EGGVP
European Group for Generic Veterinary Products

ACTIVITY REPORT 2020

Striving for affordable, high quality, safe and effective veterinary medicinal products to veterinarians, farm and companion animal owners across Europe.

EUROPEAN GROUP FOR GENERIC VETERINARY PRODUCTS

We are the voice of the European industry of generic and added-value veterinary medicines.

We interact with authorities and decision-makers, and other stakeholders in the EU to achieve sustainable animal health policies and legislation.

OUR MISSION

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

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.

OUR MISSION BECAME EVER MORE IMPORTANT

Year 2020 has been special in many ways, not least due to the global COVID-19 pandemic. It has forced us to embrace the changes to our ways of life.

At EGGVP, we worked around the clock with our members and EU and national authorities to secure the continuity of our supply chains and uninterrupted access to animal health products. We were pleased that the EU Steering Committee on medicines shortages considered veterinary medicines essential service. EGGVP took part in the discussions and coordinated actions aimed at reinforcing public health in the EU. Access to veterinary medicines is vital to avoid unnecessary pressure on food chain and to allow animals access to veterinary treatments.

Throughout the year, EGGVP continued its efforts in implementing its mission values to increase the access - availability, compliance, convenience, efficacy, safety, and savings - of veterinary medicines to veterinarians, and farm and companion animal owners in Europe.

We continued to proactively shape the regulatory, legislative and political framework where EGGVP operates, with a focus on generic and added-value veterinary medicines.

Through collaboration with the experts in our working groups and taskforces, that are at the very heart of our activities, we continue building trust with our members and remain accountable to our stakeholders.

EGGVP welcomed two new members, Beaphar and Karizoo. I am especially proud of the family expansion considering we could not hold our face-to-face meetings that have always given us great feedback and community support to move forward. We also saw the EGGVP team, responsible for the day-to-day operations, grow. Both developments reflect the increasing importance of EGGVP.

I was re-elected chair in October during an extraordinary general managers' meeting to which all members attended. I am grateful for the trust. I also thank my colleagues in the board.

A day will come when this pandemic is over. I am looking forward to that day to be able to meet and greet again. Until that day though, let's stay safe and connected!

DOLORES CAINZOS

EGGVP chair

MAJOR EFFORTS TO THE DEVELOPMENT OF THE NEW LEGISLATION

In 2020, we faced a busy legislative period due to the implementation of the Regulation 2019/6 on veterinary medicines coming into effect in January 2022.

There were numerous legal acts developed which will have a notable impact on the daily business of our member companies: new classification and process for handling variations, re-built pharmacovigilance system, new central databases, updated dossier requirements, new rules for data protection and online sales, novel requirements and restrictions for antimicrobials to be used in animals, future harmonisation of SPCs, and feasibility of a monograph system for ecotoxicity packages for veterinary medicines.

With negotiations taking place under ambitious timelines, we participated in all the relevant projects and discussions with regulators and elaborated proposals and position papers to make impact and to defend our members' interests as an industry association.

EGGVP made all the efforts to maintain and even increase its service to members providing training and information on the implementation of the new policy.

This year we introduced an increasing amount of virtual technical meetings and made an extra effort to keep our members informed and involved in technical and regulatory projects. Surprisingly, the member connections were not lost but reinforced. Creating added value for the companies while maintaining the family feeling has been more important this year than ever.

Our achievements were possible thanks to the engagement and trust of our members.

ELSA VECINO

Technical director, EGGVP

IMPACT OF BREXIT TO OUR MEMBERS

The pharmaceutical sector had worked on the preparations long before Brexit became operational in January 2021. Still, as the United Kingdom became a new third country, the companies importing and exporting had new supply chain and logistic issues to deal with.

The EGGVP members, the generic veterinary medicines manufacturers had to make sure that any product imported from the UK into the European Union had been subject to a new test or release within an EU member state. Also, the location of their marketing authorisation holder and the qualified person responsible for pharmacovigilance associated to their EU licenses had to be based in the EU.

