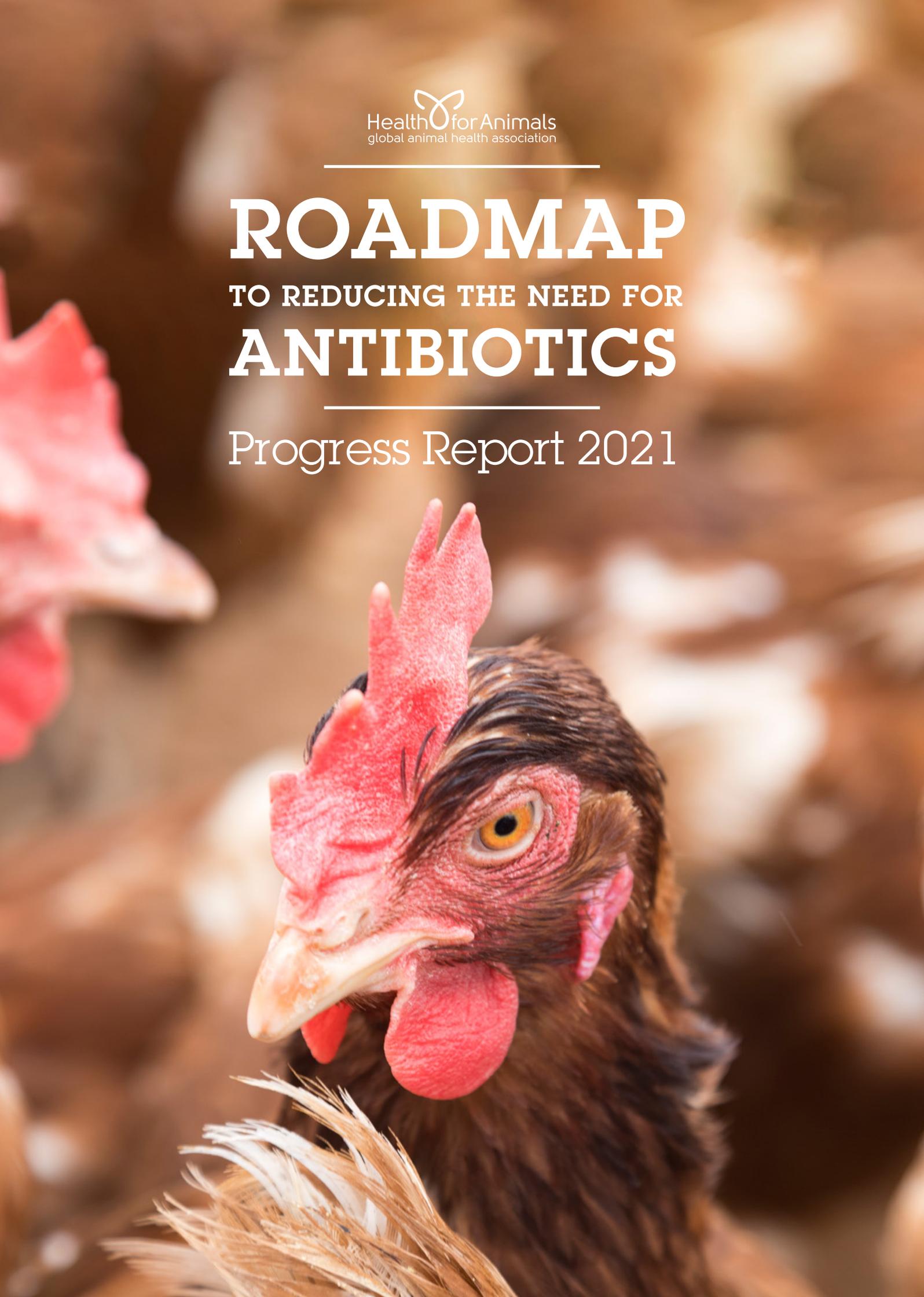


ROADMAP

TO REDUCING THE NEED FOR

ANTIBIOTICS

Progress Report 2021



Introduction

In August 2019, HealthforAnimals published the 'Roadmap to Reducing the Need for Antibiotics', a strategy for addressing antimicrobial resistance and improving responsible use. It was undersigned by the world's largest animal health companies and demonstrated a unified approach to a global challenge.

