animalhealth europe
THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Annual report 2023

Message from the Secretary General and President

As Secretary General and President of AnimalhealthEurope we start our annual report with some words of thanks to our secretariat for all their hard work and dedication throughout this past year. We invite you to browse through our annual report to find out what 2023 had in store for us and to learn more about our efforts to raise awareness on why animal health matters.

All eyes on animal welfare

As member of the EU Platform on Animal Welfare we had a keen focus on the planned revision of the EU legislation on animal welfare, contributing where relevant to the various consultations to promote the prominent role of animal healthcare and new technologies for better animal welfare. Our annual event saw participants discuss the different role that different parties play with the aim of achieving the same goal of high levels of animal welfare in Europe. This was a key opportunity to promote the animal health sector as a solutions provider.

Like many other stakeholders we were surprised to learn in the second half of the year that the full package of new rules would not be published within the stated timeframe, but we understand the need to ensure that a proper cost and time assessment is given in order to ensure the updated rules can be implemented feasibly and properly. We were pleased to see pet welfare get a priority for once, with the rules on the welfare of dogs and cats being published in December alongside the transport rules which are also partly applicable to dogs and cats.

One Health, Sustainability and Innovation our driving force

We've been pleased to be invited to speak at a number of events this year, many focusing on One Health and how to ensure we move from concept to application. We've also had a number of opportunities to showcase the key role that modern-day animal health technologies can play in Europe's drive for more sustainable food systems.

Roxane Feller
Secretary General

This past December we were privileged to be able to stand alongside a farmer using today's monitoring technology and smart collars to protect the health and welfare of his herd of dairy cows during the first ever Agri Digital Conference which took place in the auspices of the EU Agri Food Days. This was a great opportunity not just for us to talk about what our industry is doing and where we're going in terms of innovation, but also to show the technology in action with a live demo and to hear feedback from the farmer using it.

Files to the left of us, dossiers to the right

Animal welfare, sustainability and innovation aside, our secretariat had to have their ears to the ground to monitor and react as necessary to the relatively large number of files that could have an impact on the availability of animal medicines in the future. From water and soil related dossiers, to packaging and packaging waste rules, via a stream of chemicals-focused files, our secretariat has been busy ensuring that the benefit-risk approach remains top of mind to ensure the health and welfare of all animals is not unduly jeopardised.

Our core focus – application of the new EU rules on veterinary medicines

Monitoring of all this horizontal legislation of course went hand-in-hand with the monitoring within our various national associations of how the new EU Regulations on Veterinary Medicines and Medicated Feed are being applied in each of the Member States. As reported in 2022 some technical hiccups with the new databases and processes have still not quite found their groove. Our Technical Director Rick Clayton can fill you in on the details in this year's in-depth article – read on!

A final word of thanks

None of what we have achieved this year would have been possible without the support of our member companies, associations and various experts we work with on a daily basis. Thanks also go to our partners in the Brussels sphere, regulatory authorities and the EU decision-makers who have kindly taken part in our events, invited us to speak at important events, and generally remained open throughout the year for exchanges on animal health related topics.

Rob Kelly

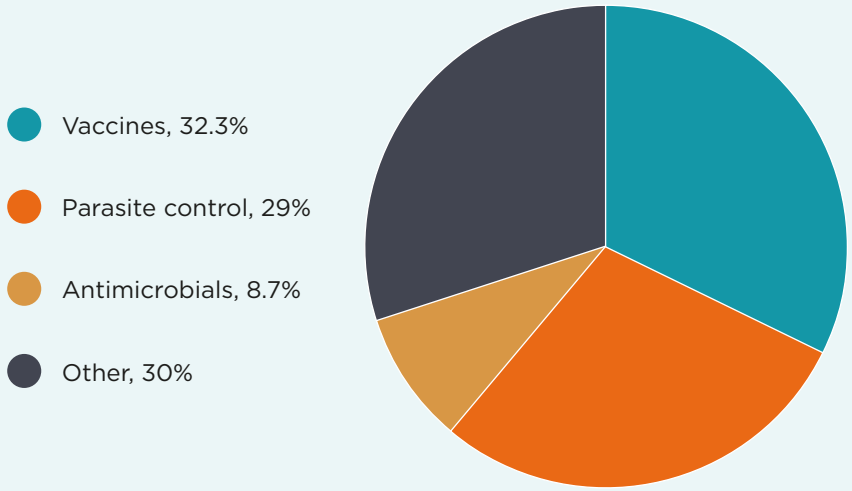
Rob Kelly
President

Key figures 2023

AnimalhealthEurope represents 12 of Europe's leading manufacturers of animal medicines and 16 national associations in 19 countries.

