Access VETMED

Committed to animal well-being in Europe

2024 European generic and added-value veterinary medicines market study

Index

01 Introduction

01. Introduction

About This Report

In 2019, Access VetMed commissioned the first-ever market study on generic veterinary medicines to obtain reliable data on the economic importance, weight, and added value of generic veterinary pharmaceuticals in Europe.

This third edition is therefore part of an ongoing series of periodic studies implemented by Access VetMed to gather reliable data that supports strategic decision-making within the sector.

The objective is to understand the impact of generics on the European veterinary market, taking into account regulatory changes that have emerged in recent years, especially Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC.

However, its ultimate purpose is to help Access VetMed and its members prepare for future regulatory and market changes by optimising their participation in the European veterinary medicine sector.

01. Introduction

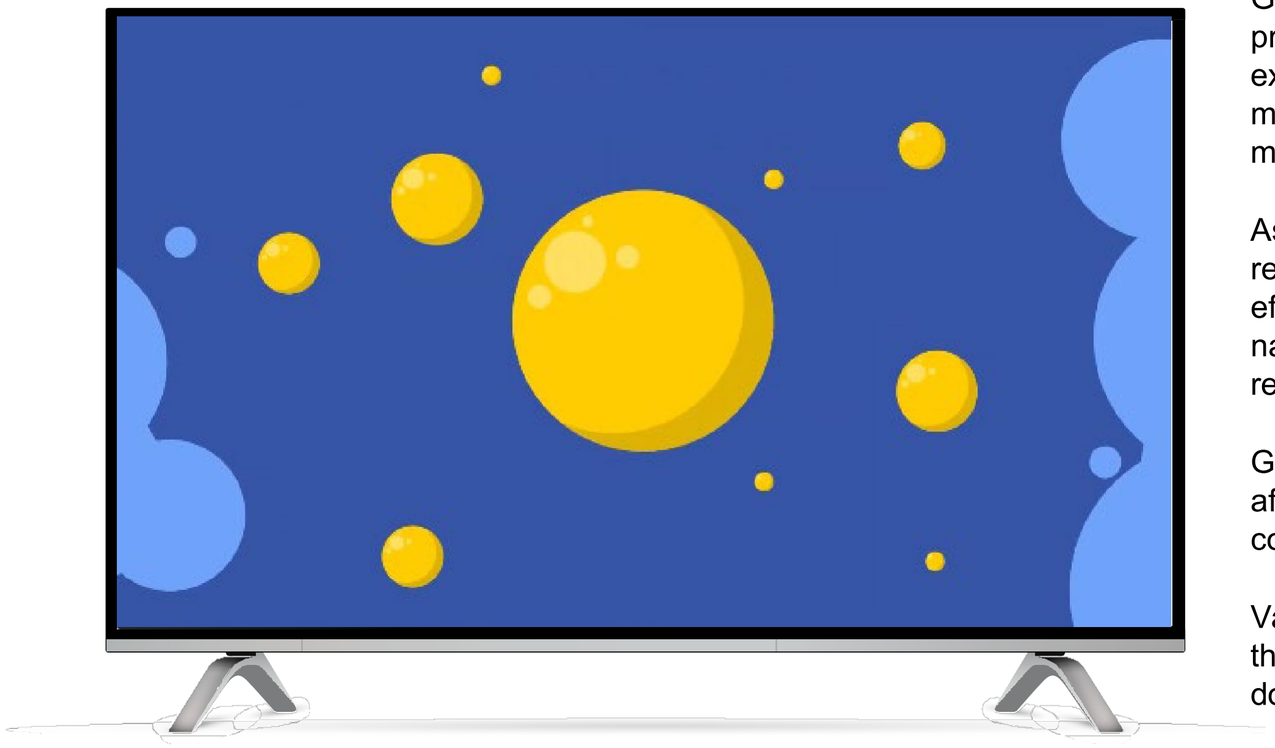
About Access VetMed

Access VetMed, formerly known as the European Group for Generic Veterinary Products (EGGVP), was founded in 2002 to be the voice of the generic veterinary medicines industry in Europe. Today, we represent 27 generic and value-added veterinary medicine companies based in different European countries. Collectively, our members have a turnover of €2.4 billion, generate over 8,600 direct jobs, and hold 52% of all generic veterinary medicine Marketing Authorisations (MAs) in Europe (11.214 of a total of 21.626 generic authorisations in EU).