The Roadmap offered a vision for decreasing disease levels, reducing the need for antibiotics and preserving welfare by fundamentally improving how we care for animals. It called for greater commitments to veterinary access, farmer training, AMR monitoring, vaccine development and more.

The objective was to build upon actions seen in recent years, such as:

- Sales Reductions:** Antimicrobial sales declined by 34% in the EU¹ since 2011, 38% in the U.S.² since 2015 and over 50% in the UK³ since 2014. However, sales are a flawed mechanism for surveillance. It is essential to also track how this affects actual human resistance levels and recognize it will only be effective with complementary actions in human health.
- Coordinated Action:** Coalitions such as the UK's Responsible Use of Medicines in Agriculture Alliance or the EU's Platform for Responsible Use of Medicines in Agriculture have been in place for decades. These coalitions bring together farmers, veterinarians, research, retail, etc. to deliver improvements in responsible use, a unique approach that has not been replicated in human health.
- Increased Training:** HealthforAnimals Members have created major programs to educate veterinarians in responsible medicine use, such as a new collaboration between HealthforAnimals, the World Veterinary Association and the UNFAO's EUFmD Program to train para-professionals in Africa.
- Greater Prevention:** Adoption of prevention technologies like vaccines, nutrition supplements and more have been significantly rising in recent years. For instance, the market share for vaccines rose 22.5% in the EU from 2015–2020.⁴

The Roadmap offered four areas for public sector action (Regulation, Consumer Acceptance, Funding for Livestock and Access to Veterinary Expertise), and a list of 25 actions the Animal Health sector committed to completing by 2025. This Progress Report outlines the Animal Health sector's success and work to-date on our Roadmap Commitments.

Overall, all Commitments are on track for completion by 2025 and some are well ahead of schedule. As a result, the sector is evaluating how it can push itself and expand these Commitments even further in coming years.

In 2019, HealthforAnimals Members set 25 Commitments for the sector to undertake by 2025 to help improve responsible use and address AMR. All but one are either on track, ahead of schedule or already completed. These include results like, at least:



49 out of **100**
new vaccines
delivered



657,000
veterinary professionals
indirectly trained



US\$6.7M in veterinary
scholarships, exceeding
our US\$5M goal

This Progress Report provides an update on all 25 Commitments. Another version will be published in 2023.

¹ Sales of veterinary antimicrobial agents in 31 European countries in 2018, European Medicines Agency
² 2019 Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals, U.S. Food and Drug Administration
³ UK VARSS 2019, UK Veterinary Medicines Directorate
⁴ European Animal Medicines Industry in Figures, <https://figures.animalhealtheurope.eu/>



Our commitments to

Research & Development

If we are to continue to maintain and improve animal health as well as reduce the need for antibiotics, we will need new innovation. HealthforAnimals Members made the following five commitments in our Roadmap to Reducing the Need for Antibiotics to advance our R&D between 2019 and 2025.

Invest at least \$10 billion in research and development¹

\$3.17B

➤ **Progress:** at least 3.17B has been invested to-date

On track

Deliver at least 100 new vaccines²

49 out of 100

➤ **Progress:** 49 vaccines delivered to-date

Ahead of schedule

Deliver at least 20 new diagnostics tools

17 out of 20

➤ **Progress:** 17 delivered to-date

Ahead of schedule

Deliver at least 20 new nutritional enhancement products

7 out of 20

➤ **Progress:** 7 delivered to-date

On track

Deliver at least 30 other products that can reduce the need for an antimicrobial by reducing animal stress or boosting the natural immune system

8 out of 30

➤ **Progress:** 8 delivered to-date

On track

¹ This figure represents only R&D investment in traditional medicines (pharmaceutical and biologics) and is likely an underrepresentation. Future progress reports will seek to capture new non-traditional areas such as products and services.

² 22 specifically address bacterial disease while others address other issues like viral illness that can lead to or exacerbate secondary bacterial infections.