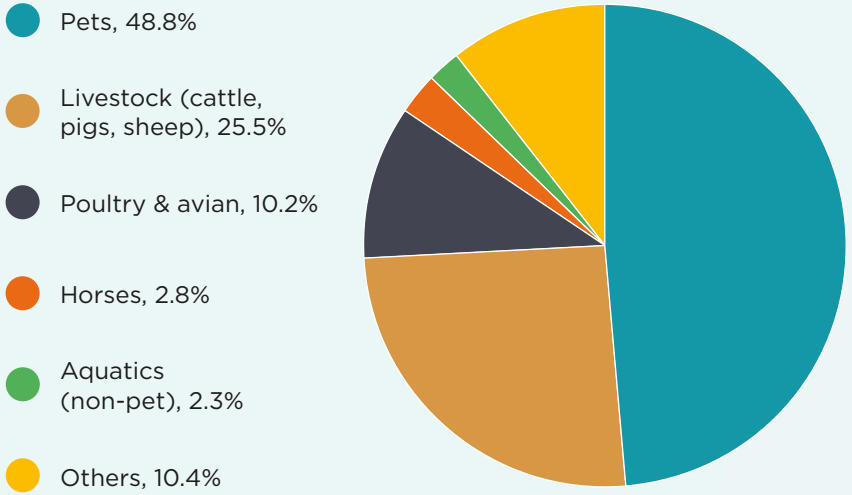
Covering 90% of the European market, our member companies invest around 8% of turnover in research and development every year.

Sales by product category in Europe



Countries covered include AT, BE, BG, BY, CH, CZ, DE, DK, ES, FI, FR, GR, HU, HR, IE, IL, IT, NL, NO, PL, PT, RO, RU, RS, SE SI, SK., TR, UA, UK.
Source: 9 AnimalhealthEurope and CEESA member companies. 20% added for non-participating companies. CEESA stands for Executive Animal Health Study Centre
www.ceesa.eu

Sales by animal species



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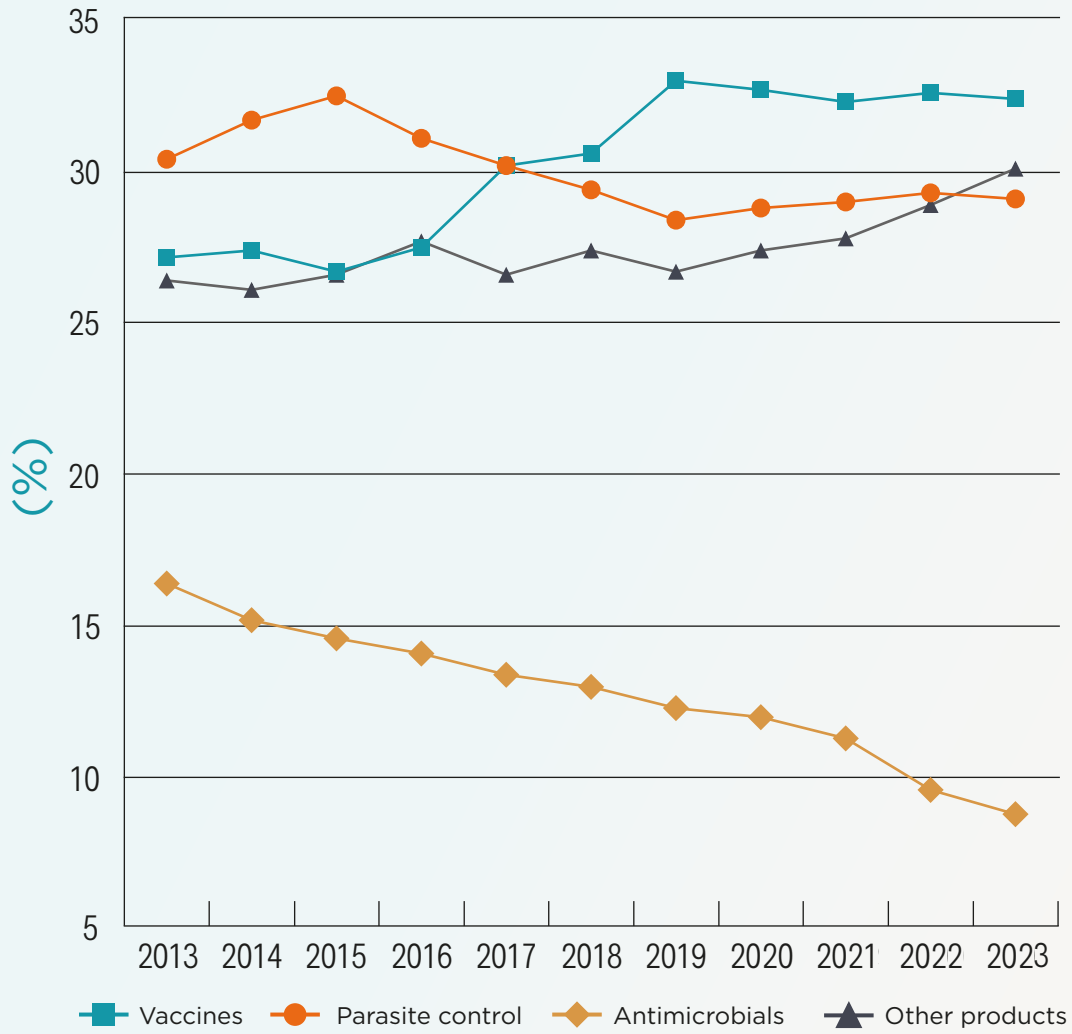
Source: 9 AnimalhealthEurope and CEESA member companies. 20% added for non-participating companies. CEESA stands for Executive Animal Health Study Centre
www.ceesa.eu

