

Ms. Raven and FAIRR Staff,

Thank you for your recent questions regarding our Members and the animal health sector. HealthforAnimals appreciates the opportunity to answer these questions in order to provide detail on our sector's perspective and actions on antibiotics, antimicrobial resistance and responsible use.

We also believe in open, transparent dialogue on these topics as the best way to build productive conversations that can lead to collaborative solutions. Therefore, we have also posted [this letter on our website](#) so others may also view our responses and better understand our perspectives.

Your questions requested our Members insights at each step in the antibiotic lifecycle, from discovery to training to sales. Therefore, we have provided some introductory details then organized information around these steps.

However, answers are tailored to your questions and information at each lifecycle stage should not be viewed as comprehensive. Animal medicines are a complex, innovative area and there is a wide array of topics that can be discussed. We hope this information provides a valuable introduction.

### **HealthforAnimals Member Overview**

HealthforAnimals is the global representative of the 'Animal Health' sector. [Our Members](#) provide products that help protect the health of livestock and pets, including vaccines, parasiticides, nutritional supplements, diagnostics, antibiotics and more.

Animal health is highly innovative sector. Emerging technologies such as monoclonal antibodies, herd-specific vaccines, immunotherapy treatments, or A.I.-driven digital technologies demonstrate our sector's ability to deliver cutting-edge innovation into the market and improve the health of animals.

Other companies operate in this sector who are not represented by HealthforAnimals though, including companies focused on specific regional markets and/or generic animal health products. For instance, the hurdles in developing a class of antibiotics (as explained in *Discovery*), mean older, off-patent products are widely produced and local companies in areas like South Asia can have notable market share.

HealthforAnimals Members believe deeply in proper stewardship of antibiotics as they are a cornerstone of good animal care and the only treatment for a bacterial infection. We cannot afford to lose them. Our companies urge those outside our Membership to ensure they have stewardship and responsible use strategies in place.

### **Antimicrobial Resistance and One Health**

Antimicrobial resistance has been at the top of the global agenda, especially since the United Nations' *Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance*. However, the animal health sector has recognized and worked on this challenge for many years prior.

For instance, the UK Responsible Use of Medicines Alliance (RUMA) was established in 1997 and the European Platform for Responsible Use of Medicines in Animals (EPRUMA) was established in 2005. More recently, Brazil has also formed 'Aliança', a responsible use alliance in the country. Our sector has

been active and supportive of these organizations since their inception, and Our [Antibiotics Commitment](#) and [Roadmap to Reducing the Need for Antibiotics](#) demonstrate how we have worked to bring these same principles to the global level.

We believe these types of activities are why Lord O'Neill [described himself](#) as 'positively surprised' by the agricultural sphere in a recent Chatham House review of AMR progress. The fight is certainly not over though, but this early progress coupled with the plans outlined in our *Roadmap* have provided the agricultural sector with strong momentum.

However, even if progress continues to accelerate in agriculture, the challenge of resistance will not be solved. [Modelling by the University of Edinburgh](#) found that *only* addressing antibiotic use in animals, but not people, will have "*little impact on the level of resistance in humans.*"

Antimicrobial resistance is fundamentally a 'One Health' challenge that requires action from both human and animal health.

The European Centre for Disease Prevention and Control [estimates](#) that "*75% of disease linked to resistant bacteria is due to healthcare-associated infections*" and the European Medicines Agency stated in its [2015-2020 AMR strategy](#) that "*the biggest driver of AMR in people is the use of antimicrobials in humans or human health.*" According to [the OECD](#), measures "*as simple as handwashing and more prudent prescriptions*" in human health could reduce future AMR deaths by 75%.

The information provided in this letter demonstrates that our sector is committed to tackling AMR and taking the necessary actions to help stem the tide. However, complementary action is also needed from human health to truly manage this One Health challenge and we hope FAIRR recognizes this when evaluating AMR progress.

### **Antibiotic Discovery**

Medicine discovery is a challenging, expensive and lengthy process. It entails years of research and robust testing that requires a significant investment.

This challenge can be compounded in antibiotics. The WHO has recommended that any new class of antibiotics found to be effective in humans will be considered 'critically important' and recommends these are reserved for human use.

This limits the range of molecules available for animal antibiotic research, which highlights the importance of animal-only antibiotics. These medicines are the only type of new animal antibiotic class that can be brought to market and therefore are a cornerstone of bacterial disease management and innovation in animal health.

### **Development**

Once a new molecule is discovered, it must be developed into a market-viable product. This includes identifying the necessary information for the product label. All animal medicines, including antibiotics, come with product labels that offer detailed guidance on how to use the medicine appropriately. This can include information such as:

- **'Indications of use'**: The situations and diseases where the antimicrobial is approved for use.