Fortunately, the UK continued to allow the EU marketing authorisation holders and products tested or released in the EU in their market - at least until the end of 2022. Having said that, we will need to closely monitor the upcoming UK animal health legislation to see what the conditions will be from 2023 onwards. We will be wiser already at the end of the second half of 2021 when the legislative proposal is published for consultation.

The introduction of the Northern Ireland protocol* added additional administrative burden and uncertainties, especially for those companies located, or with operational bases in the UK. According to the protocol, despite being part of the UK, Northern Ireland will need to follow the EU legislation. Any product placed into the Northern Irish market will need to be tested or released in an EU member state, and in theory, the marketing authorisation holder should also be based in either Northern Ireland or the EU.

As the EU and UK authorities did not reach an agreement on the location question, companies will have until January 2022 to fully implement the protocol.

*https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised_Protocol_to_the_Withdrawal_Agreement.pdf

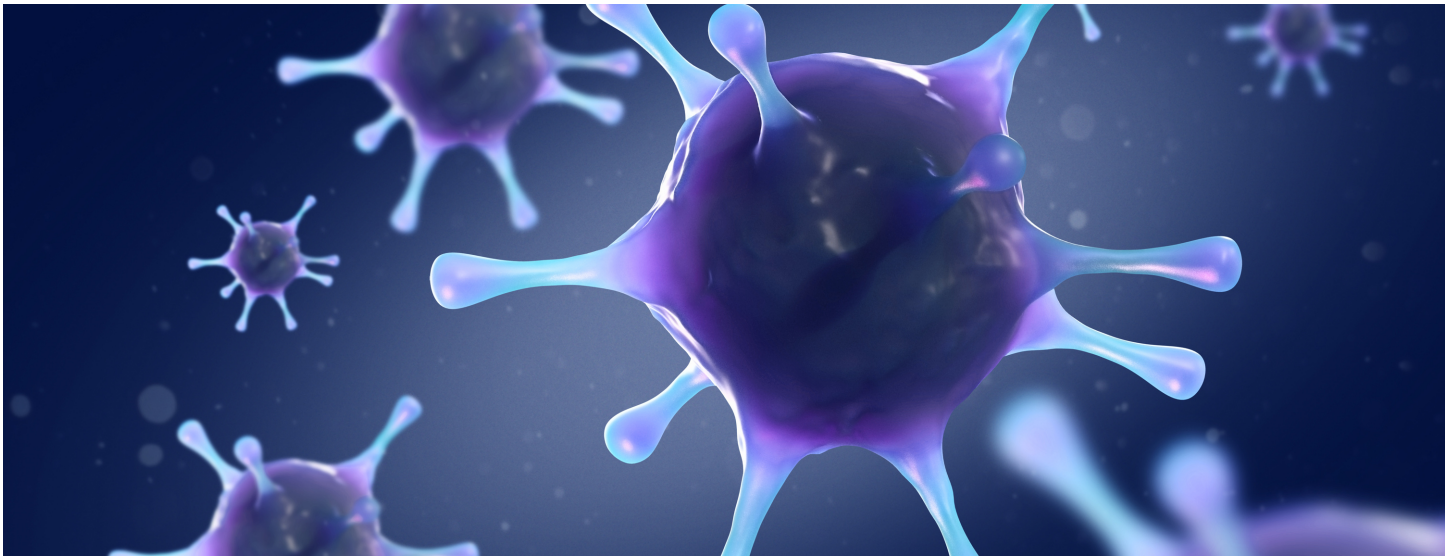
Introducing a regulatory border between Northern Ireland and Great Britain is foreseen to add administrative burden which EGGVP have fought against already in the EU front.

Because the British Veterinary Medicines Directorate remains the competent authority for both Great Britain and Northern Ireland, companies who want to obtain a new license valid in the UK, will need to submit two separate applications, one for each.

Despite the remaining uncertainties, the UK authority has thankfully made efforts to minimise the additional burden on companies, including by updating a new version of the Veterinary Medicines Digital Service to licence veterinary medicines.

