2021 Activity report

Access VETMED

Committed to animal well-being in Europe

Striving to increase the ACCESS - availability, compliance, convenience, efficacy, safety, and savings - of veterinary medicines to veterinarians, and farm and companion animal owners in Europe.

Table of contents

Timeline

YEAR 2021

Timeline

YEAR 2021

2nd edition of the generics market survey

EGGVP becomes Access VETMED

Pasteur Filiala Filipesti from Romania joins as a new member

Cooperation with EPRUMA on responsible use of antibiotics

Year 2021

FROM THE CHAIR

DOLORES CAINZOS

R&D, Regulatory Affairs Director, Maymó

In the autumn, our rebranding project was ready. We said goodbye to the European Group for Generic Veterinary Products and began a new era as Access VetMed. Even though the core business of our members is dealing with generic veterinary medicines, we had to acknowledge their increasing activity in added value medicines. We continue working for better access of veterinary medicines to veterinarians, and farm and companion animal owners in Europe.

Our second market survey published in September showed that the generics industry is very active in the market supplying over half of the new product registrations. The generic companies also continue investing in R&D to bring products that are specifically fit-for-purpose. The increased interest in health and well-being of companion animals will give our industry new opportunities to provide high quality medicines that are efficient, convenient, safe and affordable to all animal owners.

I thank our members and stakeholders for the valuable collaboration and support. We hope to continue the important joint efforts for animal health and well-being in the European level.

Year 2021

FROM THE TECHNICAL DIRECTOR

ELSA VECINO

During the second year of the pandemic, I am pleased that we were able to keep, and even increase, the level of the member services.

In terms of technical and regulatory activities, year 2021 was exceptionally busy. We focused on facilitating the industry's smooth transition to the new legislative environment by solving challenging issues with EU regulators and keeping our members fully informed through a growing number of online trainings and learning tools.

We thank the representatives of our member companies for their dedication and their expertise that they shared for the benefit of all in our working groups and EMA committees.

Highlights

WORKING GROUPS

Highlights

WORKING GROUPS

Achievements and efforts in 2021

The working groups participated intensively in preparing the industry for the new veterinary medicines legislation. Thanks to the efforts and expertise of our members, we were able to bring the generic and added value medicines producers' and small and medium-sized enterprises' views to the regulators and into the legislation.

JAKA PETRIČ

Informatics in Projects and Regulatory Affairs, Krka

Telematics – user acceptance UPD

"We focused on the union product database by reviewing the implementation guide and participating in user acceptance testing on 'variations not requiring assessment' and 'volume of sales'. We were, and we still continue to be in EMA's product owners' group aiming for a database that best serves all involved, the agency, national authorities and the pharmaceutical companies."

MARGA VAN LIESHOUT

Senior RA Scientist - Regulatory Affairs, Dechra

Telematics – database variations

"Although the union product database is not fully there yet, the biggest achievement were the relationships built with EMA, national authorities and the other industry representatives in the variations group. Working closely and openly together, we were able to bring our ideas and raise concerns towards one goal - a perfectly working database we can all benefit from!"

Highlights

WORKING GROUPS

Pharmacovigilance system and guidelines

"The pharmacovigilance reporting on the safety of medicines was changed from every three years to constant signal detection, prioritisation and assessment. The reporting on the results will now be required at least once a year. We revised the guidelines and made proposals for improved formulations, many of which were adopted."

ANDREAS WERNER

Senior Regulatory Affairs and QPPV, Bela-Pharm

SONJA SCHWAB

Product Development and Deputy QPPV, Richter Pharma

Pharmacovigilance database

"We were invited to be part of the EVVET3 product owners' group. Even though we could not influence the overall design of the pharmacovigilance database, we were able to tell the development team about the processes in smaller companies, and by doing that improve the system for Access VetMed members."

Highlights

WORKING GROUPS

INMACULADA ZORRILLA

Director, Regulatory Affairs, Livisto

Regulatory procedures

"We reviewed 18 best practices guides that were updated to incorporate the interaction with the union product database that will simplify several regulatory procedures. They are destined to national authorities and marketing authorisation applicants to ensure the process is consistent, timely and efficient. The majority of our comments were taken into consideration. Also new procedures were introduced to reinforce the coordination between licenses of one company and the harmonisation of product leaflets of generics/hybrids and reference products."

ANNA BALBÉ

R&D, Regulatory Affairs, Maymó

Labelling

"We revised, among others, the new template for quality review of documents with dozens of comments. We are happy to see that many of them were taken into consideration and are part of the new legislation."

Highlights

WORKING GROUPS

XAVIER MOLINS

Head of Regulatory Affairs, Bimeda

Environmental risk assessment

"We can be proud of our efforts to ease the administrative burden: generic applications with a reference product authorised before 1 October 2005 will not require a full environmental risk assessment (ERA) if another essentially similar product has already been authorised after that date.
We also dedicated time to propose a reasonable and scientifically sound way of operating the future ERA monograph system or alternative. We look forward to the European Commission and the other relevant stakeholders taking it into consideration."

