ACTIVITY REPORT

2025

Access VETMED

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INDEX

1 FROM THE CHAIR

The past year has marked an important period of consolidation and strategic progress for Access VetMed. Building on the publication in 2024 of the most comprehensive market study ever undertaken by our association, our collective efforts in 2025 have focused on translating robust evidence into concrete policy outcomes.
Our 2024 European generic and added-value veterinary medicines market study, grounded in official European Union databases and enriched by extensive qualitative and quantitative input from our member companies, delivered a clear and authoritative picture of our sector.

For the first time, it rigorously quantified the economic, societal and public-health contribution of veterinary generics and value-added medicines across Europe, materially strengthening our position in structured dialogue with European institutions.
In 2025, we further advanced this evidence-based agenda with the launch of our Manifesto, "Advancing access to veterinary medicines in Europe by streamlining processes." It sets out practical and targeted proposals to improve how regulatory and administrative frameworks function in practice.

The message is clear: Europe needs a regulatory environment that delivers predictability, supports availability, enables investment and fully recognises the essential role of veterinary medicines in animal health, public health and food security. The Manifesto has been actively shared with the European Commission and other key stakeholders, supported by targeted media engagement and sustained visibility across our communication channels. Maintaining constructive but firm engagement around these priorities will remain central in the year ahead.

2025 has also been a milestone year for Access VetMed from a membership perspective. We were pleased to welcome new member companies, reflecting the growing relevance and credibility of our association. Importantly, we have now exceeded 30 member and associate companies, confirming the value of collective representation and a strong, unified European voice.
This continued growth reinforces our influence at EU level and our shared ambition to ensure that veterinary generics and added-value medicines are fully recognised as a cornerstone of resilient, sustainable animal-health systems. In a context of increasing regulatory complexity, fragmentation is not an option. Our guiding principle therefore remains unchanged and more relevant than ever: together, we are stronger.

Internally, our working groups have been further reinforced through new expertise, active participation and strong member engagement. In parallel, we are developing new communication tools to better articulate the value of our sector, challenge persistent misconceptions and demonstrate the indispensable contribution of veterinary generics and added-value medicines within a holistic One Health approach.
The year ahead will bring challenges, but also a real opportunity to shape outcomes. With a growing membership, a clear strategic direction and a shared commitment to constructive engagement, Access VetMed is well positioned to continue influencing a policy environment that supports innovation, ensures availability and safeguards access to veterinary medicines across Europe.

#TogetherStronger

Xavier Molins
Chair of Access VetMed.

2 FROM THE TECHNICAL DIRECTOR

Throughout 2025, our technical discussions centred on navigating the evolving regulatory landscape under Regulation (EU) 2019/6, driving harmonisation, improving transparency, and mitigating increasing administrative burdens for generic and added-value veterinary medicinal products. The year was marked by sustained engagement with the European Commission, EMA, CMDv, and national authorities, with Access VetMed acting as a coordinated industry voice for predictability, proportionality, and efficient implementation.

Overall, across 2025, our technical work focused on increasing regulatory predictability, advocating for proportional requirements, supporting harmonised EU-wide processes, and mitigating cost and burden increases, all critical for ensuring continued availability of veterinary generics and hybrids in the EU and UK/NI markets.

Elsa Vecino.
Technical Director, Access VetMed.

MAIN TOPICS

Regulation 2019/6 Monitoring

Monitoring the impact of Regulation 2019/6 through data collection and market analysis, highlighting administrative burden and regulatory fees.

PTD Transparency

Advocating for predictable and accessible data protection expiry information for generic applications.

SPC Harmonisation

Supporting harmonisation to reduce regulatory fragmentation and improve regulatory predictability.

ADRA Project

Supporting members in the ADRA project on amoxicillin products for pigs.

Multilingual Labelling & QRD

Monitoring QRDv9 implementation and regulatory workload across Member States.

Guidance to Applicants

Supporting correct interpretation and reporting implementation issues to regulators.

3 FROM THE BOARD

You have been a member of the Board of Access VetMed for some time now. How would you describe your experience on the Board?