Sales per product category in Europe (%) (2013–2023)



Total European sales for 2023: €7.9 Billion

Two years into the new veterinary medicines rules for the EU: a reflection on where we are now

The EU Veterinary Medicines Regulation (2019/6) came into law on 27 January 2019, bringing with it many changes, some highly significant. With a three-year transition period for all parties to make the necessary changes and put everything in place to implement the new laws in each of the member states, the new rules finally became applicable on 28 January 2022. Our Technical Director Rick Clayton reflects on where we are now.

The implementation of the new rules required four substantial areas of work. Firstly, it required an unprecedented number of implementing acts and delegated acts to be drafted, to navigate the infamous 'comitology procedure', and to be adopted and published. And 12 of the 26 acts required had to be adopted before the end of the three-year transition period. Secondly, the rules required the development, validation and launch of a substantial new IT system, comprising three large and inter-connected databases with sophisticated functionalities. The idea was to ensure workflow efficiencies and more modern information management capabilities. Thirdly, many procedural and scientific guidelines had to be revised or, in some cases, new guidelines developed. And lastly, the labelling and packaging of all existing products needs to be updated to comply with the new rules, within a 5-year deadline ending on 29 January 2027.

Implementing acts and delegated acts

The European Commission is on schedule with the implementing measures, with 16 acts published, although there were significant delays to one relating to detailed rules on exports from third countries – Article 118 for those in the know. Remaining obligatory acts have deadlines in 2025 and 2027.

The databases

The second substantial area of work is the development of 3 databases: a Union Product Database (UPD), to house data on every veterinary medicine authorised in the EU; a pharmacovigilance database to collate every adverse event reported; and a database on every licenced wholesale/ distributor and every good manufacturing certified premises.

Work on these databases is not on track as the amount of time and resources needed for the work was totally underestimated. And delays in the European Medicines Agency (EMA) securing the necessary funding from the Commission have not helped. It's fair to say that the EMA moved mountains to deliver a 'minimum viable product' for the UPD by the 3-year transition

deadline but was hampered by IT bugs and the challenge of shepherding 26 resource-stretched members states to upload all their legacy product data.

Unfortunately, the various bugs and incorrect or missing product data has meant the system is currently not viable. To top that, many of the regulatory processes or requirements depend upon the functioning of these IT systems. This has created a massive increase in regulatory administrative burden to navigate the obstacles, the opposite of one of the main objectives of the new regulation.