Our commitments to

One Health

In addressing issues such as AMR, we must recognize that this is not an issue limited by species or location. AMR affects animals, people and the planet, and can only be addressed by recognizing the intersection of all three. HealthforAnimals Members made the following two commitments to help provide a One Health lens to our work.

Deliver new tools that reduce the likelihood of human exposure to a resistant pathogen such as Salmonella, Campylobacter, or E. Coli

On track

Tools offered by HealthforAnimals Members included:

- Animal vaccines against zoonotic public health threats like salmonella, e.coli and campylobacter;
- Nutritional products that help reduce the presence of clostridia in the gut;
- Sensitivity tests that reduce chances of resistance development when antibiotics are needed;
- Diagnostic tests to accurately detect bacterial infection and support swift treatment.

Conduct an AMR risk analysis for every new antibiotic brought to market

On track

➤ **Progress:** HealthforAnimals Members introduced three new antibiotics to the market in the past two years.³ Each received an AMR risk analysis prior to market introduction.

³ This does not include generics as these are not new antibiotic formulations or APIs.



Our commitments to

Communications

Reducing the need for antibiotics can only be possible when the importance, benefits, scientific basis, and barriers are properly understood. HealthforAnimals Members made the following four commitments to help our partners and stakeholders recognize how we can mutually advance this vision.

Strengthen communications on benefits of biosecurity, in-feed supplements, vaccinations, and products that support good animal health

On track

Types of HealthforAnimals Member Communications included:

- Boehringer Ingelheim's ADVANCE study on the value of vaccination to increased production
- Ceva's series on the value of vaccination at TogetherBeyondAnimalHealth.com
- Elanco's 8-point antibiotic stewardship plan
- IDEXX's social media toolkits and opinion articles
- Merck Animal Health's 'Time to Vaccinate' program
- Phibro's robust 'Phibro Academy Program' that provides guidance on prevention
- Virbac's 2020 Annual Report highlighting work on alternatives to antimicrobials
- Zenoaq's analysis of the value of biosecurity
- Zoetis' 2020 Sustainability Report outlining a preventive approach to animal health and AMR.

Progress: All HealthforAnimals Members offered robust communications campaigns and materials on the value of preventative care in animal health over the past two years.

Participate in forums and public dialogues to help build understanding of risks, benefits, and actions that different stakeholders can take to improve public health outcomes in the fight against AMR

On track

Major forums where HealthforAnimals Members spoke included:

- 2020 World Health Summit
- French government's One Health Forum
- U.S. Presidential Advisory Council for Combatting Antibiotic Resistance
- World AMR Congress
- United Nations One Health Global Leaders Group
- AMR Action Fund
- Forbes AgTech Summit

Progress: HealthforAnimals Members have been active and vocal in forums across the globe, even during the pandemic, promoting the need for One Health collaboration, antibiotic stewardship, strategies for reducing antibiotic need in animals.

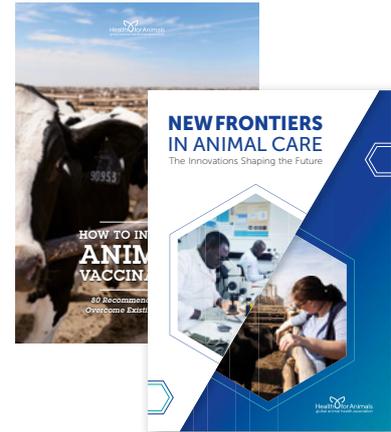


Issue regular report(s) and/or white paper(s) identifying barriers to adoption of prevention tools (e.g. vaccination, biosecurity, etc) and how they can be addressed

On track

➤ Progress:

- In November 2019, HealthforAnimals published a comprehensive report entitled “How to Increase Animal Vaccination,” outlining the systemic economic, political, technical, regulatory, practical, and social barriers facing greater adoption of these medicines.
- In 2021, HealthforAnimals published “New Frontiers in Animal Care: The Innovations Shaping the Future”. The report explained how new technologies like digital innovation could improve veterinary care and the steps necessary to accelerate adoption.