- **Dosage and Administration:** Detailed instructions for how to administer the antibiotic effectively. Can include details as specific as quantity, recommended injection location, amount based on animal body weight, etc.
- **'Adverse Reactions':** List of possible side effects from a medicine that should be monitored.
- **Withdrawal Periods:** Amount of time a farmer must wait after administering the antibiotic before slaughter to ensure no 'residues' or trace amounts can be found in the meat or other produce. Withdrawal periods are strictly enforced by authorities.
- **Pharmacology:** Clinical explanation of how the antibiotic functions, efficacy levels, etc.
- **Precautions/Warnings:** Cautions for the user (e.g. *Not for Human Use*) and information on what to do in case of an accident (e.g. accidental human injection).
- **Contact:** Contact information for the manufacturer to report adverse events or other issues.

Product labels are highly detailed because the objective is to help ensure these medicines are used properly, effectively and responsibly when administered to an animal. The exact contents of labels included in the packaging are legal requirements and the language is established by national regulators.

### **Assessment**

During the authorization process, government regulators assess all animal medicines, including antibiotics, 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. Animal health companies comply with the stringent legal standards/requirements set by national and international health, animal and environmental regulatory agencies.

### **Manufacturing**

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. For the animal health sector, this often happens in the same facilities where human health products are manufactured. Third party production facilities must comply with detailed procedures and rules set out in legislation and regulation. Continuous efforts are made to improve emission control at manufacturing facilities. Animal health 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. Many companies have also published their 'Predicted No Effect Concentration' (PNEC) value for antibiotics as part of the AMR industry alliance, which can help with environmental monitoring.

### **Distribution**

Global manufacturing companies – from medicines to any consumer product – rely on a network of distributors to help their goods reach the customer. HealthforAnimals Members have contracts with distributors that help ensure products reach farmers, veterinarians and pet owners.

Companies closely monitor all parts of the supply chain -- from active pharmaceutical ingredient (API) producers to distributors to final customers -- to ensure medicines are reaching markets and successfully managing any animal health challenges. This is the foundation of any business. If any partners are not meeting expectations, companies will address it. Not doing so would risk a company's ability to deliver products into a marketplace

## **Marketing and Sales**

Decisions about how a product is marketed are made by individual companies and cannot be addressed by HealthforAnimals. This is outside our purview as marketing coordination by an industry association can raise anti-trust issues.

However, the underlying assumption behind FAIRR's statement that *'antibiotics are a volume business – a decrease in usage will ultimately have an impact on revenue'* is not correct. It overlooks the fact that HealthforAnimals Members offer a full suite of technologies and medicines for the health of animals.

For instance, the European animal health market – the second largest in the world – has experienced a decline in [antibiotic sales in recent years](#), while the overall market continues to grow due to other product categories. This same trend is occurring the U.S., which has seen antibiotics sale [fall in recent years](#) while the wider animal health market expands.

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.

## **Antibiotic Use**

All antibiotics are sold with defined dosages (*See product label information above*). This helps ensure an animal receives the amount necessary to tackle the bacterial disease(s) listed under the indication of use. This is an essential piece of information that is required before a medicine can be approved by regulators. One key reason is because using less than the recommended amount of an antibiotic can lead to resistance development.

Duration of use is not included on all products. Strict, defined durations can severely hamper a veterinarian's ability to not only tackle a bacterial disease but manage resistance. That is why in many countries, the regulators have given that judgement call to veterinarians.

For instance, a veterinarian may administer a course of antibiotics to an animal. If the animal is not fully recovered at this time, the veterinarian may recommend continuing the treatment for a few more days.

However, if the antibiotic provided a longer duration of use on the label (e.g. 14 days), the veterinarian is *required* to administer the antibiotic for this complete period. This leads to unnecessary medicine use.

Providing flexibility in duration of use allows for professionals to evaluate an animal and decide what course of treatment best fits the situation.

This expertise is also essential in deciding exactly *when* an antibiotic should be administered.

Veterinarians are highly skilled animal health professionals. They undergo extensive training and real-world experience that teaches them how disease spreads in an animal, herd, flock or region. This spread is often predictable because of the nature of livestock production.

The animals live in a defined space (i.e. the farm) and are raised on a relatively uniform schedule. For instance, animals will receive vaccines at specific ages and will be raised on a relatively uniform schedule. This efficiency maximizes the natural resources used in raising an animal and leads to a more sustainable operation.

It also leads to predictable times of stress or disease susceptibility for animals, and veterinarians understand when this puts an animal at high-risk of contracting a bacterial disease. This risk puts an entire herd or flock in danger as infections will spread during the incubation period before symptoms are shown.

Therefore, a veterinarian may decide to use a prophylactic antibiotic treatment instead of waiting for animals to suffer an infection and an outbreak to form. They will rely upon epidemiological, diagnostic, and clinical knowledge to inform their decision. This protects the welfare of that animal and those around it.

Veterinarians are a key part of farm animal health plans, including providing oversight on antibiotic use. In some countries this is a legal requirement, in others it is not.