We actively and constructively work with EU regulators and other stakeholders for transparent, harmonised, pragmatic, and balanced animal health regulation to increase ACCESS – availability, compliance, convenience, efficacy, safety, and savings – of veterinary medicines for veterinarians, farmers, and companion animal owners in Europe.

01. Introduction

What is a Generic Veterinary Medicine?



Generic medicines are authorised and marketed after the original product's intellectual property and other protection periods have expired, which can take up to 25 years. Generics are produced using modern technologies, as well as rigorous analytical standards and materials, meeting the latest regulatory requirements.

As with originator medicines, generics are subject to stringent EU regulations and controls. These ensure their quality, safety, and efficacy, with thorough assessments conducted by both EU and national regulatory authorities before they are approved for market release.

Generics are high-quality products offering safe, effective, and affordable treatment options for veterinarians, farmers, and companion animal owners.

Value-added medicines are products that are enhanced versions of the original products. Enhancements may include improvements to dosage, administration, or the approval for use in additional species.

02 Differences from previous editions

02. Differences from previous editions

This study presents several key differences from previous editions (2019 and 2021), both in terms of methodology and content. The first two studies covered the periods up to 2016 and 2017-2019, respectively. The 2024 edition extends this scope, covering the time period from the first authorisations of Veterinary Medicinal Products (VMPs) in the 1950s, and up to May 2024.

Key Improvements

Unlike the previous studies on the generic and added value veterinary product market in Europe (2019 and 2021) which were conducted in collaboration with an external company, the 2024 edition was directly managed by Access VetMed. This allowed for a significant reduction in both costs and the burden on the association's members.

1

GREATER DATA ACCURACY

While previous studies included some assumptions based on the "best available knowledge," this study is based on quantitative data gathered from official sources and direct surveys.

2

SHIFT IN CONTENT FOCUS

Previous editions included analysis on the economic importance of the animal health sector and the affordability of generic products. These sections are omitted in 2024, which may limit direct comparisons with earlier studies.

In summary, the 2024 study is more precise and comprehensive, due to the use of more reliable qualitative and quantitative data. However, content shifts may restrict certain direct comparisons with previous editions.

Study limitations
The data analysis was based on a snapshot of the situation in May 2024. There are some limitations in data quality, as certain databases (such as those from the UK) do not provide complete information on the legal basis of product authorizations.

03 Scope

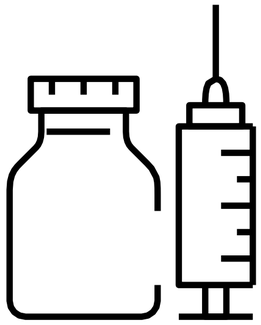
03. Scope

Product Scope

The term “generic” in the context of this study refers to products registered under different regulations within EU law, including bibliographical applications (independent and well-established use), generic applications (based on proof of bioequivalence), and hybrid applications. Informed consent was also included within the scope of the study.

Geographic Scope

The study covers the market of the 27 EU countries, in addition to the UK, Norway, Iceland, and Liechtenstein. Throughout the report, this group is referred to as “Europe,” providing a comprehensive view of market trends and regulatory contexts across the region.



04 Methodology

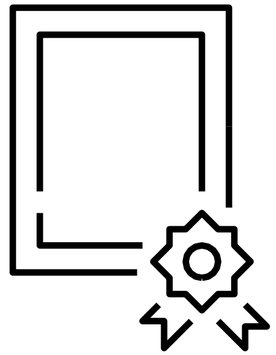
04. Methodology

The principles used in the study ensure it was conducted efficiently, providing tangible value both in terms of use of resources and quality of the information obtained.

04. Methodology

Public Sources

The data analysis was based on the information of over 40,000 veterinary medicines registered in Europe from public databases in the EU and the UK. The data was standardised for analysis with filters applied, including animal species, administration routes, MAHs, and others. The result is a combined UK and European proprietary database herein referred as the “Access VetMed Database”.