Issue Roadmap Updates in 2021 and 2023

On track

➤ **Progress:** This Progress Report offers a valuable update for stakeholders and a second version is still planned in 2023. Furthermore, HealthforAnimals published French and Spanish translations of the original Roadmap in 2020.



Our commitments to

Veterinary Training and Access

Veterinarians and veterinary paraprofessionals are on the frontline of the battle against AMR, using their expertise and knowledge to make a difference. They are trained to use antibiotics in a responsible manner that reduces animal suffering while limiting the emergence of resistance. HealthforAnimals Members made the following six commitments to improve veterinary knowledge by 2025.

Provide clear labels on every, single product

On track

➤ **Progress:** All HealthforAnimals Members provide comprehensive labels on every medicine sold. Labels will differ depending upon the market and regulatory requirements, but the common goal is to provide clear information to the end user.

Information on labels provided by HealthforAnimals Members include information such as:

- **'Indications of use':** The situations and diseases where the medicine is approved for use.
- **Dosage and Administration:** Detailed instructions for how to administer the medicine effectively.
- **'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 medicine before slaughter.
- **Pharmacology:** Clinical explanation of how the medicine 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.

Note: this is not an exhaustive list and product labels may include other details.

Make technical guidance available to all product users

On track

➤ **Progress:** All medicines sold by HealthforAnimals Members include detailed guidance on the label and accompanying materials. Furthermore, contact information is available on the label to seek additional detail as needed. Other animal health products such as diagnostics and monitoring technologies also include clear instructions on proper use of the product for accurate results.



Train more than 100,000 veterinarians in responsible use of medicines

➤ **Progress:** HealthforAnimals Members directly trained over 37,000 veterinarians in the past two years through various partnerships and initiatives. Through 'Train the Trainer' style programs, an additional 650,000+ veterinarians have received valuable instruction on disease control and responsible medicine use.

Direct Training
37,000 out of 100,000



Indirect Training
657,000 veterinary professionals



On track

Undertake at least 15 veterinary training partnerships

➤ **Progress:** HealthforAnimals Members undertook at least 25 veterinary training partnerships in the past two years. These activities spanned geographies as diverse as China, USA, Bangladesh, Ethiopia, Spain, Australia and more. Partnerships delivered on-the-ground results in regions where veterinary expertise is often lacking.

25 veterinary training partnerships undertaken, exceeding our target of 15



Ahead of schedule

Invest at least \$5 million in veterinary education scholarships and grants

➤ **Progress:** HealthforAnimals members provided over US\$6.7 Million in scholarships and grants in 2020 and 2021.

\$6.7 Million



Ahead of schedule

Deliver a white paper on opportunities in telemedicine for improving access to veterinarians in high-income and low- and middle-income nations

On track

➤ **Progress:** HealthforAnimals published new data on the use of telemedicine during the pandemic in 2020 and expects to further research this topic in the coming years.



Our commitments to

Cooperation

The animal health industry does not work in a vacuum and a global issue like AMR cannot be addressed by one sector alone. HealthforAnimals Members made the following five commitments to help build partnerships and work across disciplines to reduce the need for antibiotics by 2025.

Participate in responsible use coalitions in major markets

On track

➤ **Progress:** HealthforAnimals Members continue to be active in coalitions such as the UK's Responsible Use of Medicines in Agriculture Alliance (RUMA), the European Platform for the Responsible Use of Medicines in Animals (EPRUMA), and Brazil's Aliança. In markets without a formal coalition, Members often still work closely with the value chain through direct relationships and informal working groups.

RESPONSIBLE USE OF MEDICINES IN AGRICULTURE ALLIANCE

ruma

EPRUMA

ALIANZA
Para el uso responsable de antimicrobianos

Share sales data in every market where it is required

On track

➤ **Progress:** HealthforAnimals Members continue to meet their regulatory requirement to supply sales data in various markets. These show sharp reductions in recent years such as:

- UK: 50% reduction since 2014
- USA: 38% since 2015
- EU: 34% since 2011
- France: 53% since 2011

Sales data is a flawed mechanism for surveillance though. HealthforAnimals and Members support tracking resistance itself to provide more actionable data.

