ACTIVITY REPORT

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2024 Access VETMED

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1 FROM THE CHAIR

As we look back on 2024, it is evident that Access VetMed has continued its unwavering commitment to ensuring the availability, compliance, convenience, efficacy, safety, and affordability of veterinary medicines across Europe.

One of the most significant milestones of the year was the publication of the **2024 Market Study on Veterinary Generics and Added-Value Medicines in Europe**, which offers a comprehensive analysis of our industry's current landscape. The study confirmed that generic veterinary medicines now account for a substantial share of the market, underscoring their vital role in fostering competition, affordability, and accessibility.

Among its key findings, the report highlighted:

- The steady rise in the adoption of generic veterinary medicines across Europe, reinforcing their importance in increasing availability and providing cost-effective treatment options.
- The growing presence of small and medium-sized enterprises (SMEs) in the sector, driving innovation and market diversity.
- The ongoing regulatory challenges that hinder industry growth, particularly the increasing administrative burden of pharmacovigilance requirements.

Armed with these insights and a clear understanding of the impact of new legislation on our sector, Access VetMed is now preparing a **manifesto** outlining key demands to European authorities. Our objective is to advocate for a more balanced regulatory approach that acknowledges the specific characteristics of the veterinary generics sector. This includes:

1. **Reducing unnecessary administrative burdens** to ensure that companies, especially SMEs, can continue to provide affordable and accessible medicines.
2. **Promoting a fair and competitive market** that allows generic veterinary medicines to thrive alongside innovative pharmaceuticals.
3. **Ensuring that pharmacovigilance practices** align with the scale of the veterinary pharmaceutical industry, avoiding excessive constraints that could limit market availability.

Looking ahead, we remain committed to constructive engagement with policymakers, industry stakeholders, and animal health professionals. The findings of the **2024 Market Study** reinforce the need for continued advocacy and collaboration to shape a regulatory environment that supports both innovation and accessibility.

As we move into 2025, we invite all stakeholders to join us in this effort. **Together, we can ensure that veterinary medicines remain both effective and accessible, safeguarding animal health and welfare across Europe**.

#TogetherStronger

Xavier Molins
Chair, Access VetMed

2 FROM THE TECHNICAL DIRECTOR

Elsa Vecino has been serving as the Technical Director of Access VetMed since 2011. In this interview, she shares her insights on various industry and association-related matters. Additionally, she offers some personal tips to help us get to know her a little better.

1. What have the milestones for the Association been in 2024 from a technical standpoint?
One major achievement in 2024 was the publication of the new Guidance to Applicants in spring. This document plays a crucial role for our members, as it provides interpretation of new provisions regarding the protection of technical documentation.

We have also actively supported our members in navigating the evolving regulatory landscape. This includes helping them interpret and implement new scientific guidelines and procedures, including clarifications on the SPC harmonization process, which is currently being applied to the first generic medicines.

We also participated in the consultation process for the new UK Veterinary Medicines Regulations 2024, to ensure that any divergence with EU Regulation 2019/6 would have no significant impact on the day-to-day operations and business of the Animal Health industry. In general terms, the UK is well aligned to EU Regulations, except for the area of pharmacovigilance, where more significant follow-up, workload and adaptations were required.

2. What new challenges will we face as an Association this year and in the coming years?

While the implementation of Regulation (EU) 2019/6 has brought important harmonization, it has also introduced significant financial and administrative burdens. Addressing these challenges is a top priority. One of the most pressing challenges is the revision of veterinary medicine labelling and packaging, which must be completed by 29 January 2027. This update affects all veterinary medicinal products licensed in the EU, creating an enormous workload and requiring substantial resources in a limited timeframe. Ensuring that companies can meet this deadline efficiently is a key focus for our efforts.

The ongoing development of the Union Product Database and the Pharmacovigilance Database also requires a significant investments and workload both at the side of the industry and regulators. The transition has been more complex than initially expected, with unforeseen technical issues adding to the workload. As many daily regulatory processes now depend on the smooth operation of these databases, ensuring their proper functioning remains a crucial priority.

Despite these challenges, our approach remains solution-oriented and collaborative. We are committed to supporting our members through advocacy, expert guidance from our members and working groups, and continuous dialogue with policymakers to ensure a sustainable and efficient regulatory environment for the veterinary medicines sector.

