
ACTIVITY
REPORT
2023
Access
VETMED

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01 FROM THE CHAIR

Xavier Molins has been chairing Access VetMed since September 2023. Find out through this interview, what is his vision of the generic veterinary industry and what are his goals and interests for our association.





What does it mean for you to assume the position of Chair within our association?

Chairing Access VetMed is undeniably a privilege. In that respect, I have to say I am deeply appreciative of the unwavering assistance from our dedicated Board and the tireless support from our Technical Director.

In addition, collaborating with colleagues across the various Working Groups and Task Forces is always a source of pleasure. Being part of Access VetMed often feels akin to being part of a close-knit family!

In essence, assuming the position of Chair of Access VetMed is an honor, a commitment to serving our members, moving our industry forward, and effecting positive change in the lives of animals and society at large.

My position at Access VetMed allows me to represent and advocate for the interests of the Animal Health generic industry in Europe, steering the strategic direction of our association, establishing clear goals and objectives, and rallying stakeholders towards a shared vision of promoting animal welfare and access to affordable veterinary medicines.





What milestones would you highlight in the recent history of Access VetMed?

When I initially joined Access VetMed (EGGVP at the time), approximately 15 years ago, we were a relatively small consortium of companies representing the Animal Health generic Industry in Europe. However, with the commitment of those founding companies and the excellent leadership of the Board at that time, our Association has experienced significant growth, expanding to nearly 30 companies across much of the European continent.

Most importantly, Access VetMed has successfully established itself as a recognized stakeholder within the relevant EU Competent Authorities, giving us a sense of being listened to.

Last but not least, the investment in and implementation of a robust communications strategy, coupled with our own Market analysis and the rebranding of our organization, have also resulted in a notable increase in the number of stakeholders showing interest in our work. As a matter of fact, I distinctly recall that by the end of 2018, our LinkedIn following barely surpassed 200; now, however, that number has surged to over 1.200.



What are in your opinion the main challenges of the veterinary generics industry?

With the introduction of Veterinary Medicines Regulation 2019/6, there was optimism that administrative burden could be reduced, and costs streamlined. However, two years later, we are still far from achieving that goal. There are certain areas of the new Regulation where burdens certainly persist.

In terms of generic penetration, the extension of the periods of data protection, and most importantly, the cumulative data protection, will not play in favor of the generic industry. Additionally, we are still very concerned that the lack of transparency could potentially result in many investments from the generic industry not yielding a reasonable return.



How can the Association contribute to the companies to overcome them?

Access VetMed fosters collaboration and partnerships among our member companies and other stakeholders. By pooling the adequate resources, expertise, and capabilities in Working Groups and Task Forces, we can collectively tackle those common challenges, thereby enhancing the competitiveness and sustainability of the Animal Health generic industry in Europe.



What are the main lines of action that the Association will undertake this year?

We will focus our main efforts in making sure any outstanding Implementing and Delegated acts from Regulation 2019/6 are aligned with the mission of our Association. In addition, we are aiming to release our 3rd edition of the Animal Health generic Market analysis with the contribution and input of a newly created, motivated and experienced Task Force.

I truly believe the new ideas and suggestions from this Task Force will finally result in a robust and extremely useful document for all our associates and the rest of European stakeholders involved in Animal Health.



How do you visualize Access VetMed in the medium term?

Staying abreast of regulatory changes is key for our members, so Access VetMed will inevitably and continuously monitor evolving regulations to ensure they are aligned with our mission. Having said that, there is a growing trend towards preventive healthcare in veterinary medicine, so I personally believe our association will also need to align to areas such as Animal wellness, vaccination, parasite control, and nutraceuticals.

Access VetMed will also need to continue building strong relationships with the relevant stakeholders to foster trust and loyalty. In that respect, the organization of educational workshops and participation in community programs and regional events should be an option to be considered by our Association. I also envisage our association establishing partnerships with other European associations and groups that may share common vision and goals.

In the long term, Access VetMed can integrate new members from those geographical regions in Europe where we still have a gap (e.g. Nordic countries).

