategy and how is non-compliance addressed? For example, using corrective action preventative action plans (CAPA).**

Environmental strategies cover production of all medicines, not simply antimicrobials. Furthermore, when a problem is found with a supplier – whether in adherence to environmental standards or any other part of the manufacturing process – companies take corrective action.

HealthforAnimals Members recognize that high-quality, reliable medicines require high-quality, reliable production. In many markets, it is this recognition that sets our Members apart from local suppliers. Allowing a supplier to produce medicines in breach of contractual requirements is a poor business decision that risks a company's reputation for quality medicines.

**4. Please provide a breakdown of the countries of origin where the APIs and finished pharmaceutical products (FPPs) in your antimicrobial portfolio are manufactured.**

HealthforAnimals is unable to address this question. Coordinating and collecting this type of data across companies creates anti-trust concerns.

**A.2. Supporting efforts to reduce antimicrobial residues entering the environment from farms**

**1. How is the company supporting efforts to reduce antimicrobial residues from farm effluent entering the environment?**

Once a medicine reaches the farm and is administered to an animal, it is important to limit entry into the environment. Companies work with customers on this process through actions such as:

- Clear labels on every product that provide guidance on use, management and disposal
- Guidelines and education for responsible use and disposal
- Incident monitoring through pharmacovigilance systems
- Partnerships with veterinary, farmer and other value chain groups in some markets for improved use and disposal

However, environment entry must also be address across the value chain, including actions such as:

- **Authorities:** Creating systems of proper disposal
- **Retailers:** Distribute only authorized products
- **Veterinarians:** Prescribe the most appropriate products and dosage; Collect unused products or help educate users on disposal
- **Users:** Use and dispose of products according to the label; Create and implement manure management plans
- **All stakeholders:** report adverse incidents into pharmacovigilance systems

In addition, all veterinary medicines (not just antimicrobials) are subject to an environmental risk assessment before reaching the market. These assessments are a multi-phase process evaluating potential impacts on the environment, non-target organisms, etc. and a positive opinion is required for approval. Environmental risk assessments are a unique process for animal medicines that ensure these products do not pose any undue risk to the wider environment.

It is important to also note that although residues of various types of medicinal products have been detected in the environment, the [European Commission has stated](#), "No clear link has been established between pharmaceuticals present in the environment and direct impact on human health." The [World Health Organisation has also found](#) 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."

**B. SALES & MARKETING PRACTICES**

## **B.1. Applying a consistent sales and marketing approach in line with best practice**

- 1. What is the company's strategy for the responsible sale and marketing of antimicrobials and how does this apply across the company's operating markets and geographies? For example, phasing out marketing of shared-class antimicrobials in one region, reducing packaging sizing across the business. How does the company define responsible antimicrobial use?**

Animal health companies' strategy for marketing and sales is to provide the right product for the producer's specific situation. This may be vaccines, nutritional supplements, diagnostics, digital monitoring technologies, parasite control or antibiotics.

Furthermore, responsible use of antimicrobials will ultimately look different dependent upon the species, region, disease pressures, etc. Veterinarians typically rely upon an approach of -- the right drug at the right time at the right dose for the right duration. Guidelines found in human medicine, such as the [UK's NICE guidelines](#) and U.S. CDC's [stewardship activities](#), follow a similar approach.

Overall, companies support prevention as the first line of defense against disease. Increased adoption of vaccines, nutritional supplements, digital monitoring tools, diagnostics, etc., supports animal welfare, while also reducing the need for antibiotics.

The global shift in the animal health product portfolio over the past eight years shows that customers support this message. [Since 2013](#), antimicrobials have fallen 28% as a proportion of the wider product portfolio, while vaccines have risen 11%.

- 2. Has the company considered removing indications for growth promotion and prophylaxis from the labels of medically important antibiotics (MIAs) and critically important antimicrobials (CIAs) across the business?**

The World Organization for Animal Health (WOAH) [states that](#) the use of medically important antimicrobials for growth is no longer a practice in 70% of countries. This includes large markets like the European Union, United States, and China. Animal medicines companies worked proactively with governments in these countries to help implement these regulations and help avoid a negative impact on farmer livelihoods or animal welfare.