To truly deliver increased efficiencies in regulatory processes and data management, it's clear that functionalities beyond the bare minimum are needed. And although development of the IT systems continues, progress is slow, and business cases for regulators are prioritised over those for industry. Furthermore, the budget for this work will end after 2025.

Updating regulatory processes and guidelines

The changes in regulatory procedures have required many procedural guidelines to be updated, for example CMDv[1] best practice guides, particularly for product life cycle management. There is also guidance for the new SmPC[2] harmonisation process and the new provisions for the protection of technical documentation.

In addition, the new rules introduced some new concepts and definitions requiring new or revised scientific guidelines, such as: limited markets and exceptional circumstances, novel therapies (e.g. cell-based therapy or use of bacteriophages), vaccine antigen master file, vaccine platform technology master files, and for multi-strain dossiers. Of particular interest has been the revision of the CVMP[3] Recommendation on the evaluation of the benefit-risk balance of veterinary medicines to reflect new wording in the regulation and the implementation of provisions to reduce the risk of antimicrobial resistance (AMR).

Pharmacovigilance – reporting of adverse effects of medicines – has undergone significant revisions under the new rules, requiring substantial (re)development of both company and regulatory agency systems. Workload burden to implement the changes has been compounded by the new systems not being ready or not functioning correctly, and the necessary guidance not being in place. This is further hampered by the need to 'learn as you do', particularly in the transition from periodic adverse event reporting to more frequent signal detection and management.

Updating labelling and packaging of all existing products

One major activity, which is currently stretching the resources of both companies and regulatory agencies, is the requirement to update the labelling and packaging of all existing products by 29 January 2027. For each product a licence update dossier must be prepared, submitted and potentially assessed. Considering that there are an estimated 40,000 plus products

1 Committee for the mutual recognition and decentralised procedures – veterinary
2 Summary of product characteristics
3 Committee for veterinary medicinal products, EMA

in the EU, this is a monumental task, and perhaps even 'mission impossible' within the 5-year deadline. We would question why there is such a strict deadline, given this is purely administrative and not in response to any safety concerns.

So where are we?

Does the new regulation meet its objectives?

Objectives of the new EU rules on veterinary medicines

1. Increase availability of veterinary medicinal products
2. Reduce administrative burden
3. Stimulate competitiveness and innovation
4. Improve the functioning of the internal market
5. Address the public health risk of AMR

The answer for each of the objectives is 'it is too soon', particularly as the full implementation is not yet complete. Furthermore, the full benefits of the IT systems will only be delivered when all the necessary functionalities are put in place – and all bugs eliminated! With doubts around the future funding of this work, there are questions whether the full potential to reduce administrative burden will ever be attained.

So at the moment, the new rules have actually largely increased administrative burden with the development and implementation of new systems and the one-off but massive exercise of updating packaging. And this burden will continue for at least another three years.

Looking to the future

Despite the current situation, we must look to the future with positivity. The AnimalhealthEurope regulatory and technical working parties have been heavily engaged in the consultation process for every element of the development and implementation of these new rules on veterinary medicines.

When implementation is complete both the regulatory authorities and industry can focus on refining the systems to reduce administrative burden wherever possible, for the benefit of everyone involved. We must also remember that the new rules bring new opportunities, for example opening the door to novel therapies and new approaches for the registration of vaccines.

Acknowledgements

I would like to thank all the experts in AnimalhealthEurope working parties for their dedication and accomplishments during this unprecedented period of intense work. In particular, my thanks go to the subject matter experts representing AnimalhealthEurope on the EMA stakeholder groups for IT and Pharmacovigilance. Finally, I wish to acknowledge the hard work of my colleagues, Dave and Jaume, managing and coordinating the workload.

Rick Clayton,
Technical Director

2023 at a glance

Feeding Europe in Times of Crisis

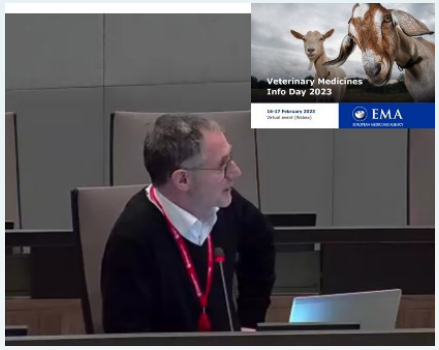
10/02/2023

Agri-food sector associations, agriculture ministers, and MEPs discussed food production related challenges for Central and Eastern Europe in times of crisis.