UP CLOSE

A dream...	Travel to Lapland and be able to see an Aurora borealis
A movie...	The name of the Rose
A melody...	Don't you (Forget about me) from Simple Minds
A book…	Lord of the Flies
An animal...	Dog
In your spare time...	Mountain climbing

02 FROM THE TECHNICAL DIRECTOR



Elsa Vecino

Yet another year, during 2023, supporting our members in the implementation of the 2019/6 Regulation has been the main focus at Access VetMed.

Our members continue to report to us the many challenges they face at a time when neither the objectives nor the overall benefits that the new regulation can bring to us are a reality yet.

The new requirements and reporting tasks have consumed resources and added a considerable workload on companies, especially regarding the resources associated with adaptations to new labeling and packaging, and also in the area of pharmacovigilance and IT developments.

Many delegated and implementing acts have been discussed and adopted, and comments have been prepared by our members. Numerous guidelines, concept papers, best practice guides… have also been published and reviewed by our working groups and task forces, and we thank them all for their dedication, sharing of comments and experiences and time invested. We are aware this is often volunteer and extra work carried out alongside their daily responsibilities, but worth for the common benefits of our members and industry.

2023 has been a year with many opportunities to exchange views and experiences with regulators, to collaborate more closely and help us understand each other to find workable solutions for smoother implementation. From here I want to express our gratitude to the staff at the European Commission (DG Sante), EMA Veterinary Medicines Division, CMDv and CVMP, for their active listening and numerous opportunities for dialogue in good discussions. We greatly value the good collaborations with all of them.

Besides the intense work related to rules and regulations, I have to remark the honor that being selected as member of the One Health Network has meant to us, as well as our participation in the One Health Conference celebrated last November in Luxembourg. Our membership in the European Platform for the Responsible Use of Medicines in Animals (EPRUMA) allows us, the generic veterinary industry, to face in a better position those challenges related to antimicrobial and antiparasitic resistance and, in general, adequate and responsible use of veterinary medicines by EU veterinarians, farmers and companion animal owners. Last but not least, we have celebrated our quarterly face to face meetings in Brussels which are always joyful and plenty enriching exchanges of experiences. This allows us to continue working for a better defense of the generic veterinary industry interests, while strengthening the networking opportunities and the sense that Access VetMed is a true platform for cooperation and partnership with other member companies.

With many thanks to all of our members for their active participation and support to the association.

Together we are stronger!



General Managers Meeting. Utrecht 07/09/2023.



STRIVING TO INCREASE THE ACCESS, AVAILABILITY, COMPLIANCE, CONVENIENCE, EFFICACY, SAFETY AND SAVINGS OF VETERINARY MEDICINES IN EUROPE

03 WORKING GROUPS HIGHLIGHTS

ROBERT ALZ



Inmunulogical and Novel Therapies Working Group

The new Regulation 2019/6 offers generics companies a new field of activity, being now permitted to develop generic immunological or biological drugs. As a result, the range of tasks for our working group has expanded significantly, which is also reflected in the renaming of the group. The working group now also deals with novel therapies and biosimilars. In this context, a number of new legal provisions on these issues were processed and commented on in 2023. We also took part in an Interested Parties Meeting of the CVMP's IWP-V and gave a presentation on current key topics together with AnimalHealthEurope (AHE): limited markets, elemental impurities, plasmid DNA vaccines for veterinary use and VICH EA testing guidance.

CORMAC CARAHER



Safety and Efficacy Working Group

The most relevant feedback received from the group was in relation to the “Concept paper on the revision of the Guideline for the Demonstration of efficacy of ectoparasiticides” (EMA/CVMP/EWP/56030/2023) and the “Concept paper on the revision of the Guideline on User safety of topically administered veterinary medicinal products” (EMA/CVMP/SWP/721059/2014).

Numerous other draft guidelines and concept papers were reviewed throughout the year and members of the group attended the VetCast Hybrid meeting in April. This deals with the susceptibility of bacterial pathogens to current anti-microbial treatments.