3. What would you highlight as the key benefits of an Access VetMed membership?

Being part of Access VetMed provides numerous advantages for companies in the generic and added-value veterinary medicines sector.

CLOSE UP

- ☑ **A dream...** More than a dream, a project: be back to playing drums
- ☑ **A movie...** Edward Scissorhands
- ☑ **A melody...** Gimme Shelter
- ☑ **A book...** Any from Manuel Vázquez Montalbán
- ☑ **An animal...** Dog
- ☑ **In your spare time...** I sing in a choir

As the only EU-level organization exclusively focused on this industry, we offer a dedicated platform where members can actively shape our priorities and activities, ensuring that their voices are heard. Our association operates with a member-driven approach, where each company has equal rights and direct involvement in decision-making.

As an official acknowledged EMA stakeholder, we work closely with EU and national authorities to ensure that the interests of our members are effectively represented in policy discussions. By actively engaging early in the European policymaking process, our members contribute to regulatory debates and help shape policies that directly impact the industry. We foster collaboration and partnerships, providing opportunities for companies to connect and work together on shared initiatives, such as work-sharing projects and joint consortia. Our members also gain access to expert insights, with timely updates, alerts, and specialized training sessions that keep them informed on regulatory developments.

Networking is another important aspect of our work. Through working groups, task forces, and industry meetings, members have the opportunity to engage with peers, exchange knowledge, and build valuable relationships. By being part of Access VetMed, companies not only stay ahead of industry changes but also strengthen their position in the European veterinary medicines sector.

At Access VetMed, we are committed to providing our members with the resources, representation, and collaborative environment they need to navigate an evolving regulatory landscape, amplify their voice, and ensure a sustainable and competitive future for the industry.

WORKING GROUPS

3 HIGHLIGHTS

Alazne Goldaraz
Antimicrobials and AMR

Over the past year we have been focused on preserving the effective use of antimicrobials and promoting access to veterinary antimicrobials.

Access VetMed is an active member of the EU community of interested parties within the framework of AMR. As a member of EPRUMA, JAMRAI and the AMR One Health Network, Access VetMed´s visibility continues to growth. In this context, the members of the WG are committed to actively contributing with their scientific and technical expertise to the objectives of the organizations under the umbrella of the One Health approach.

I would like to highlight contributions on several consultations, such as the Commission Implementing Regulation (EU) 2024/1973 on the responsible use of antimicrobials used under the cascade, which was published in July 2024, and the EMA's guideline for the demonstration of efficacy of veterinary medicinal products containing antimicrobial substances. Additionally, the working group also participated in discussions on responsible use guidelines.

I am confident that new challenges, such as the ADRA project, the monitoring of antimicrobial resistance, and the evaluation of the impact of antimicrobial policies on the regulatory framework, will continue to drive our commitment to these goals.

Pablo Tejero
Environmental Risk Assessment

2024 has not been an intense year of activity for this group. However, most relevant trends in this area involve the discussion about the assessment of the ecotoxicity of parasiticidal medicines for cats and dogs; as well as specific environmental risks of antibiotics and development of a guideline for assessment of aquaculture medicines.

Robert Alz
Immunological VMPs and Novel Therapies

Our group is committed to advancing immunological and novel therapies through continuous dialogue and intensive collaboration.

In 2024, the Immunological and Novel Therapies WG actively engaged in key discussions on animal health. In January, on behalf of Access VetMed, I participated in a Ministerial Conference on "Biosecurity and Vaccination: Essential Tools for the Prevention, Control, and Eradication of Animal Diseases" in Brussels.
This event, held under the Belgian Presidency of the Council of the European Union, was highly interesting and provided valuable opportunities for discussions and networking.

In September, our working group attended an Interested Parties Meeting of the IWP of the CVMP. This annual meeting serves as an excellent platform to share our suggestions, ideas, and concerns with regulatory authorities and other stakeholders.

Beyond these key engagements, we have actively contributed to regulatory processes by reviewing and commenting on various legislative proposals on biological or immunological veterinary medicinal products to ensure that Access VetMed´s views are well represented.

Jessica Harrison
Labeling and Packaging

The labelling working group is actively addressing the challenges associated with the implementation of QRDv9.0 by 2027. We are collaborating with CMDv to ensure that the industry's position on this issue is effectively communicated. As part of this effort, we regularly conduct surveys of our members and present the findings and key conclusions to CMDv.