EU Veterinary Medicines Regulation one year on from application

17/02/2023

At the EMA info day industry and regulators discussed progress and challenges experienced during the first transition year for the new veterinary medicines Regulation.



One Health Summit in Brussels

21/03/2023

Roxane Feller spoke on a panel about innovation in veterinary medicines and their role in One Health.

Working together for more balanced views on European Livestock

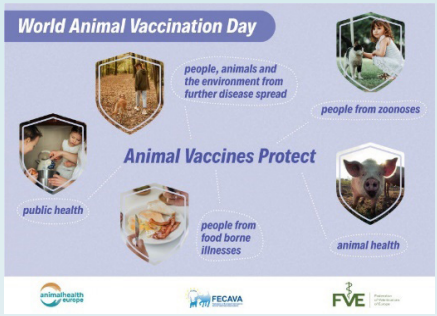
30/03/2023

European Livestock Voice partners joined together with the Spanish platform Somos Ganaderia to discuss political, economic and societal challenges the livestock sector in Europe is facing today.

Animal vaccines protect our shared One Health

20/04/2023

We joined together with veterinary associations FECAVA and FVE to promote the positive role that animal vaccines play in protecting One Health.



Animal health and animal welfare: different role, same goal

01/06/2023

Our annual conference gathered over 100 participants to discuss the role different parties can play in reaching the same goal: high levels of animal welfare in Europe.

AnimalhealthEurope shares views on EU Animal Welfare Legislative Review

05/06/2023

AnimalhealthEurope positions itself as a provider of solutions and supporting improvements in breeding and keeping of farm animals and companion animals.

President and Vice–presidents Confirmed at General Assembly

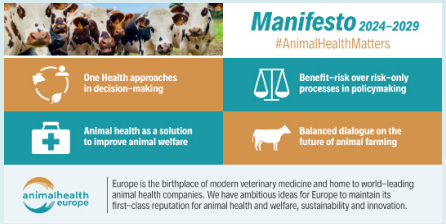
06/06/2023

Rob Kelly, MSD continues as president alongside vice-president Claire Fowler, Boehringer-Ingelheim, with new vice-president Adam Estrup, ViNordic, and Juan Pascual, Elanco as Treasurer.

AnimalhealthEurope publishes Manifesto for 2024–2029

15/06/2023

Ahead of the EU elections coming up in June 2024, our association published a Manifesto outlining four key asks and promoting the industry's MorethanMedicine approach.



The European animal medicines industry in figures updated

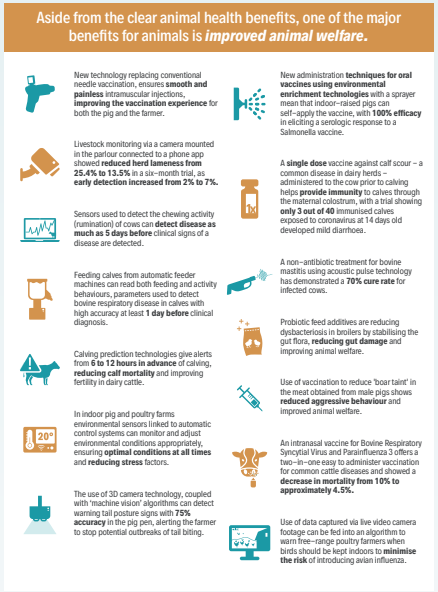
12/07/2023

With data on sales, animal numbers, R&D investment and more, our facts and figures webpage has been updated for 2023.

How today's animal health care is benefiting people, animals and our planet

15/06/2023

AnimalhealthEurope commissioned Oxford Analytica to research modern animal health technologies and their various benefits for animal and human health and ecosystems.



First-ever Veterinary Medicines Awareness Day

12/09/2023

AnimalhealthEurope was invited to speak at the first-ever Veterinary Awareness Day organised by the European Medicines Agency.

FEDIAF and AnimalhealthEurope welcome FVE and FECAVA to Pet Alliance Europe

26/09/2023

PetPower Night saw the annual awarding of winners of the Best Buddies in the Brussels Bubble photo contest alongside the announcement of new partners for the alliance.