Countries with this practice are typically smaller, 'developing' areas where the average livestock producer is a smallholder with 1-2 head of cattle or a small flock of chickens. Livestock provides essential subsistence and nutrition, and these farmers rely on this to avoid hunger and poverty. When certain indications of use for a medicine are phased out, it's essential that these farmers are supported through that transition. Every kilo of milk, meat or eggs that an animal may no longer produce has a direct effect on local food security.

Furthermore, decisions on veterinary medical use of antimicrobials (defined by the World Organisation for Animal Health as encompassing prevention, control and treatment) are best made by veterinary professionals. They have training and real-world experience that teaches them how disease spreads and when animals are infected or at high-risk of bacterial disease. They will rely upon epidemiological, diagnostic, and clinical knowledge to inform their decision, which protects the welfare of that animal and those around it. In markets where access to a licensed veterinarian is a significant challenge, such as developing nations, other trained experts such as veterinary paraprofessionals and trained owners can help fill this gap.

- 3. What key performance indicators (KPIs) are sales incentives for antimicrobials linked to?**

As noted above, a farm that reduces its need for antibiotics often does so through increased adoption of vaccines, nutritional supplements, digital monitoring technologies, rapid diagnostics, etc. HealthforAnimals Members excel at developing these innovations that can improve disease control, which better protects animal health and reduces the need for antibiotics.

It's why sales and/or marketing staff's incentive is to provide the right product for the producer's specific situation. This may be vaccines, nutritional supplements, diagnostics, digital monitoring technologies, parasite control or antibiotics.

A singular focus on antibiotic sales for a company or salesperson would not be a sound business practice. It would ignore the other needs of a farmer and pass up opportunities to provide other tools that can help improve their operation. The producer would likely turn to another company that can help provide much more comprehensive care for their animals.

## **B.2. Reducing exposure to antimicrobials**

### **1. How does the company view AMR as a material risk to the business and is the company considering strategies to reduce its exposure to antimicrobials?**

HealthforAnimals recently published a document, [Global Trends in the Animal Health Sector: 2022 Outlook](#), which provides a breakdown of the global animal health product portfolio. Antimicrobials have seen a steady decline in recent years, falling to 15.2% in 2021, a relative decline of 28% compared to 2013. Currently, vaccines are 28.5% of the global product portfolio. This data demonstrates a continued push by HealthforAnimals Members for disease prevention as the foundation for health and well-being.

The relative decline of antibiotics as part of the overall portfolio has had no notable negative impacts on companies' performance overall. The Global Trends document shows annual average revenue increases of the top 20 companies of 9.4% since 2011, and in 2021 of 12%. Many HealthforAnimals companies have grown even faster. As noted previously, companies strive to provide the right product for a producer's specific situation, which increasingly includes greater preventative care.

All HealthforAnimals Members have also signed on to the industry-wide [Roadmap to Reduce the Need for Antibiotics](#), which provides a clear global strategy for reducing the need for antibiotics. This includes 25 measurable actions that HealthforAnimals Members committed to completing by 2025. The 2021 [Roadmap Progress Report](#) shows that all actions are either on track or ahead of schedule.

### **2. Can the company provide a breakdown of revenue from antimicrobials by (i) intended species, (ii) WHO classification, (iii) geography, and (iv) application method?**

Although some sales data is collected at a global level by HealthforAnimals Members as seen in our [Global Trends report](#), it is done so in a strictly regimented way that has undergone extensive legal review to ensure anti-trust compliance. This data requested here is *not* currently collected and not expected to be done in the future.

### **3. [For those that do not disclose] Has the company considered disclosing this information in the future, if not, why not?**

See previous answer.