Sonja Schwab

IT Pharmacovigilance systems

2024 marked the last year of the cooperation between EMA, national competent authorities and industry on the development of the pharmacovigilance databases. A milestone was the implementation of product groups in almost all dashboard, significantly enhancing the performance of most queries. The development of a new dashboard on trends was started, however it could not be completed. Depending on the resources available at EMA further development will be coordinated via the joint implementation group. One significant point of discussion was the calculation of incidence rates, which resulted in a revision of the public portal. However, even after the second release, industry has still concerned regarding the methodology and will continue to raise it with the competent authorities.

While the systems may not be perfect, the collaboration was highly appreciated and considered successful by all parties involved.

Andreas Werner

Pharmacovigilance

We participated in the Pharmacovigilance Joint Implementation Group meetings of the EMA. A personal presence at the PhVWP-V Interested Parties meeting in Amsterdam enabled more intensive discussions with regulators and other stakeholders.

The results of the survey of Access Vet Med members on administrative burdens were presented at this meeting, demonstrating a considerable increase in personnel workload since the introduction of the new Regulation 2019/6.

Other topics discussed in the meetings with competent authorities and EMA included the experience gained with the observation of anaphylactic reactions in cattle to various veterinary medicinal products and the pharmacovigilance communication with regulatory authorities.

The update of the product texts according to the QRDv9.0 template required the competence of the pharmacovigilance team in classifying the frequency of adverse events. Unfortunately, this experience is not recognised in the conversion, since the regulatory authorities relatively often require a classification in ‘undetermined frequency’, which does not provide vets with clear guidance on safe treatment.

Xavier Molins
Quality

During 2024 we actively participated in EMA's QWP/ Interested Parties Meeting in October and provided several comments on EMA's proposed Guideline on Quality data requirements for applications for Veterinary Medicinal Products (VMPs) other than biologicals intended for limited markets, as well as the Guideline on stability testing for applications for variations to a marketing authorisation for VMPs. The comments reflected fair remarks raised by our members.

Most notably, our members thoroughly challenged EMA's advice on the implementing measures on VMPs, as regards the GMP for VMPs and active substances. In this regard, the EU Commission (EC) recently released the Draft Implementing Act, and the industry should be satisfied with the final outcome of the consultation process, as the EC confirmed that no changes to status quo would apply.

Concerning the potential ban on PFAS, this group has been closely monitoring this issue. Recent developments indicate that the relevant Committees may not reach a final decision until late in 2025. However, there is still hope that pharmaceutical industry may be granted a separate category, as the EU Commission has made it clear that they do not want to over-regulate and prefer to allow appropriate derogations.

Inmaculada Zorrilla
Regulatory Procedures

The most notable regulatory event over the past year was the publication of the Guidance to Applicants – VMPs, a document designed to assist stakeholders in complying with their obligations under the Regulation 2019/6 on veterinary medicines. The document was thoroughly reviewed in collaboration with other members of the association, with a particular focus on the new marketing authorizations that can be used as reference veterinary medicinal products and the rules surrounding the protection of technical documentation.

Continuing with the follow-up on the implementation of the Regulation 2019/6, several issues of interest for the group were addressed throughout the year in different meetings with the authorities, aiming to clarify and simplify some regulatory procedures.

Finally, close monitoring of national requirements was conducted, primarily to detect duplications arising from the new tools introduced after the implementation of the Regulation, as one of its goals is to reduce the administrative burden.

Cormac Caraher and Špela Miklič
Safety & Efficacy - Bioequivalence

2024 allowed the Safety and Efficacy working group the chance to review a wide range of draft guidance documents and concept papers. The opportunity to provide feedback on the draft guidance document for multicentre/multinational clinical trials was particularly welcome with a broad range of comments received.

Members of the working group also attended (on-line) the VetCast meeting/presentation in April which discussed ongoing susceptibility testing projects and gives a good indication of future efficacy requirements for antimicrobial products.

Members of both Bioequivalence and Safety and Efficacy working groups also were involved in preparing/reviewing its views on 3Rs approaches and opportunities, which were then presented to EMA. This was done with the aim of Replacing, Reducing and Refining the use of animals required for regulatory studies.