### Growth Promotion

Most countries do not allow the use of medically important antibiotics for growth promotion. The European Union ended the use of antibiotic growth promoters in 2006, and major markets like the U.S. and China have also adopted these measures. Animal medicines companies worked proactively with governments in these markets to help implement these regulations and help avoid a negative impact on farmer livelihoods or animal welfare.

Today, the World Organization for Animal Health (OIE) states that most countries do not allow antibiotics for growth promotion and the number is falling. Countries where it does still exist are typically those in the global south or 'developing' regions.

The average livestock producer in these markets 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.

### **'Alternatives to Antibiotics'**

It is important to note that 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. It's why antibiotics will always be necessary for good health, and systems such as ‘Raised Without Antibiotics’ can be [harmful to welfare](#).

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.

Farmers recognize the value of tackling bacterial disease early and reducing the need for antibiotic treatments. Adoption of tools and technologies that can facilitate this are on the rise around the world, and HealthforAnimals Members are proud to support this effort.

### **Responsible Use Training**

HealthforAnimals and our Members support robust training on antibiotics because it provides the on-the-ground knowledge necessary to recognize, diagnose and treat the threat of bacterial disease effectively.

Our sector often partners with respected global institutions like the Bill and Melinda Gates Foundation, the World Organization for Animal Health (OIE) and the United Nation's Food and Agriculture Organization (FAO) to provide trainings in regions where veterinary access is a massive challenge. Companies also work with national veterinary authorities to provide this training support.

These partnerships are a testament to our sector's ability to provide clear, competent and neutral trainings that help support responsible use and strengthen veterinary expertise in key regions. These organizations and governments recognize that these trainings offer immense value and are not a ‘sales seminar’ as FAIRR's questions seem to suggest.

### **Tracking Sales**

Individual national governments determine whether and how they collect and publish sales data. Animal Health companies share this information in countries where this is part of the regulatory regime.

For instance, in the U.S., all companies producing approved antibiotics for use by food producing animals are legally required to report sales data to FDA, and all companies, regardless of product, are required to provide sales data as part of their pharmacovigilance reporting. This data is compiled and published on the FDA site. In the EU, each country collects the data nationally and shares it with the EMA who publishes it annually in the reports from “European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)”. The reports are on the EMA site. Data shows that antibiotic sales have trended downwards in both markets in recent years.

In Brazil, the government also formally requests this data annually and industry collects and submits it. In other markets, such as China, Australia, and Canada, the authorities collect data and industry always provides this.

In addition, the OIE collects data at global level from countries and those compilation reports are on their site. The latest version is the “Fourth OIE annual report on the use of antimicrobial agents intended for use in animals”. The fact that most countries share data with OIE indicates that most are collecting it – almost always based on input from the companies, and sometimes based on inputs from distributors and veterinarians.

However, sales data is a flawed mechanism for surveillance. If the objective is to manage AMR, then tracking resistance itself provides much more actionable data. For instance, in the United States, the government has operated the '[National Antimicrobial Resistance Monitoring System](#)' (NARMS) since 1996. This public health surveillance system samples bacteria from people, animals and foods to understand if and how bacterial resistance is evolving. It provides valuable, granular insights that allows stakeholders to take targeted action that can better manage resistance.

Sales data can indicate whether disease pressures were especially heavy one year, if outbreaks were lower than expected, types of antibiotics used in response, etc., but it cannot tell us whether bacterial resistance is developing. Only testing for resistance itself can achieve this.

### **Future Demand**

FAIRR asked about changing consumption trends. HealthforAnimals Members recognize that demand for food and protein is quickly evolving. By 2030, our global population is expected to grow to 8.5 billion – nearly 1 billion more than live on our planet today -- and 2 out of 3 people will be in the middle class. This rapid population increase means that even if per capita animal protein consumption were to fall (it is not projected to do so), overall production will still need to rise.

At the moment, FAO and OECD estimate that livestock production will [need to increase](#) by 14% by 2029. However, simply increasing the size of current production systems to meet these future needs would require unsustainable increases in natural resources use. We must increase production efficiency and drastically cut food waste from farm to fork.

This must occur in developed regions, but also emerging markets in South America, Asia and Africa. These regions are becoming increasingly sophisticated agricultural producers. In livestock, this often means greater use of technologies like vaccines, nutritional supplements, and rapid diagnostics.

HealthforAnimals Members, as animal health companies with comprehensive portfolios, are committed to providing tools that can facilitate these shifts and ensure sustainable production well into the future.

### **Looking Ahead**

HealthforAnimals Members are committed to being responsible stewards of antibiotics and ensuring these products remain effective well into the future. Our [Roadmap to Reducing the Need for Antibiotics](#) outlines our strategy and provides many examples of specific actions undertaken. We will also release an interim report in 2021 to demonstrate progress towards our Roadmap Commitments.

However, AMR is not a challenge we can solve alone. We look forward to working with others across the value chain to address this joint challenge.

Sincerely,



Carel du Marchie Sarvaas  
Executive Director  
HealthforAnimals