Access VetMed

MEMBERS

Access VetMed

MEMBERS

26

Generic and added value veterinary medicines companies

Based in the EU

Turnover

€2.2 billion

Employ

8,000 people

Active in

31

European countries, including smaller markets

Offer products for most therapeutic groups and animals, including minor species

Hold

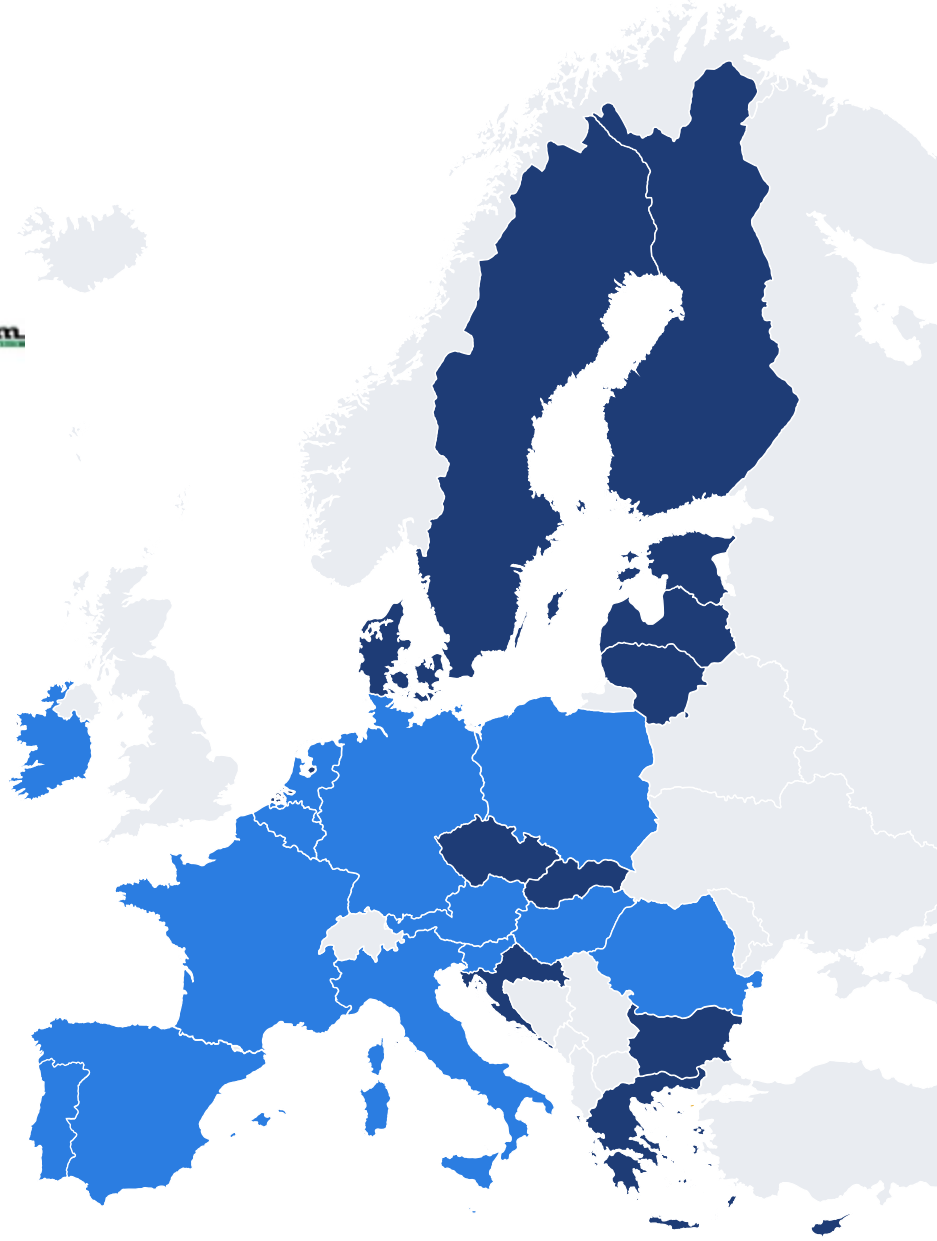
45%

of all the generic veterinary medicines marketing authorisations in Europe

Access VetMed

MEMBERS

Alfasan NEDERLAND
ALPHAVET
andrés pintaluba
SERVICE AnimeD TIERARZNEIMITTEL
beaphar Because pets are family too
bela-pharm
Bimeda
CALIER
chanelle
chemifarma
Dechra Pharmaceuticals PLC
DP DÔMES PHARMA
dox-a
FARMAVET GROUP
InoVet
KARIZOO
kela focus on health
KRKA
LABIANA LIFE SCIENCES
LIVISTO
MAYMO
richter pharma
s.p.® veterinaria
vetAgro
WDT Das Tierarztunternehmen.
ZOOPAN SAÚDE E NUTRIÇÃO ANIMAL




Access
VETMED
Our vision is to achieve a transparent and competitive regulatory and business environment where all stakeholders have equal share of voice and play an active role in protecting animal health and welfare, human safety, and the environment.
FOLLOW US
accessvetmed.eu