XAVIER MOLINS

Vice-chair, EGGVP



RESILIENCE IN THE PANDEMIC

The COVID-19 pandemic was and continues to be a huge lesson and a survival test for many sectors. Europe's dependency on the third countries became evident and made it clear that for the future, we need to build self-sufficiency in critical raw materials and supplies.

Despite market tensions, the generic veterinary medicines manufacturers were able to continue production, but with extra efforts. The companies had difficulties to purchase certain active ingredients due to manufacturing in the third countries and disruptions in shipping. The delivery times prolonged and prices went up due to high demand in the human medicines. Labelling and packaging materials were also short of supply for veterinary products.

Unlike many other industry supply chains, the supply chain of veterinary medicines resisted. Stockpiling occurred but the stocks did not run out.

Early on, the EU level coordination was handled by the already existing executive steering group on shortages of medicines caused by major events. EGGVP was part of this weekly monitoring, reporting and updating on the status of the medicines supplies and needs to respond. At the same time, EGGVP kept regular contact with its members and national competent authorities to ensure rapid situation updates on all levels.

The shortage of personal protective equipment became one of the key concerns in the member states. The veterinary industry stepped in to provide masks, gloves, and basic disinfectants for the health care sector in many countries.

By listening to the veterinary industry and acting swiftly, the EU authorities helped the veterinary industry survive through the first wave. The European Commission declared the veterinary medicines as essential goods which allowed them to move freely on the Green Lanes after borders were closed.

The authorities also gave flexibility for regulatory and inspection processes while travel restrictions would not allow factory visits. Administrative burden was also eased to accept digital documents, and fast-track procedures were put in place to manage variations and allow alternative suppliers for urgent cases.

Even though the logistical delays continued, the veterinary medicines sector was less impacted in the following waves of the pandemic. Thanks to the EU actions and the cooperation with our peer industry organisations, we were able hold on to our mission to protect the well-being of animals and secured the availability of and access to veterinary medicines.

Unlike many other industry supply chains, the supply chain of veterinary medicines resisted. Stockpiling occurred but the stocks did not run out.

ACTIVITIES IN NUMBERS

34

Positions and comments to EU legislation

13

Representatives in EMA's, CVMP and CMDv technical working groups

12

EGGVP working groups and taskforces

71

Participants in EGGVP working groups and taskforces

8

Info sessions and trainings organised for members

389

Internal and external meetings

"With negotiations taking place under ambitious timelines, EGGVP participated in all the relevant projects and discussions with the regulators."

Elsa Vecino, technical director

ACTIVITIES IN 2020

Through active contributions and constructive discussions, EGGVP participated in the formulation of *the implementing and delegated acts of the new veterinary medicines regulation EU 2019/6* to achieve a practical, harmonised and coherent approach for the licensing of generic veterinary products in Europe. All EGGVP's working groups were active in making our members voices are heard.

REGULATORY PROCEDURES

- This group worked on analysis and advice regarding the new rules on protection of technical documentation (PTD). It took part in constructive discussions with regulators to achieve a practical, harmonised and coherent approach for the licensing of generic veterinary products in Europe. The objective was to overcome possible hinders to generic competition, especially the extension of the protection period for the non-generic companies and the criteria and conditions regarding the protection of technical documentation for existing products.

VARIATIONS

- The group analysed and prepared positions on the proposals on the draft implementing regulation establishing a list of variations not requiring assessment in accordance with the new regulation. Exchange of views took place with regulators in various forums, including with the heads of medicines agencies (HMA), the veterinary coordination group for mutual recognition and decentralised procedures (CMDv), and the Commission. The final adopted list was in line with EGGVP's proposal.

QUALITY

- The group gave its input to the last review on quality in the draft delegated regulation amending Annex II of the new regulation.

TELEMATICS

- The group commented on the draft implementing regulation laying down the necessary measures and practical arrangements for the union product database (UPD).
- The group actively contributed also to the implementation guide and access policy of the veterinary medicines product data.