ALAZNE GOLDARAZ

Antimicrobials and AMR Working Group



Although antimicrobials and its resistance are currently a major concern and always present in European Commission and CVMP roadmaps, from last July 2023, there were no significant issues for us. From my point of view, issues related to AMR have to be always kept in mind, because they play a chronic role in the EU pharmaceutical framework; many background subjects are always under the legislative umbrella. For the next months, according to CVMP AM WP, further documents will be published that may impact on pharmaceutical industry: e.g. Guideline on data requirement for post-authorisation studies for antimicrobials medicinal product that is included in the CVMP's Strategy on Antimicrobials 2021-2025. This strategy foresees providing opinions and advice to ensure safe and sustainable use of antimicrobials. On the other hand, the impact of such opinion and measures in practice are also a hot spot, such as the use of Veterinary Antimicrobials in accordance with terms of SPC (Art 106 of VMR); or the (potential) national measures beyond the categorisation of antibiotics for use in animals, among others.

Variations Working Group

AAFKE HUIZENGA

The more experience we gain with Regulation 2019/06 the more questions arise about the practical implementation and interpretation. Especially when submitting variations and not only the structure changed, but also working in the UPD can be a challenge. The past year we have brought-up multiple questions for clarification to the CMDv. One of the topics was the implementation time for VRA G.I 18, commonly known as the update to QRD v9. Our call for a 12 month implementation time has been accepted by the majority of member states. Together with AnimalHealthEurope (AHE) and Association of Veterinary Consultants (AVC) we have drafted an update for the VRA Best Practice guidance note to clarify the implementation time which has lead to an update to the guidance note in-line with our proposal. Also discussions are on-going on the fees and super-grouping of VNRA's. I appreciate the opportunity I have had to speak about the Industry Perspective on Regulation 2019/6 at the EMA-info day 2023. And the possibility to attend CMDv meetings to bring-up the above mentioned topics to them.



JESSICA HARRISON



Labeling and Packaging Working Group

I would like to highlight our significant contribution to the joint Access VetMed/AnimalHealthEurope (AHE) proposal for the Implementing acts under Article 17(2) of Regulation 2019/6 and pictograms under articles 10 and 11, including attending the European Comission meeting in October 23.
In addition to the implementing acts consultation, we have dealt with a number of challenges on implementation of QRDv9. In this regard, we surveyed our members and presented the results and main conclusions in a presentation to CMDv, where the industry-wide challenges faced with QRDv9 implementation were shown.

Telematics Working Group

Among our main achievements, I would like to highlight the regular meetings with industry representatives ahead of the VSIAG (Advisory Group on VMP-Reg systems improvements), as well as with regulators, aimed at aligning efforts to amplify the voice of Access VetMed. Additionally, email discussions on topics supporting current SMEs have been conducted, given that our organisation no longer has a representative in the SME group.
As Chair of Telematic Working Group, I endeavor to report all bugs and defects I notice to the European Medicines Agency, averaging at least one per month.

JAKA PETRIČ



ŠPELA MIKLIČ



Bioequivalence Working Group

Our group was very busy in 2023 preparing comments and opinions on the a new VICH project/guideline related to In vitro Dissolution for Immediate Release Solid Oral Veterinary Dosage Forms (incorporating biowaivers with bioequivalence established on one strength). Exchanges with international stakeholders took place on this topic to ensure that the views of the European generic industry were taken into consideration. Additionally, I can mention that we have also contributed to the 3Rs area of activity.

Quality Working Group

We participated at EMA's QWP/ Interested Parties Meeting on June 2023 and provided several comments to EMA proposed Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water and Draft Annex on compatibility studies between veterinary medicinal products and biocidal products, with very valid remarks raised by our members.

In relation to the consultation for the Concept Paper on a Guideline on stability testing for applications for variations to a marketing authorisation, we agreed to not spend resources and timing at this stage. Instead, efforts will be concentrated in assessing and commenting the future Guideline once this comes to light for final consultation.

Regarding the potential ban of per- and polyfluorinated Substances (PFAS), this group can be proud as all efforts and lobbying activities were quite successful and an unlimited derogation for active pharmaceutical ingredients (APIs) in veterinary medicinal products was obtained. However, the battle has not yet finished, and we will continue working on it.

XAVIER MOLINS



SONJA SCHWAB



New IT Pharmacovigilance systems

In regular meetings, planned weekly in principle, we drive the development of new features for EVWEB, DWH and IRIS. This is further substantiated by being a member of VSIAG (Veterinary System Improvement Advisory Group), where we have quarterly meetings to provide input on development prioritisation. In addition, I attend JIG and PhV WP-V interested parties meetings to stay updated on the regulatory issues to better understand the relevance of certain features.