Being a member of the Board of Access VetMed has been a highly valuable and enriching experience. It has allowed me to collaborate with senior professionals from across the industry and to engage in strategic discussions that shape the future of our sector at European level.

The Board provides a space for constructive dialogue, where different perspectives—business, regulatory, and technical—come together to define common priorities. This exchange has been particularly insightful and has strengthened my understanding of the broader challenges and opportunities facing added-value and generic medicines in Europe.

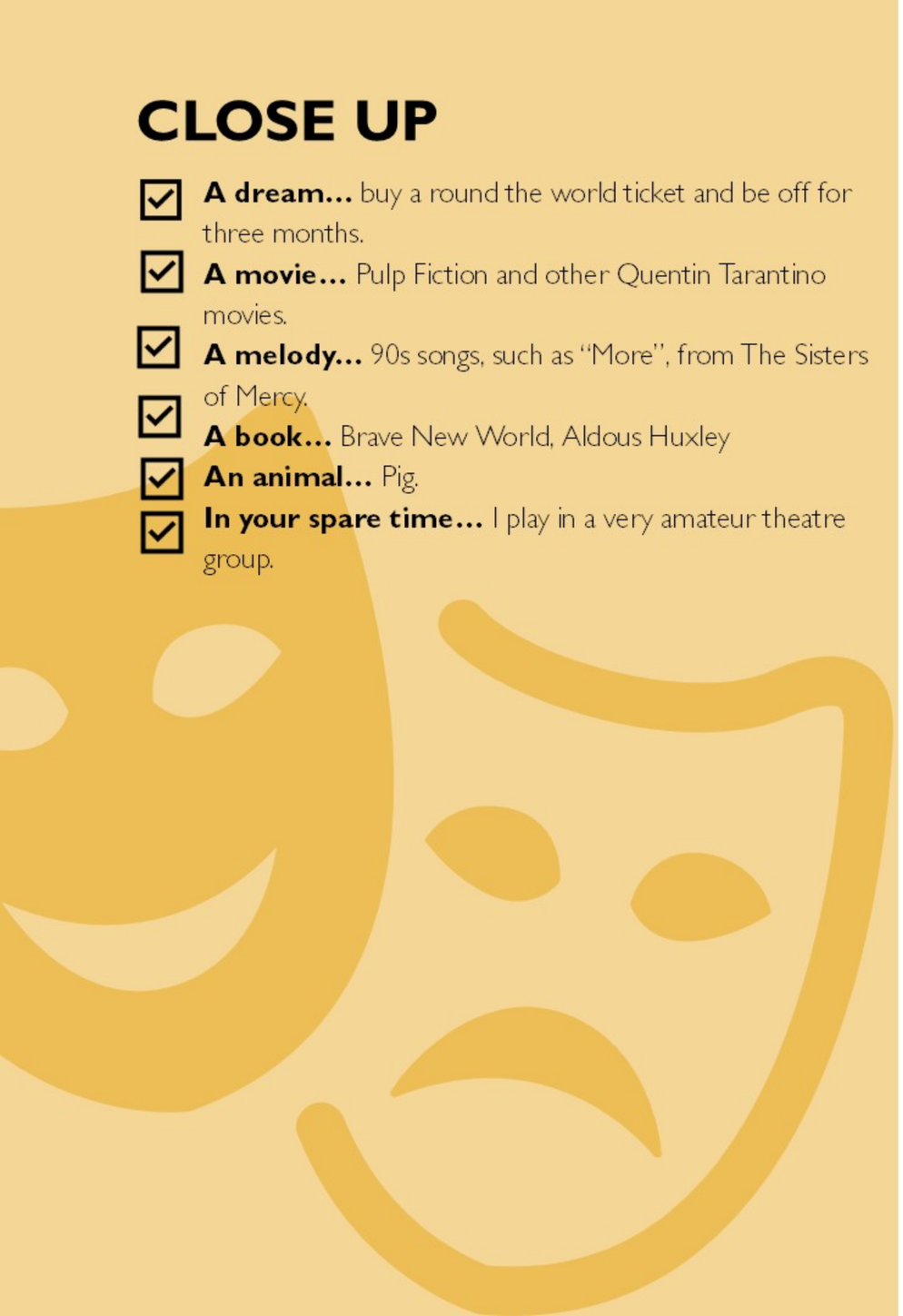
As CEO of a company within the pharmaceutical industry, what do you believe your professional experience brings to the association? How can industry leadership help strengthen Access VetMed's mission and impact?