ACTIVITIES IN 2020

"I am most proud of the active participation of the working group members in our meetings to develop the new pharmacovigilance guidelines."

Andreas Werner, Bela-Pharm, chair of the EGGVP pharmacovigilance working group

PHARMACOVIGILANCE

- The group participated in the pharmacovigilance working party and the veterinary good vigilance practice stakeholder meetings. It provided comments on the new pharmacovigilance guidelines, especially regarding their suitability for daily practice of the marketing authorisation holders. These comments were incorporated into the guidelines.
- As part of the EVVet 3 product owners' group, EGGVP participated in user testing of the pharmacovigilance database to improve the functionalities and secure its user-friendliness.

ECOTOX AND ERA

- The group worked on the environmental risk assessment (ERA) monograph system, including viewed alternatives, and contributed to Commission's feasibility study through meetings and interviews.

ANTIMICROBIALS AND AMR

- The group had its views reflected in the methods for collecting data (delegated act), and in the requirements for the collection of data on antimicrobial medicines used in animals (implementing act).
- The group gave comments to the veterinary medicines committee's (CVMP) reflection paper on promoting the authorisation of four alternatives to antimicrobials in the EU, and to EFSA's scientific opinion regarding maximum levels of cross-contamination for antimicrobial active substances in non-target feed.

SAFETY AND EFFICACY

- The group provided input to the Annex II of the new regulation on safety and efficacy requirements for authorisation of veterinary medicinal products.

LABELLING AND PACKAGING

- The group worked with CMDv and the national authorities on harmonised requirements that included blister labelling, templates for quality review of documents, pictograms, and distributor's name and logo.
- The working group supported the EGGVP members with changes in patient information leaflets in the UK due to Brexit.

THE ASSOCIATION GREW IN 2020

In the midst of the intensive year of regulatory activities, EGGVP welcomed two new companies as members and an addition to its staff. EGGVP board was also strengthened with a new member.

TWO NEW MEMBERS

EGGVP grew by two new member companies, Beaphar from The Netherlands and Laboratorios Karizoo from Spain. At the year end, EGGVP hosted 26 European generic veterinary products manufacturers from thirteen member states.

ADDITION TO STAFF

EGGVP strenghtened its team in Brussels by hiring a communications and public relations manager to support association's visibility, messaging and stakeholder relations.

NEW BOARD

In the annual general managers' meeting, a new board was elected for the following three years. Dolores Cainzos, from Laboratorios Maymó, was re-elected chair. Vice-chair Xavier Molins, from Bimeda, was also re-elected together with Slavka Pavlič from Krka, as secretary, and Leo Aerden from Inovet, as treasurer. The board gained a new member as Andreas Werner from Bela-Pharm was voted in.

"I am especially proud of the family expansion considering we could not hold our face-to-face meetings that have always given us great feedback and community support to move forward."

Dolores Cainzos, EGGVP chair

OUR MEMBERS

Alfasan
The Manufactures of Veterinary Medicines

ALPHAVET

andrés pintaluba

SERVICE AniMeD
TIERARZNEIMITTEL

beaphar
Because pets are family too

bela-pharm
Arzneimittelfabrik

Bimeda

chanelle

chemifarma s.p.a.

Dechra
Pharmaceuticals PLC

dox-a

InoVet

kela
focus on health

KRKA

LABIANA
LIFE SCIENCES

tvm lab
INNOVATIVE ANIMAL HEALTH

CALIER

KARIZOO

MAYMO

OVEJERO
LABORATORIOS

LIVISTO

richter pharma ag

s.p. veterinaria

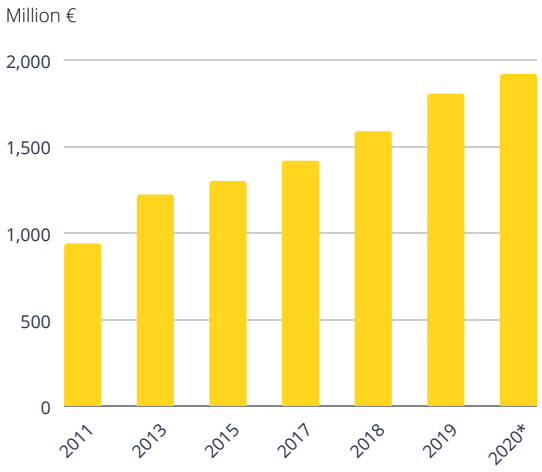
vet A agro

WDT
Das Tierarztunternehmen.