## C. RESEARCH & DEVELOPMENT: INCREASING AVAILABILITY AND USE OF ALTERNATIVES TO ANTIMICROBIALS

### C.1. Defining alternatives to antimicrobials

#### 1. How does the company define alternatives to antimicrobials?

The term ‘alternatives to antibiotics’ is a misnomer. Antibiotics are currently the *only* way to treat a bacterial infection. There is no alternative. Without antibiotics, animals facing a bacterial disease will suffer and many will die. Its why antibiotics will always be necessary for good health, and systems such as ‘Raised Without Antibiotics’ can be harmful to welfare<sup>1</sup>.

However, there are products and practices that can reduce the *need* for antibiotic use. This can include medicines such as vaccines or nutritional supplements, as well as good biosecurity and husbandry.

#### 2. Please indicate (i) the percentage of the product portfolio for food-producing animals that are classified as alternatives to antimicrobials and (ii) how the company assesses the effectiveness of alternatives at reducing antimicrobial use.

As noted above, HealthforAnimals recently published a [document](#), *Global Trends in the Animal Health Sector: 2022 Outlook*, which provides a breakdown of the global animal health product portfolio. Antimicrobials have seen a steady decline in recent years, falling to 15.2% of global sales in 2021. This is a relative decline of 28% compared to 2013. Currently, vaccines are 28.5% of the product portfolio.

In our [Roadmap to Reducing the Need for Antibiotics](#), HealthforAnimals Members also committed to bringing products to market that could help reduce antibiotic need. Our [2021 Progress Report](#) shows that all commitments are on track. This includes delivering 49 new vaccines, 22 of which specifically address bacterial disease while others address other issues like viral illness that can lead to or exacerbate secondary bacterial infections.

Furthermore, products that could potentially reduce the need for antimicrobials are evaluated the same way as any animal health technology. Companies will assess whether it effectively meets the claims listed on the label.

#### 3. Please provide a breakdown of revenue from alternatives to antimicrobials.

As noted above, the [Global Trends in the Animal Health Sector: 2022 Outlook document](#) provides a breakdown of the global animal health product portfolio. This data is collected by CEESA directly from HealthforAnimals member companies. The process has been carefully crafted to meet anti-trust guidelines and the data that may be collected is strictly defined.

However, it is important to note that CEESA only covers approximately 2/3rds of the global animal health finished products’ market. There are also significant national or ‘local’ companies, which are not a Member of CEESA nor HealthforAnimals. We cannot speak to, nor account for, their practices.

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<sup>1</sup> Raising Animals Without Antibiotics: U.S. Producer and Veterinarian Experiences and Opinions  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6910073/>

## **C.2. Increasing availability and use of alternatives to antimicrobials**

### **1. What percentage of research and development spending is supporting the development of alternatives to antimicrobials and does the company have plans to increase this?**

The [Global Trends in the Animal Health Sector: 2022 Outlook document](#) shows how R&D spending continues to rise across the animal health sector. Companies are increasing their R&D budgets, many by double digits, and investments in preventative care are growing, as demonstrated by the product portfolio data.

The results of this investment can be seen in our Roadmap to Reducing the Need for Antibiotics [Progress Report](#), where companies reported bringing to market 49 new vaccines (22 specifically for bacterial disease), 17 diagnostics, 7 nutritional products, etc. between 2019-2021.

### **2. What percentage of marketing spend is spent on alternatives to antimicrobials and what percentage is spent on antimicrobials?**

This data is not available at a sector-wide level.

## **D. IMPROVING TRANSPARENCY AROUND LOBBYING ACTIVITIES AND POLITICAL EXPENDITURE**

### **1. What is the company's approach to lobbying and political expenditure and do you have any policies in place around how lobbying is carried out?**

Companies have clear policies and strategies for every segment of their business, whether government relations, investor relations or sales strategies. All such activities are done in compliance with all local regulations. When it comes to antibiotics, we note that animal medicine companies proactively worked with authorities in US and EU to implement new regulations on responsible use.