I believe I have been able to contribute more of the business perspective to the association. Leading a company in this sector means addressing operational, financial, and strategic challenges on a daily basis, and I aim to bring those real-world concerns into the Board's discussions.

This includes conveying what truly matters to companies like mine: the sustainability of our business models, regulatory predictability, market access conditions, and the ability to continue investing in development and innovation. It is essential that the association understands our key concerns, our priorities, and how our interests can best be represented and defended.

CLOSE UP

- **A dream…** buy a round the world ticket and be off for three months.
- **A movie…** Pulp Fiction and other Quentin Tarantino movies.
- **A melody…** 90s songs, such as "More", from The Sisters of Mercy.
- **A book…** Brave New World, Aldous Huxley
- **An animal…** Pig.
- **In your spare time…** I play in a very amateur theatre group.



Balancing our Board, with members that have more general management roles as well as regulatory or technical profiles, is fundamental. It ensures that strategic decisions are not only technically sound but also aligned with business realities, ultimately strengthening both the association and the companies it represents.

Looking at the initiatives carried out by the association this year, which action or milestone would you highlight as particularly significant, and why?

One of the key milestones during this period was the launch of the generic medicines market study in 2025. The association carries out this study every two years; however, this latest edition was significantly more comprehensive. It was developed using official databases, complemented by detailed quantitative and qualitative surveys conducted among association members. This more exhaustive approach allowed us to present robust, evidence-based data on the economic and healthcare impact of the generic medicines industry in Europe.The study was later complemented by the publication of a manifesto setting out a series of requests to European authorities, particularly regarding legislation and administrative barriers affecting generic medicines.

Without the solid data provided by the market study, it would have been far more challenging to establish a strong and credible position to support these policy proposals. In my view, both documents represent major contributions to the industry and essential tools for engaging constructively with European policymakers.

From your perspective, how do you see the future of added-value medicines in Europe?

I see a solid and necessary future for both generic and added-value medicines in Europe. Healthcare systems are under constant pressure to deliver high-quality care while maintaining financial affordability. Generics ensure broad access and cost-efficiency, while added-value medicines build on existing molecules to improve adherence, safety, convenience, or overall patient outcomes.

That said, the sector faces important challenges. These include regulatory complexity, pricing pressures, supply chain and quality constraints, and, in some cases, a lack of adequate recognition of the added value these medicines provide.

Andreas Asamer. CEO of VetViva Richter Austria. Board member, Access VetMed.

WORKING GROUPS

4 HIGHLIGHTS

Alazne Aldaraz
SP Veterinaria
Antimicrobials and AMR

Throughout 2025, the activities of the Antimicrobial and Antimicrobial Resistance Working Group have been aligned with the One Health framework and with the common objective of addressing the development of antimicrobial resistance.

Our priority has been to preserve the therapeutic value of the veterinary antimicrobial products, while ensuring their availability and responsible use. We believe that availability and responsible use must go hand in hand.

We have also focused on the importance of the Summary of Product Characteristics (SPCs). We consider it essential that the information included in the SPC contributes to ensuring availability, while supporting effective and responsible use of antimicrobials.

In 2025, a major priority has been the follow-up of the ADRA initiative — the European Medicines Agency programme on Veterinary Antimicrobial Dosage Review and Adjustment of Established Doses. We support the objective of reviewing and, where necessary, adjusting established doses to ensure continued efficacy and alignment with resistance prevention principles. The first review under the ADRA framework started in 2025, and our member companies are actively involved in contributing data and closely following the process to ensure a balanced and science-based outcome.

Through this working group, we are committed to supporting practical and science-based solutions that preserve antimicrobial effectiveness and ensure responsible access to veterinary medicines throughout Europe.