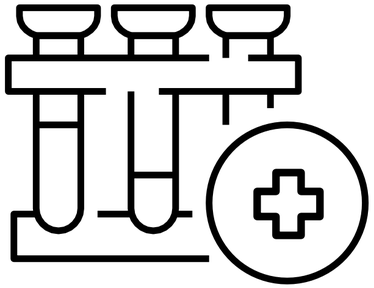
Regulatory Impact on Administrative and Financial Burden

A quantitative survey was conducted with Access VetMed members to assess how Regulation (EU) 2019/6 affects companies in terms of administrative and financial costs.

Quantitative survey

Business Aspects

To evaluate growth opportunities and current market risks, a qualitative survey was conducted among Access VetMed members. This survey provides internal insights into members’ perceptions of industry development and its current and future challenges.



The methodology applied combines quantitative and qualitative analysis, providing a solid foundation for assessing both regulatory impacts and business opportunities within the sector.

Qualitative survey

05 Data Analytics

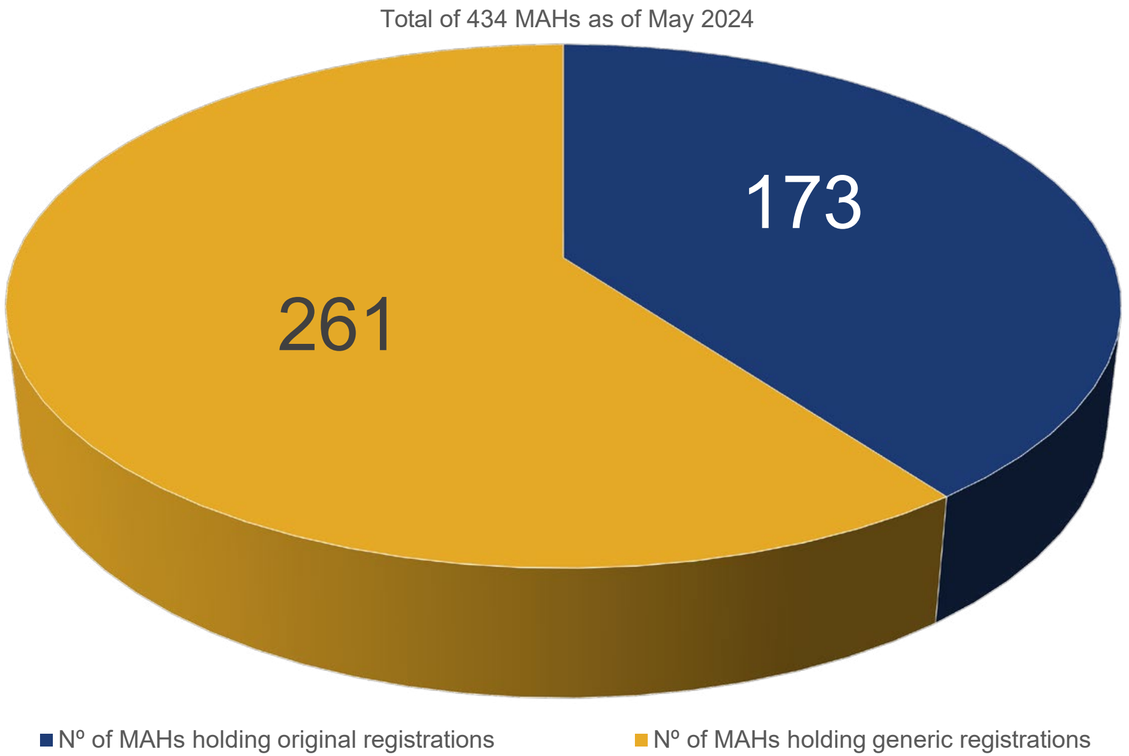
05. Access VetMed Data Analytics

Marketing Authorization Holders

The generic veterinary sector is a fundamental part of the market in Europe, with strong growth and an influential role played by Access VetMed members.