ZOOPAN
SAÚDE E NUTRIÇÃO ANIMAL

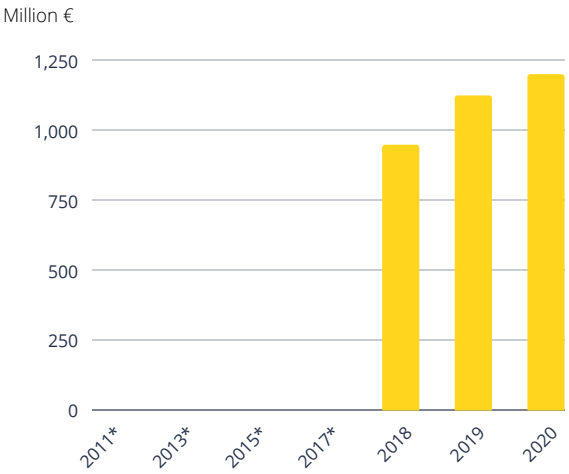
FIGURES OF THE EGGVP MEMBERS

Global sales of veterinary medicines



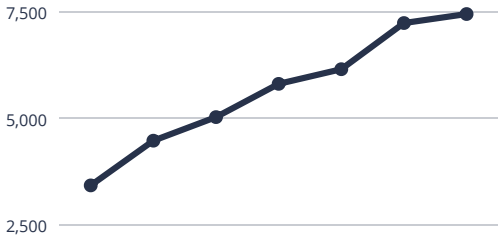
The number of members increased from 21 in 2011 to 26 in 2019.
* The results of 2020 are estimations as some members close their financial year after Q2.

EU sales of veterinary medicines



*No data available for 2011-2017

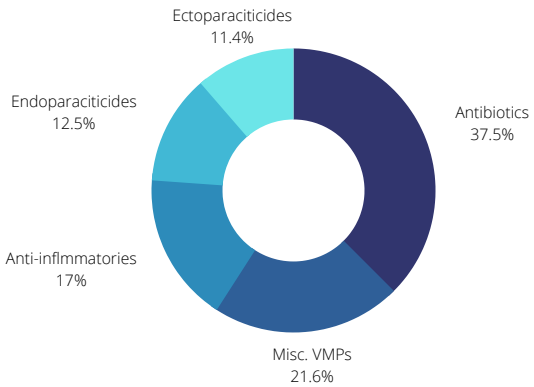
Employees in veterinary medicines business



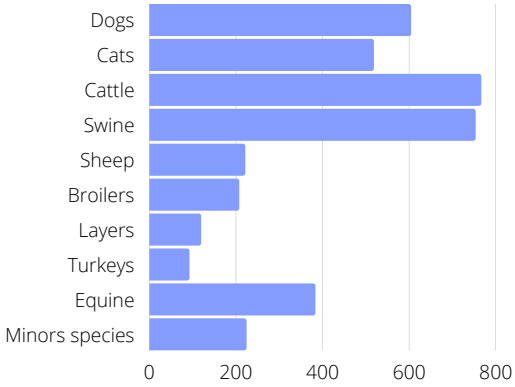
The number of members increased from 21 in 2011 to 26 in 2019.

EGGVP members held over 10,000 marketing authorisations in 31 European countries.

Main therapeutic categories



Products for companion animals, livestock and more than 10 minor species



The European Group for Generic Veterinary Products represents the generic and added-value medicines industry since 2002.

We support animal health by increasing access to veterinary medicines, many for minor species and smaller markets in Europe.

www.eggvp.org

Follow us

EGGVP
European Group for Generic Veterinary Products

Animal images: Canva