During 2025, the ERA Working Group (ERA WG) contributed to European regulatory discussions by issuing comments on two Concept Papers from the Committee for Medicinal Products for Veterinary Use (CVMP). These papers addressed the environmental risk assessment of ectoparasiticidal products for cats and dogs, and the assessment of public health risks related to antimicrobial resistance in the environment resulting from the use of veterinary medicinal products.

In both cases, the ERA WG supported the further development of these initiatives, recognizing their importance for the protection of public health and the environment. These topics are receiving increasing attention from regulators, the scientific community, and society at large, and the ERA WG agrees that they should be appropriately addressed within the veterinary regulatory framework.

At the same time, the ERA WG emphasized the importance of a proportionate, science-based and One Health approach. The Group highlighted the need for regulatory requirements to be aligned with the actual level of risk, based on exposure considerations and available scientific evidence. This approach aims to ensure effective protection of public and environmental health while avoiding unnecessary regulatory burden and supporting the availability of veterinary medicinal products across Europe.

Pablo Tejero
Labiana
Environmental Risk Assessment

In 2025, the WG Immunologicals & Novel Therapies continued its work on scientific and regulatory topics related to immunological, biological, and novel veterinary medicinal products. The group's scope includes emerging modalities such as monoclonal antibodies and phage therapy, reflecting the increasing complexity and innovation within the veterinary pharmaceutical landscape.

Following an internal restructuring within one member company, the working group experienced a temporary decline in membership. Through coordinated efforts by both, the Board and the working group—supported by targeted presentations at the General Managers Meeting and during regular Access VetMed meetings - several new and highly committed members were successfully recruited. This renewed engagement ensures that the group can maintain its activities and continue contributing expertise to the association.

A key milestone in 2025 was the participation in the CVMP Interested Parties Meeting for immunological products. This event remains an essential platform to dialogue with regulatory authorities and other stakeholder organizations, enabling the group to stay aligned with evolving expectations and scientific developments.

Throughout the year, the working group also reviewed and commented on multiple draft regulatory documents. By providing consolidated expert feedback, we contributed to shaping future guidance relevant to immunological and novel therapies in veterinary medicine.

Robert Alz
WDT
ImmunologicalVMPs and
NovelTherapies

The members of our pharmacovigilance working group participated in a virtual meeting with the new staff responsible for the pharmacovigilance at EMA. At the Pharmacovigilance Working Party Interested Parties meeting in Amsterdam on May 21st a presentation for the difficulties in reporting of incidences has been given by Sonja Schwab. Andreas Werner requested the authorities to present their experiences in pharmacovigilance inspections, frequent observations and recommendations to improve the quality of the PV systems. Access VetMed also participated in the virtual PhVWP-V industry stakeholders meeting (formerly the joint implementation group (JIG)).
At the occasion of the meeting with European Commission DG Santé that took place in October 29th, the administrative and financial burden of a variation for all VMPs of a marketing authorization holder on a change in the Pharmacovigilance System Master File (e.g. change of the QPPV) causing a high variation fee has been brought to attention of the Commission.
In the meeting of the pharmacovigilance working group on the 19th of November, a new chair for the group was elected. Sonja Schwab (Richter Pharma) was elected with the unanimous approval of all members present.

Andreas Werner
Bela Pharm
Pharmacovigilance

Sonja Schwab
VetViva Richter
IT Pharmacovigilance
systems

Xavier Molins
Bimeda
Quality

In 2025, the Access VetMed Quality Working Group played a visible and substantive role in shaping EU-level discussions on quality requirements for veterinary medicinal products.

The group actively coordinated industry representation and technical input at EMA Quality Working Party (QWP) Interested Parties meetings, ensuring that the practical realities faced by generic and added-value medicine manufacturers were clearly articulated to regulators. Through consolidated member feedback, the Working Group challenged overly prescriptive or divergent interpretations of GMP requirements, API inspections and quality data expectations, advocating consistently for proportionate, risk-based and predictable regulatory approaches. Members also closely monitored and contributed to policy debates with direct quality implications, including titanium dioxide, PFAS and evolving horizontal manufacturing controls.