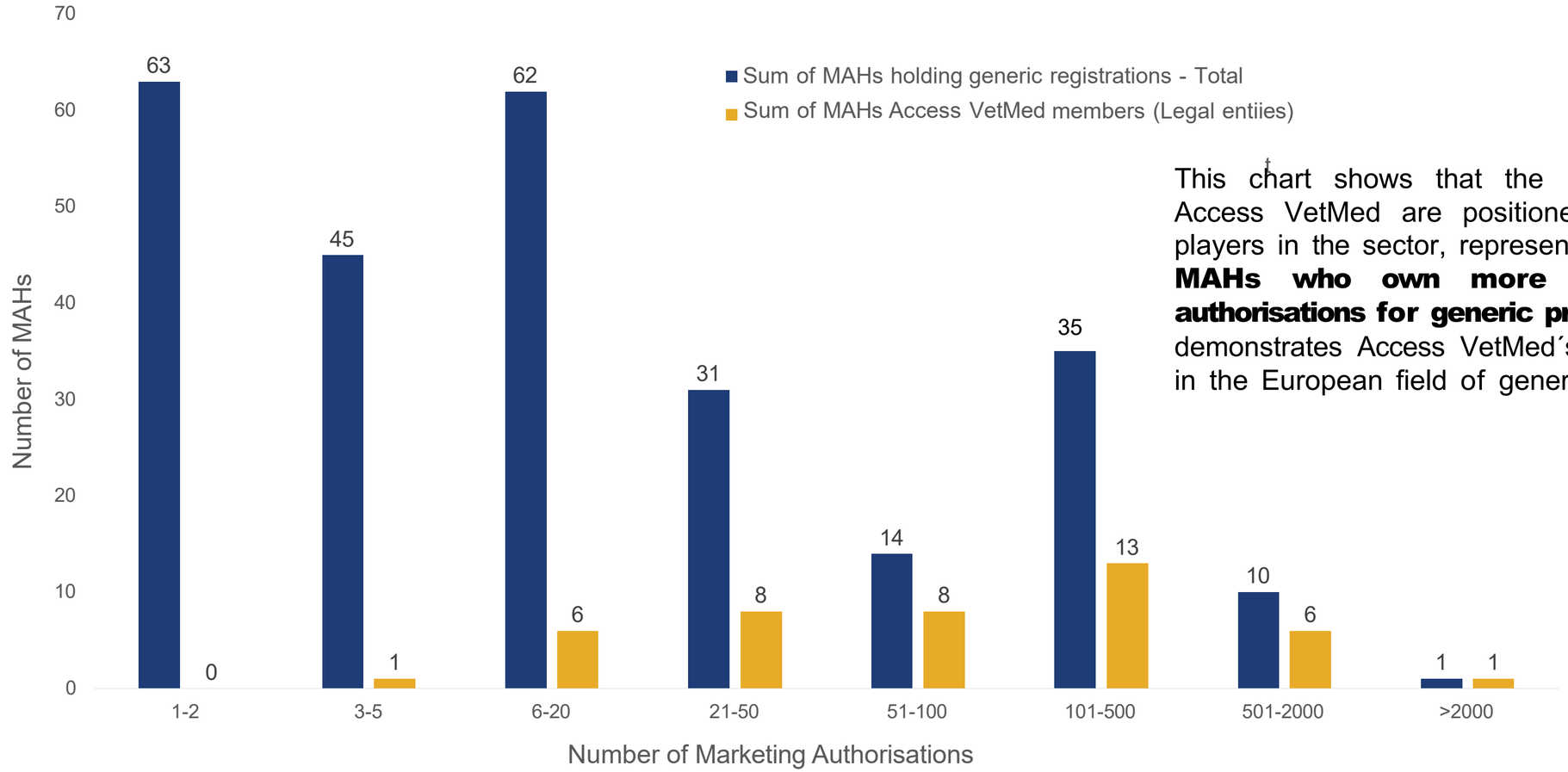
Figure 1: Marketing Authorisation Holders (MAHs) holding veterinary generic authorisations (May 2024).

Figure 1 shows that as of May 2024, from a total of 434 active MAHs, 261 own generic licenses, meaning that **60% of all MAHs in Europe have licenses for generic products.** This is a key indicator of the significant weight the generic market holds in the region's veterinary sector.



05. Access VetMed Data Analytics

Figure 2: Significance of Access VetMed among Generic MAHs.



This chart shows that the members of Access VetMed are positioned as major players in the sector, representing **64% of MAHs who own more than 500 authorisations for generic products.** This demonstrates Access VetMed´sleading role in the European field of generic

05. Access VetMed Data Analytics

Generic Veterinary Medicines in Europe

Figure 3: Evolution over the past 20 years in the number of veterinary medicines' authorisations (all medicines vs generics).

