Pharmaceutical Industry Response to the OIE AMR Campaign: "*We need you to handle antimicrobials with care*"

HealthforAnimals is the global non-profit, non-governmental organization representing companies and associations in the animal health sector: manufacturers of veterinary pharmaceuticals, vaccines and other products throughout the world. HealthforAnimals represents about 85%+ of the global animal health industry.

We support OIE's <u>"We Need You"</u> communications campaign - it is a well-thought out, targeted and actionoriented effort. Within the initiative, OIE makes seven recommendations for the 'pharmaceutical sector.' HealthforAnimals reviewed OIE's recommendations. All seven are valuable ways in which we can promote responsible use. **This document sets out the actions we are undertaking to fulfill each recommendation.**

OIE notes that our sector has a leadership responsibility. We take this role seriously. As a sector we have been working on antimicrobial resistance for over two decades. In 2017, we published our **Antibiotics Commitment**, where we formally committed to five principles with corresponding actions for addressing AMR:

- 1. Protect animal health and welfare in a unified one health approach
- 2. Use antibiotics judiciously and responsibly
- 3. Promote disease prevention and increased access to products and expertise
- 4. Invest in the development of products for prevention and treatment
- 5. Increase knowledge, transparency and communication

Our Commitment is signed by the nine largest global animal health companies and organizations representing another 200+ animal health companies. It is also supported by associations representing 700,000 veterinarians. We promote responsible use so as not to compromise the efficacy of our products and contribute to resistance. We promote "*as little as possible, but as much as necessary*" - the right product in the right dose, for the right duration, in the right way. We believe not in simply reducing antibiotic use, but, in reducing the <u>need</u> for antibiotics, through greater animal preventative care, better feed and animal husbandry and higher bio-security.

OIE Recommendation 1: Ensure the safety, efficacy and quality of their antimicrobials, and adhere to good manufacturing practices.

We agree. Safety, efficacy and quality are the cornerstones of animal medicines production. They are the foundation of the regulatory reviews that our products undergo across the world, and these principles are embedded in our R&D process. Companies provide accurate and scientifically valid data on products as part of science-based product licensing systems. HealthforAnimals companies adhere to good manufacturing practices (GMP) because it is the best way to consistently produce quality products and retain the trust of veterinarians, farmers and pet owners. Companies also undergo regular plant inspections by authorities.

OIE Recommendation 2: Obtain marketing authorization and comply with the codes of advertising to not advertise veterinary products containing antimicrobial agents directly to the food animal producer.

We agree. Selling products without a market authorization is illegal and can put animals at risk. We produced a **report about illegal products** that condemned illegal and counterfeit products, and demonstrated how these could exacerbate AMR levels. The report lists activities to fight illegal products produced and sold by criminals.

Companies abide by national advertising codes and laws which are different per country reflecting national conditions. It is important to communicate effective directions for use with veterinarians and customers appropriate for their national conditions. Many countries lack national online registers, and have low literacy levels, so communications often happen with pictures, diagrams, and other means. HealthforAnimals companies abide by **Principles of Operations** that set out principles regarding marketing, distribution and use, promotion and communication and other areas. Many national animal health associations also have advertising guidelines that are in line with, and sometimes go beyond, national laws.

OIE Recommendation 3: Only use officially authorized distribution systems for the marketing and export of veterinary medicinal products containing antimicrobial agents.

We agree. Medicine distribution happens in diverse ways - directly by a pharmaceutical company, through authorized distributors, via online sales, etc. Each country or region has regulations governing these processes and some have limited systems for regulating distributors. Our Members closely adhere to the national laws. HealthforAnimals companies believe antimicrobials should be used under the supervision of a veterinary professional, but we recognize this may not always be possible in countries experiencing shortages of veterinarians, and animals should not suffer as a result.

OIE Recommendation 4: Cooperate with the competent Authorities and share detailed sales data for the monitoring of antimicrobial use and surveillance of antimicrobial resistance.

We agree. HealthforAnimals companies cooperate with the authorities to share antibiotic sales data. We supply data to efforts like 'European Surveillance of Veterinary Antimicrobial Consumption' in the European Union and similar initiatives in the US, Canada and elsewhere. We also support and are active in the OIE data collection process. We believe that as, or maybe more important, than antibiotic use data collection, is more and better antibiotic resistance monitoring.

OIE Recommendation 5: Highlight the risk of antimicrobial resistance and the need for responsible and prudent use whenever providing or supplying antimicrobials.

We agree. Every product we distribute, including antimicrobials, contains clear instructions on how to use it responsibly. This is a regulatory requirement in nearly all markets and our Members view it as a key step to ensuring a medicine is used correctly. Integral to this is the need to responsibly manage disease to protect animals and humans.

OIE Recommendation 6: Participate in training on the prudent and responsible use of antimicrobials.

We agree. Our sector has organized responsible use trainings for many years. Company experts work directly with users to train them on best practices for antimicrobial administration. We also produce responsible use training guides for veterinarians and are part of farmer and food chain responsible use coalitions in many countries, such as the 'European Platform for the Responsible Use of Animal Medicines' (EPRUMA) or the AllianÇa (Brazilian Alliance for Responsible Use of Medicines).

HealthforAnimals participates in OIE focal point trainings. In addition, we are in talks with OIE and veterinarians to implement a multi-year program to train para-veterinarians in Africa, including in responsible use.

OIE Recommendation 7: Contribute to research to help combat antimicrobial resistance, prioritize and focus on developing alternatives to antimicrobials, such as vaccines and rapid and affordable diagnostic tests.

We agree. Prevention is the foundation of reducing the <u>need</u> for antimicrobials. Animals that are vaccinated, fed a good diet, and see a veterinarian regularly are less likely to need antibiotic treatments. That is why our companies invest an average 6-9% of their annual turnover in R&D. These investments generate new vaccines, immunostimulants, nutrition supplements, and other products that bolster an animal's defense against disease. We are also developing new diagnostics that will help veterinarians assess faster and accurately the right treatment. We need to better understand the efficacy of interventions to reduce the risk of antimicrobial resistance. But, illness cannot always be prevented. When a bacterial infection strikes – there is no alternative to antibiotics. These medicines are necessary, and animals deserve treatment.