By providing timely, technically robust input to consultations, position papers and direct exchanges with EU institutions, the Working Group strengthened Access VetMed's standing as a credible and solution-oriented stakeholder.

In 2025, the Regulatory Working Group focused on strengthening dialogue with EU institutions and on supervision of national requirements. A key milestone was the first bilateral meeting with the European Commission, where we highlighted the disadvantages of Regulation (EU) 2019/6 compared with the previous framework, particularly in relation to the implementation timelines applicable to certain type of variations.

Operational impact of the current implementation rules, with particular emphasis on Variations Requiring Assessment (VRAs) was commented. It was proposed as implementation date that corresponding to the end of procedure for variations subject to reduced timetables, as well as for those following a standard timetable but with no impact on the SPC, labelling or package leaflet.

For Variations Not Requiring Assessment (VNRAs), we submitted several proposals aimed at reducing rejection rates, including targeted revisions to specific provisions of Commission Implementing Regulation (EU) 2021/17 to achieve greater harmonisation, clarity, and predictability across Member States.

In parallel, the group conducted continuous monitoring of national requirements with the objective of minimising their number and variability, thereby reducing the administrative workload for the regulatory affairs departments and improving overall procedural efficiency.

Inmaculada Zorrilla
Livisto
Regulatory Procedures

Cormac Caraher
Bimeda
Safety and Efficacy

Although 2025 may not have been as busy as some of the previous years for the Safety and Efficacy Group, there were some notable events.
New guidelines were published, effective from Sept 2025, which would need to be reviewed and should prove useful to members of the group, these included
Demonstration of efficacy for Veterinary Medicinal Products containing antimicrobial substances
Conduct of efficacy studies for intramammary products for use in cattle.

A draft guideline was published in relation to the Target Animal Safety for Veterinary Monoclonal Antibody Products (VICH GL62) and although this was reviewed by the group, it was outside the area of expertise for most and comments were limited.

The working group was given the opportunity to review and provide comments on the reflection paper relating to the implementation of 3Rs in the testing of veterinary medicinal products. Given the ethical ramifications and the manner in which the industry is aligning itself, this was deemed particularly appropriate.There was also the opportunity to propose points for discussion by the EMA working group in relation to the implementation of 3Rs in the conduct of various anima studies.
Members of the working group also reviewed the Regulation (EU) 2019/6 and its delegated and implementing acts, with the aim of helping to make legislation more effective and workable for all stakeholders. As a result of this we were able to provide the Technical Director with 3 proposals for clarification/improvement.

During the reporting period, the AVM Working Group on Bioequivalence achieved a significant milestone. Our Chair was formally welcomed as advisor to the VICH Bioequivalence Expert Working Group (EWG) in March.

There is VICH Biowaiver Guideline developing and it remains under active discussion and refinement. Our involvement has ensured that the perspectives and expertise are represented at international level.

Therefore throughout the year, the principal focus of the WG BEQ has been the systematic review of each successive draft of the VICH Biowaiver Guideline. The group undertook a detailed and iterative assessment of the various versions, preparing consolidated and scientifically substantiated comments for submission to VICH.

To support this work, we convened multiple online meetings, enabling members to discuss the technical content in depth, align positions, and ensure consistent and high-quality input across the different consultation stages.

In addition to its contributions to VICH, our group also reviewed and provided written comments on the Reflection Paper on the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs in veterinary medicinal product development and assessment.

Overall, we continued to play an active and valuable role in advancing harmonised approaches to bioequivalence assessment at both European and at international level, reinforcing our commitment to scientific quality, regulatory coherence, and animal welfare.