The main achievement in 2023 was ensuring that the EVVET development team understood that DWH was designed with CA needs in mind, and that the focus of the dashboards on active substances or medicinal product short names is not suitable for most (even large) MAHs. The implementation of product grouping in DWH (currently available in one dashboard, with more to come soon) should finally alleviate some of the burden of signal management.

Furthermore, discussions about the publication of incidence rates took place, and we ensured that our specific comments were heard.

ERA Working Group

In January 2023, the European Commission published its Report on feasibility of the Environmental Risk Assessment (ERA) monographs, with a satisfactory result for Access VetMed´s position, since the ERA monograph system will not be implemented for the moment and will only be reconsidered if there is more certainty on its costs and its impacts on the availability of VMPs.

Also, our group had the opportunity to provide comments on the Reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs (EMA/CVMP/ERA/31905/2021). This is an emergent topic on ecotoxicity, maybe to be further developed by regulatory authorities, so we will remain vigilant to any update in this area.

PABLO TEJERO



ANDREAS WERNER



Pharmacovigilance Working Group

Access VetMed members have become more comfortable with signal management and annual reporting in IRIS. A revised list of due dates still results workload peaks for companies during the summer months, but the possibility to manage signal within 60 days allowsfor a smother flow.

The first pharmacovigilance inspections according to Regulation 2019/6 were conducted in 2023. They were characterized by a cooperative environment served as a learning process for both MAHs and inspectors.

The involvement of Access VetMed members in stakeholder and JIG meetings, as well as in IT development, facilitated a direct communication and participation of all members of the Pharmacovigilance Working Group in development processes of new guidelines and improvements to databases. A notable highlight was the participation in the development of the Dose Factor Guideline. For the first time, PV Guideline on Communication gained attention through the assessment of multiple reporting of anaphylactic reactions in cattle. While the principles of the guideline and overarching communication plan are well understood, remains uncertainty regarding practical implementation and the way forward. Most actions still rely on local networks for effective information dissemination, the European Union network is not yet mature enough.

Regulatory Procedures Working Group

I would like to highlight the efforts done by the industry to clarify some aspects of the implementation of the Regulation 2019/6 within the context of the QRD v9 update, particularly concerning the role of the local representative and/or distributor.

In this implementation year, it is important to recognise the collaborative work undertaken in the review of the VRA Guideline in collaboration with other AccessVetMed Working Groups and other associations, such as AHE and AVC.

Our Working Group met last year to discuss the structural changes of the Regulatory, Variations and Labelling working groups. Following the entry into force of Regulation 2019/6, it was agreed to refocus the group towards closely monitoring of national requirements. As part of the proposed new structure, the Regulatory Procedures WG will be renamed as subgroup of the National Requirements WG.