The Future of Livestock in the EU and Beyond

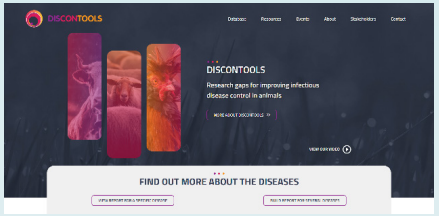
28/09/2023

Partner associations of European Livestock Voice invited scientists, NGOs, policy makers and the agri-food sector to discuss the future of livestock in EU policies.

DISCONTOOLS launches new-look website

03/10/2023

The new website has an enhanced user experience, with possibility to filter diseases by the animal host as well as by the continent where it occurs.



Animal AgTech Innovation Summit

10/10/2023

Our Secretary General Roxane Feller was invited to moderate the opening panel: One Health in Animal Agriculture alongside Thanawat Tiensin from FAO and animal health companies.

TOPRA Veterinary Symposium

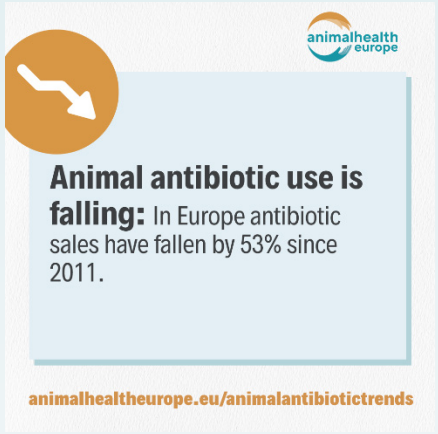
23/10/2023

Veterinary medicines regulatory professionals and authorities met to discuss the latest updates in regulatory affairs.

Continued Responsible Use of Antibiotics in Animals Shows Positive Progress Towards Farm to Fork Target

20/11/2023

AnimalhealthEurope has updated its Trends Report on Animal Antibiotic Use following the publication of the last ESVAC report.



AFCC publishes Recommendations for the EU Strategic Agenda 2024–2029

29/11/2023

Recommendations were presented at an event in the European Parliament and include strengthening European food autonomy and resilience as well as enhancing the competitiveness and sustainability of the entire EU-Agri food chain.

AnimalhealthEurope shares live demo at first EU Agri Digital Event

07/12/2023

Following inclusion of monitoring and tracking technologies in Animal Welfare proposals, AnimalhealthEurope was pleased to share a live demo on monitoring tech in action during EU Agri Food Days.

Members

AnimalhealthEurope's membership covers 90% of the European market for animal health products. Our membership includes both animal health companies and national associations, representing both innovators and generics alike, as well as large, medium-sized and small companies.

Our corporate members

Boehringer Ingelheim

Ceva

Dopharma

Elanco

HUVEPHARMA

MSD Animal Health

Norbrook

ORION

syva

vetoquinol ACHIEVE MORE TOGETHER

Virbac

zoetis

Our national association members

Belgium

pharma.be
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Czech Republic & Slovakia

AHCZSK

Denmark, Norway and Sweden

VINORDIC
VETERINARY INDUSTRY NORDIC

France

SYNDICAT DE L'INDUSTRIE DU MÉDICAMENT ET DIAGNOSTIC VÉTÉRINAIRES
SIMV

Germany

BfT

Greece

ΣΑΕΠΚΦ
ΣΥΝΔΕΣΜΟΣ ΑΝΤΙΠΡΟΣΩΠΩΝ ΕΙΣΑΓΩΓΕΩΝ & ΠΑΡΑΣΚΕΥΑΣΤΩΝ ΚΤΗΝΙΑΤΡΙΚΩΝ ΦΑΡΜΑΚΩΝ

Hungary

IVPM
Hungarian Association of Innovative Veterinary Pharmaceutical Manufacturers' Representatives

Ireland

APHA
ANIMAL & PLANT HEALTH ASSOCIATION

Italy

FEDERCHIMICA AISA
Associazione nazionale imprese salute animale

Netherlands

Fidin

Poland

POLPROWET

Portugal

APIFVET
Associação Portuguesa da Indústria Farmacêutica de Medicamentos Veterinários

Spain

Veterindustria
Asociación Empresarial Española de la Industria de Sanidad y Nutrición Animal

Switzerland

scienceINDUSTRIES
SWITZERLAND

United Kingdom

NOAH
National Office of Animal Health

Ukraine

EBA
European Business Association

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