Recent Antibiotic Sales Reductions by Market



The Animal Health sector is taking valuable action to promote responsible use of antibiotics. However, sales data does not indicate whether AMR is rising or falling; only testing for resistance itself can achieve this. Actions by Animal Health can also only be truly impactful if accompanied by complementary steps in human health.



Undertake five new partnerships that deliver products that help to reduce the need for antibiotics in underserved markets

On track

➤ **Progress:** HealthforAnimals Members have undertaken at least 5 new partnerships in the past two years that are delivering products to underserved markets.

Partnerships undertaken by HealthforAnimals Members include:

- 'Village Poultry Project', offering tools and training to smallholders in East Africa.
- ALPHA Initiative, which aims to improve access to quality veterinary medicines and services in Africa.
- Partnership with Cowtribe, a Ghana startup that distributes medicines in rural regions.
- PREVENT Project, a partnership to provide vaccinated chicks to hatcheries across eight African countries.
- East Africa Growth Accelerator, helping farms in East Africa access quality medicines tailored to smallholders.

Conduct at least 50 audits of active ingredient suppliers to ensure they are meeting appropriate standards

Ahead of schedule

➤ **Progress:** HealthforAnimals Members have undertaken at least 206 audits of active ingredient suppliers in the past two years.



Encourage medicine users to submit efficacy reports into pharmacovigilance monitoring systems

On track

➤ **Progress:** All HealthforAnimals Members operate pharmacovigilance monitoring systems, which include details information on how users can submit reports.



Our commitments to

Knowledge

Addressing AMR will be more successful with greater knowledge and understanding about its origins, development, movement and contributory factors. HealthforAnimals Members made the following three commitments that will help contribute to a better understanding of AMR by 2025.

Provide research grants of at least \$1 million

➤ **Progress:** HealthforAnimals Members have provided at least US\$7.9 million in research grants over the past two years, well exceeding our Commitment. This has funded research into antibiotic alternatives, resistance surveillance, antimicrobial susceptibility monitoring, medicine effectiveness and more.

\$7.9M in research grants provided, exceeding our **\$1M** goal

Ahead of schedule

Publish new, scientific research within peer-reviewed publications which improves understanding of veterinary pathogens or antimicrobial resistance

On track

➤ **Progress:** HealthforAnimals Members published at least 29 articles over the past two years across a variety of peer-reviewed publications such as Journal of Livestock Medicine, Viruses, Microbiome, and Scientific Reports. Topics included new methods of bacterial infection diagnosis, antimicrobial susceptibility, antimicrobial alternatives and more. A full list of publications is available upon request.

Provide data and support to help improve disease tracking to organizations such as the World Organisation for Animal Health (OIE)

On track

➤ **Progress:** HealthforAnimals is an active supporter of the World Organisation for Animal Health and maintains an ongoing Memorandum of Understanding (MoU) that calls for collaboration on “responsible and prudent use of antimicrobials...with the aim of tackling resistance and maintain efficacy.” HealthforAnimals Members also support national, regional and global surveillance efforts. For example, one Member currently operates the longest continuous AMR surveillance program in North America, while many Members contribute to CEESA resistance monitoring programs.



Looking Ahead

Our *Roadmap to Reducing the Need for Antibiotics* offers a clear vision for improving global animal health both in the steps HealthforAnimals and our Members pledge to undertake, and in the areas where we call on others to take action and support this goal. HealthforAnimals Members have made significant progress on the Commitments we made within the *Roadmap* and are determined to fulfil or exceed all by 2025.

We encourage others in the public sector, international organisations, human health sector, or any other institution that can affect positive change to join us by making measurable One Health commitments to tackling AMR and improving responsible use. Together, we can ensure antibiotics remain a powerful tool in global human and animal health for years to come.



Data Notes

Information in this report was collected in summer 2021. It reflects HealthforAnimals Member Company activities between November 2019 (the original Roadmap Launch) and this collection date. Data was submitted confidentially by HealthforAnimals Member Companies to the Association for aggregation and presentation fully in accordance with data privacy and anti-trust considerations.