INMA ZORRILLA

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04 FIGURES

27

Generic and added value veterinary medicines companies

2.4

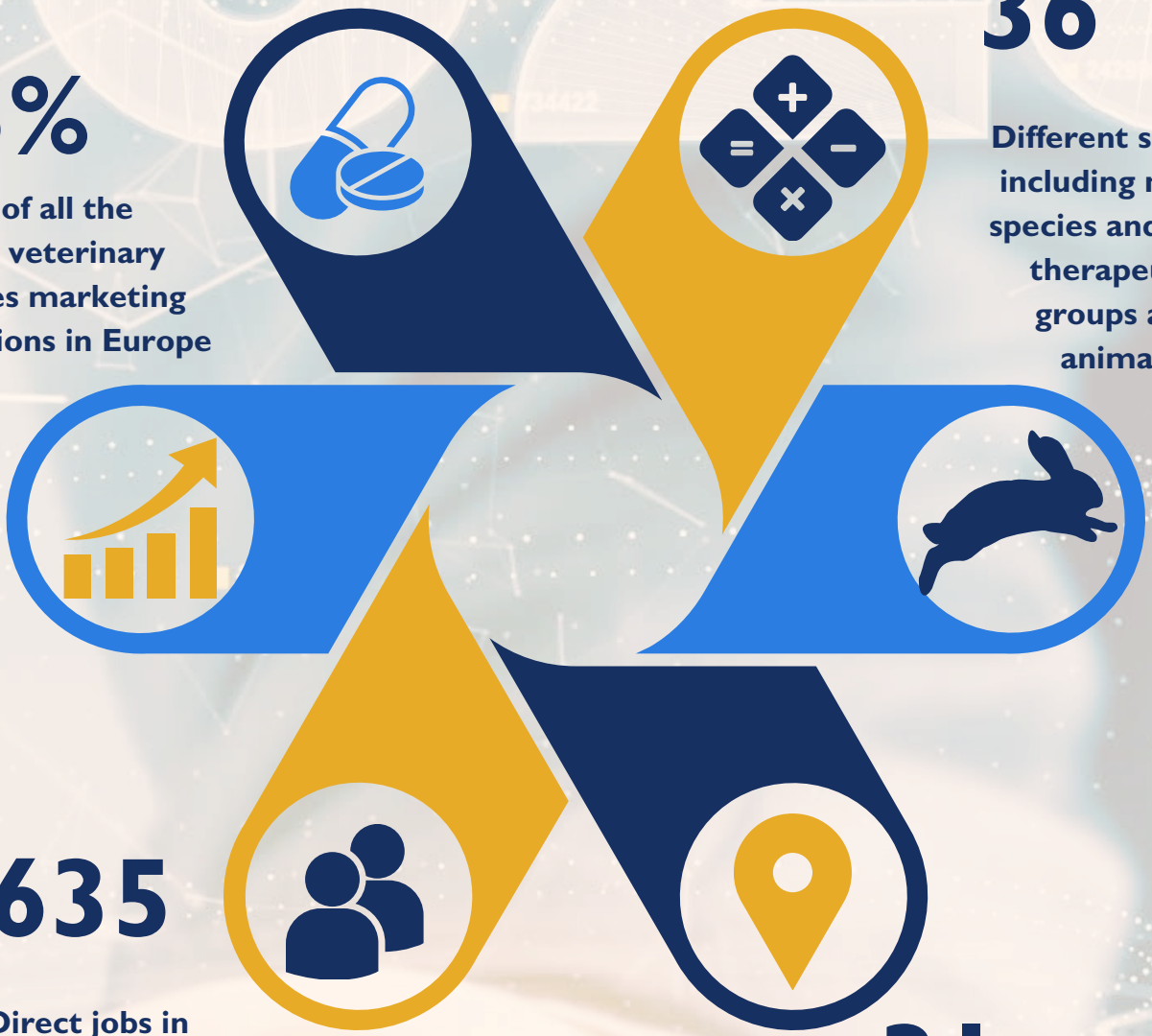
billion euros turnover

36

Different species, including minor species and most therapeutic groups and animals

45%

Hold of all the generic veterinary medicines marketing authorisations in Europe



8.635

Direct jobs in Europe, supporting local economics, employment and welfare

31

European countries, including smaller markets, where we are represented



WE WORK FOR A TRANSPARENT AND COMPETITIVE REGULATORY AND BUSINESS ENVIRONMENT

05 TIMELINE

January 11 CMDv Interested Parties Meeting

March 24 CMDv Interested Parties Meeting

April 26 Access VetMed meeting in Brussels

February 16-17 EMA InfoDay

May 25 CVMP Interested Parties Meeting

June 21 European Commission DG Sante / Access VetMed bilateral Meeting

June 16 CMDv Interested Parties Meeting

September 7-8 General Managers Meeting in Utrecht

October 5 CMDv Interested Parties Meeting

November 14 Access VetMed Meeting in Brussels

November 13 One Health Conference

07 GLOSSARY

AM	Antimicrobials
AMR	Antimicrobials Resistance
CA	Competent Authority
CVMP	Committee for Veterinary Medicinal Product
CVMP AM WP	Committee for Veterinary Medicinal Products' Antimicrobial Working Party
DWH	Data Warehouse
EMA	European Medicines Agency
EVVET	Eudravigilance Veterinary
IVMPs	Immunological Veterinary Medicinal Products
IWP-V	Immunologicals Working Party
JIG	Joint Implementation Group
MAH	Marketing Authorisation Holder
PhV WP-V	Pharmacovigilance Working Party Veterinary
QWP	Quality Working Party
SME	Subject-matter Expert
UPD	Union Product Database
VMPs	Veterinary Medicine Products
VRA	Variations Requiring Assessment
WG	Working Group



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