Aafke Huizenga
Variations

The group continued to monitoring the progress of G.I.18 VRAs (QRD) submissions and engaged with CMDv to propose solutions for a smoother and more efficient process.
We maintained our regular and technical discussions with CMDv, including topics such as the cover letter for VNRAs and text corrections following VNRA submission and approval.
The Access VetMed WG Variations also worked with regulators to look for solutions considering the prolonged duration of procedures in some NCAs, caused by severe delays with handling variations and during the national phase.
We closely followed updates to the legislative changes, including revisions to the Regulation establishing a list of VNRAs, and the implementation of associated guidelines for VRAs and VNRAs.

OTHER TASK FORCES

Marc Cayol
2024 Market Study

After several months of work, extracting and analyzing key messages to communicate it has been really a great pride for us to present our market study during last February. After several months of dedicated work extracting and analyzing key insights, we were incredibly proud to present our market study this past February. The **2024 Market Study on Veterinary Generics and added-Value Medicines in Europe**, includes the most up-to-date data on the medicines industry in Europe.

I'm sure that the AccessVetMed market study 2024 will have quite an impact on our key stakeholders, as it offers reliable data presented in a way that is understandable for everyone. The study allows us to showcase the true scale of the generic medicine industry in Europe as well as facilitate our voice to be heard.

It has been a quite laborious task for this achievement that required a lot of dedication, that is for I really would like to thank all members of the working group for their big efforts. The new UPD database from the European Medicines Agency and the thorough qualitative and quantitative surveys conducted with our members have been for sure the keys to successful outcome.

Silvia Húmera
Communications & Marketing

The newly established Marketing and Communications Expert Group has been actively working to enhance our outreach and engagement with key stakeholders, including member companies, European and national authorities, veterinarians, farmers, and pet owners. Together, we develop strategic communication plans, compelling content, and impactful messaging to ensure that the voice of the European generic and added-value veterinary medicines industry is heard.

Our goal is to strengthen relationships, increase awareness, and advocate effectively for a fair, competitive, and sustainable regulatory environment. By aligning our efforts, we ensure that our industry's contributions to animal health and welfare are recognized at all levels.

4 FIGURES

±9.000

EMPLOYEES

BASED IN EUROPE

2,6

BILLIONS

27

MEMBER COMPANIES

ALL THERAPEU-TIC GROUPS

WIDE RANGE MAJOR &MINOR SPECIES

5 AGENDA


CMDv Interested Parties – 19.01
24.01 – Belgian Ministerial Conference on "Biosecurity and vaccination: essential tools for the prevention, control and eradication of animal diseases"
EMA Veterinary InfoDay – 14 & 15.03
EMA 3Rs WP Stakeholders – 20.03
02-02 - General Managers Meeting
EC Informative session - Guidance to Applicants – 26.03
15 & 16.05 – Board meeting in Vienna
HMA Veterinary Stakeholders – 17.04
22.05 – CVMP Interested Parties
General Managers Meeting in Bucharest – 12-13. 09
20.09 – CMDv Interested Parties
EMA QWP Interested Parties – 11.10
25.09 – EMA PhVWP-V Interested Parties
EMA 4th Veterinary Big Data Stakeholder Forum – 14.10
22.10 – EMA IWP-V Interested Parties
EAAD – European Antibiotic Awareness Day – 18.11
13 & 14.11 – 7th VICH Public Conference

6 OUR MEMBERS

7 GLOSSARY

ADRA	Dosage review and adjustment of established nationally authorised veterinary antibiotics
AM	Antimicrobials
AMR	Antimicrobial Resistance
CA	Competent Authority
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary
CVMP	Committee for Veterinary Medicinal Products
EMA	European Medicines Agency
EU	European Union
EPRUMA	European Platform for the Responsible Use of Medicines in Animals
GMP	Good Manufacturing Practices
IWP	Immunologicals Working Party
PFAS	Per- and Polyfluoroalkyl Substances
QRD	Quality Review of Documents on the Regulation (EU) 2019/6
QRD V 9.0	Quality Review of Documents on the Regulation (EU) 2019/6 – Version 9
QWP	Quality Working Party
UPD	Union Product Database
Vet CAST	Veterinary Committee on Antimicrobial Susceptibility Testing
VMPs	Veterinary Medicinal Products
VRA	Variations Requiring Assessment
VNRA	Variations Not Requiring Assessment
WG	Working Group
3Rs	Replacement, Reduction, Refinement

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