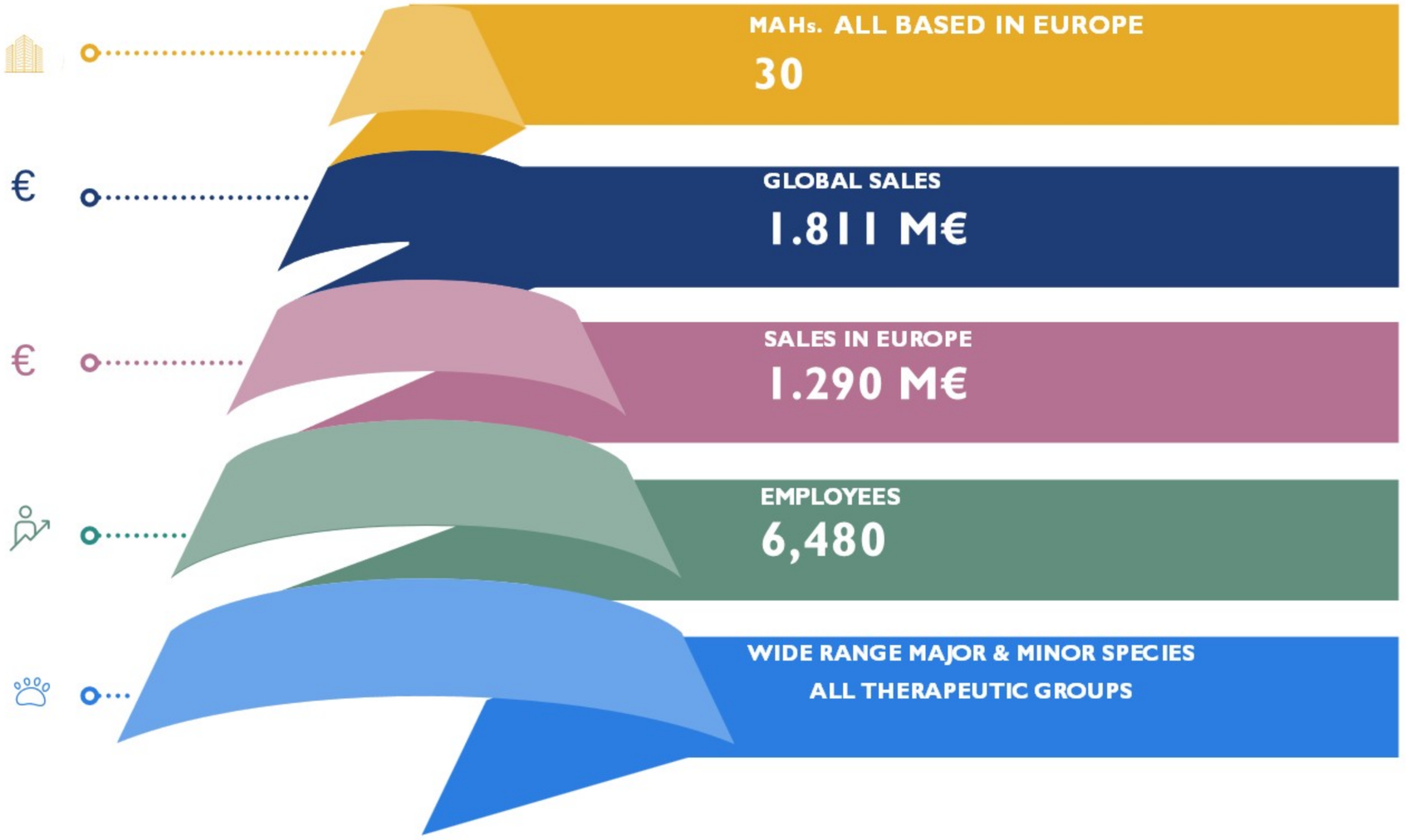
Špela Miklič
Krka
Bioequivalence

OTHER TASK FORCES

Silvia Húmera
AccessVetMed
Communications&Marketing

This year has been very intense from a communications perspective.
One of the key milestones has been the publication of our Manifesto "Advancing Access to Veterinary Medicine in Europe by Streamlining Processes."
A number of communication activities were organized around the launch of this positioning document, including a media meeting attended by nearly 20 journalists, which generated significant coverage in media outlets across Europe.
Social media campaigns were also launched to continue promoting the manifesto and the five pillars on which the association's proposals to European public authorities are based.
In parallel, we strengthened our social media presence with Instagram and Facebook, achieving very encouraging results. Campaigns such as #TogetherStronger, which highlighted some of the people behind member companies, and "Nobody tells you this in vet school", a manga-style campaign designed to connect more effectively with younger audiences in Instagram, help us engage with our audiences, deliver our messages and strengthen the positioning of generic and value-added veterinary medicines in Europe.
In 2026, we will continue working on developing content and tools to ensure our messages reach the right audiences. In this context, we will launch an interactive book addressing the five main myths surrounding generic veterinary medicines. These myths will be analysed, discussed and challenged with the support of key opinion leaders from the sector, who will help us examine and contrast the claims often made about generics.

5 FIGURES



Data at March 2026

6 AGENDA

MEETINGS 2025

Q1

- WG Regulatory Procedures
- WG Telematics
- WG PV
- WG AMs & AMR
- Access VetMed meeting
- WG BEQ, Safety & Efficacy
- Board
- PhVWP-V-PhV IWG Interested Parties
- CMDv IP
- VICH BEQ EWG
- EPRUMA
- VSIAG
- EPRUMA interested party on critical medicines / shortages
- EC meeting on new GMPs Implementing Acts – Brussels
- AHNTI – London
- AMR One Health Network – Brussels
- JAMRAI Annual Meeting – Bilbao
- EMA Innovation Days – Amsterdam
- Joint Implementation Group (JIG)

Q2

- WG Regulatory Procedures
- WG Telematics
- WG BEQ
- WG AMs & AMR
- WG PV updates HS cattle
- Board
- Board – Dublin
- Access VetMed Meeting – Brussels
- 3Rs Working Party annual stakeholders meeting
- ADRA info session EMA
- VSIAG
- Bilateral Access VetMed – NOAH
- Meeting with EMA PV staff
- Bilateral FVE – Access VetMed AMs
- EPRUMA
- HMA IP meeting – Warsaw
- CVMP IP meeting – Amsterdam
- PhVWP-V-PhV IWG Interested Parties meeting – Amsterdam
- CMDv IP – Amsterdam
- EMA 30th Anniversary – Amsterdam

Q3

- WG Telematics
- WG BEQ
- WG PV
- WG AMs & AMR
- Board
- AI Training for Access VetMed members
- GMM – Barcelona
- Bilateral Access VetMed – VSVG and CMDv SPC harmonisation
- EPRUMA ad-hoc group on medicines availability
- FVE, AHE & Access VetMed meeting on SPC AMs and dosing challenges

Q4

- PV Joint Implementation Group (JIG)
- WG AMs & AMR
- WG Telematics
- WG Regulatory Procedures
- Board
- PV WG – Brussels
- Access VetMed meeting – Brussels (hybrid)
- QWP Interested Parties Meeting
- EMA Veterinary Big Data Forum
- IWP-V Interested Parties
- European Antibiotic Awareness Day
- CMDv IP meeting

- Internal Meeting
- External Meeting

6 OUR MEMBERS

7 GLOSSARY

ADRA	Dosage review and adjustment of established nationally authorised veterinary antibiotics
AM	Antimicrobial
AMR	Antimicrobial Resistance
BEQ	Bioequivalence
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures Veterinary
CVMP	Committee for Veterinary Medicinal Products
EC	European Commission
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
EU	European Union
EPRUMA	European Platform for the Responsible Use of Medicines in Animals
FVE	Federation of Veterinarians of Europe
GMP	Good Manufacturing Practices
JAMRAI	Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections
JIG	Joint Inmplementation Group
MAH	Marketing Authorisation Holder
NI	Northern Ireland
NOAH	National Office of Animal Health (UK)
PFAS	Per- and Polyfluoroalkyl Substances
PV	Pharmacovigilance
Ph VWP-V	Committee for Veterinary Medicinal Products Pharmacovigilance Working Party (PhVWP-V)
QWP	Quality Working Party
SPC	Summary of Product Characteristics
UK	United Kingdom
VICH	International Cooperation on Harmonisation of Technical Requirements - Veterinary
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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