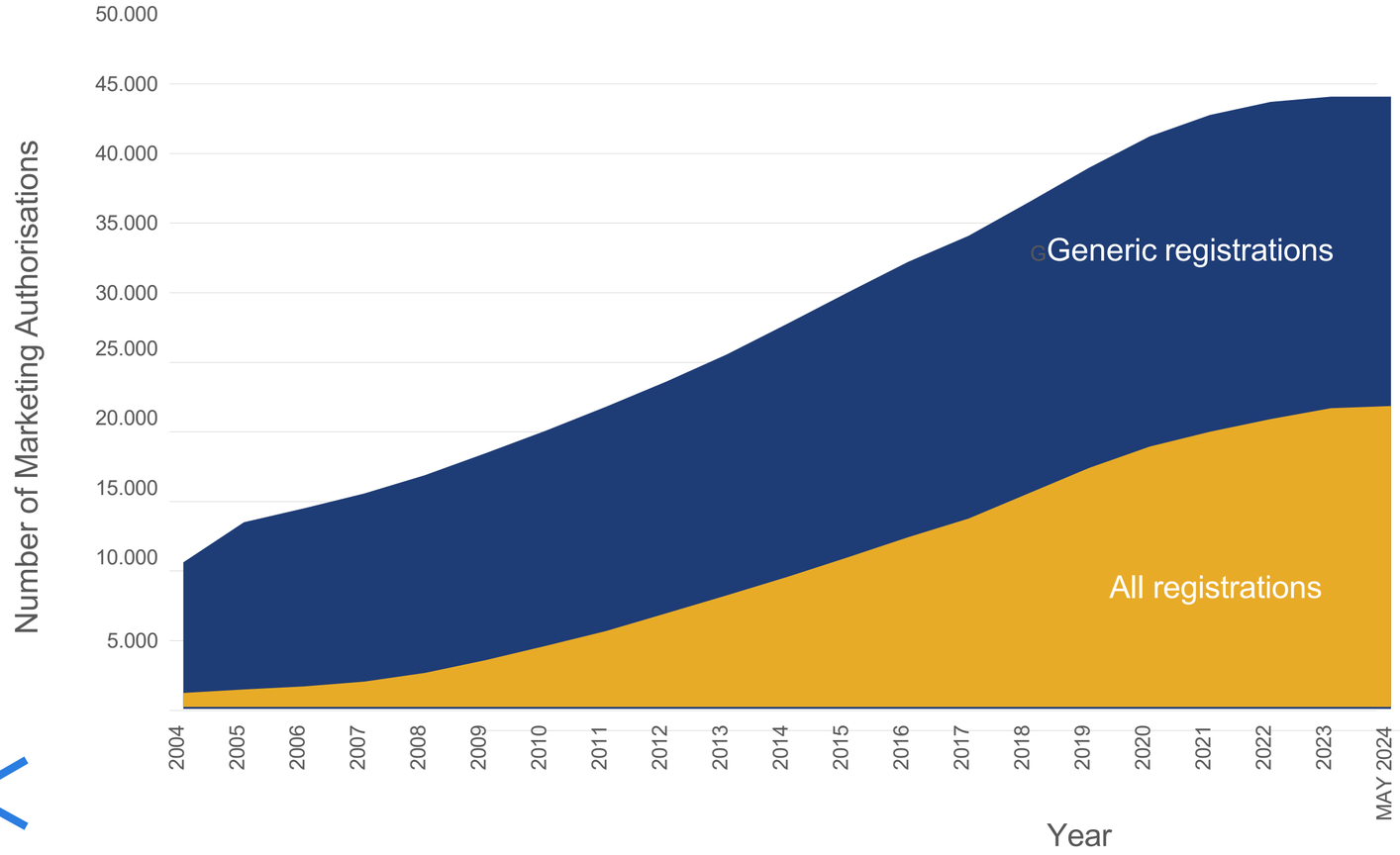


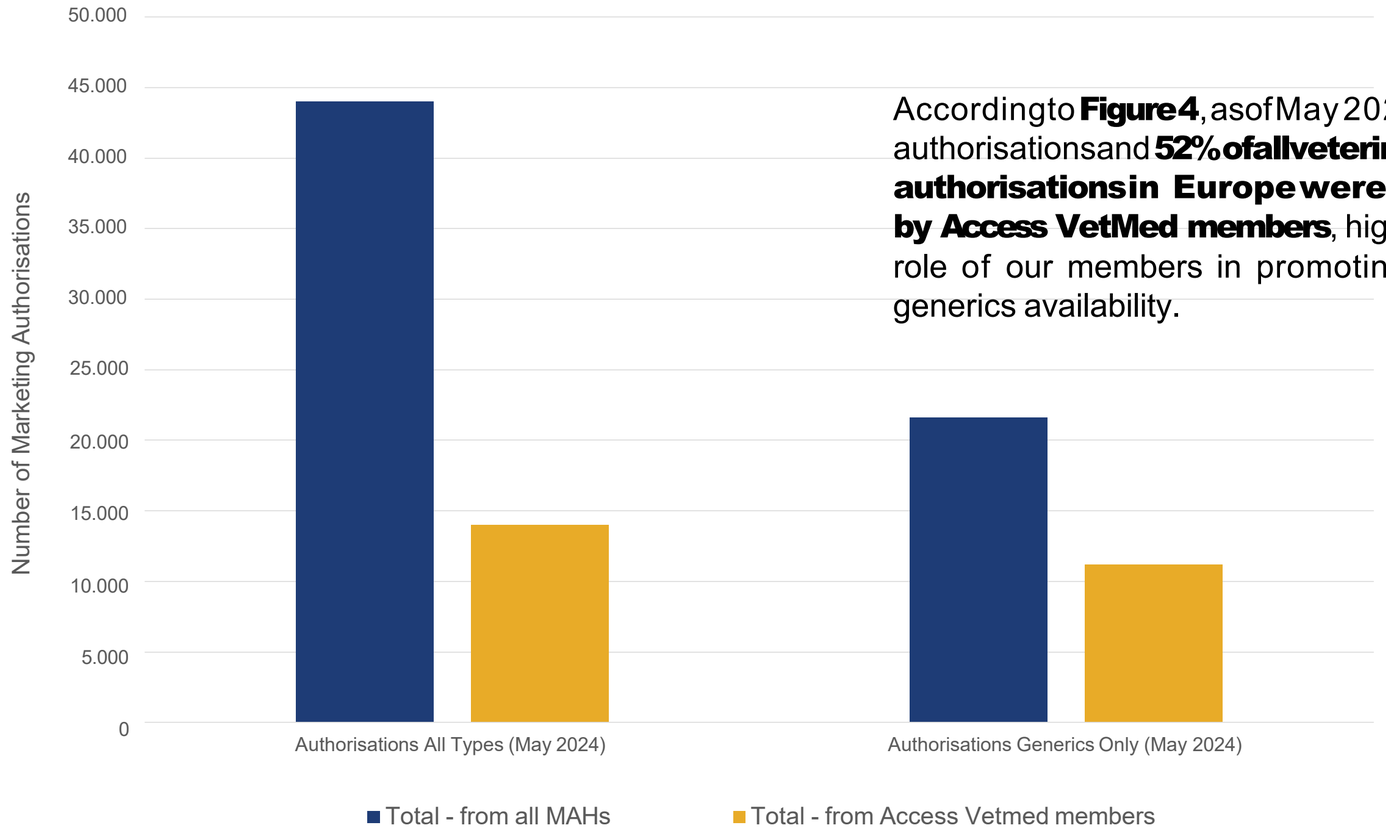
Figure 3 shows that over the past 20 years, the share of generics in the veterinary industry has steadily increased, particularly in recent years. While original products accounted for 90% of all authorisations in 2004, this figure h as now dropped to approximately 50% in 2024. Veterinary generic authorisations have grown 21-fold since 2004, whereas authorisations for all types of medicines have increased only four-fold during the same period.

Although the values only cover the period up to May 2024, it is however important to note a slower growth in terms of new MAs from 2020-2021.

05. Access VetMed Data Analytics

Significance and Contribution of Access VetMed Towards VMPs Availability

Figure 4: Number of authorisations contributed by Access VetMed Members.

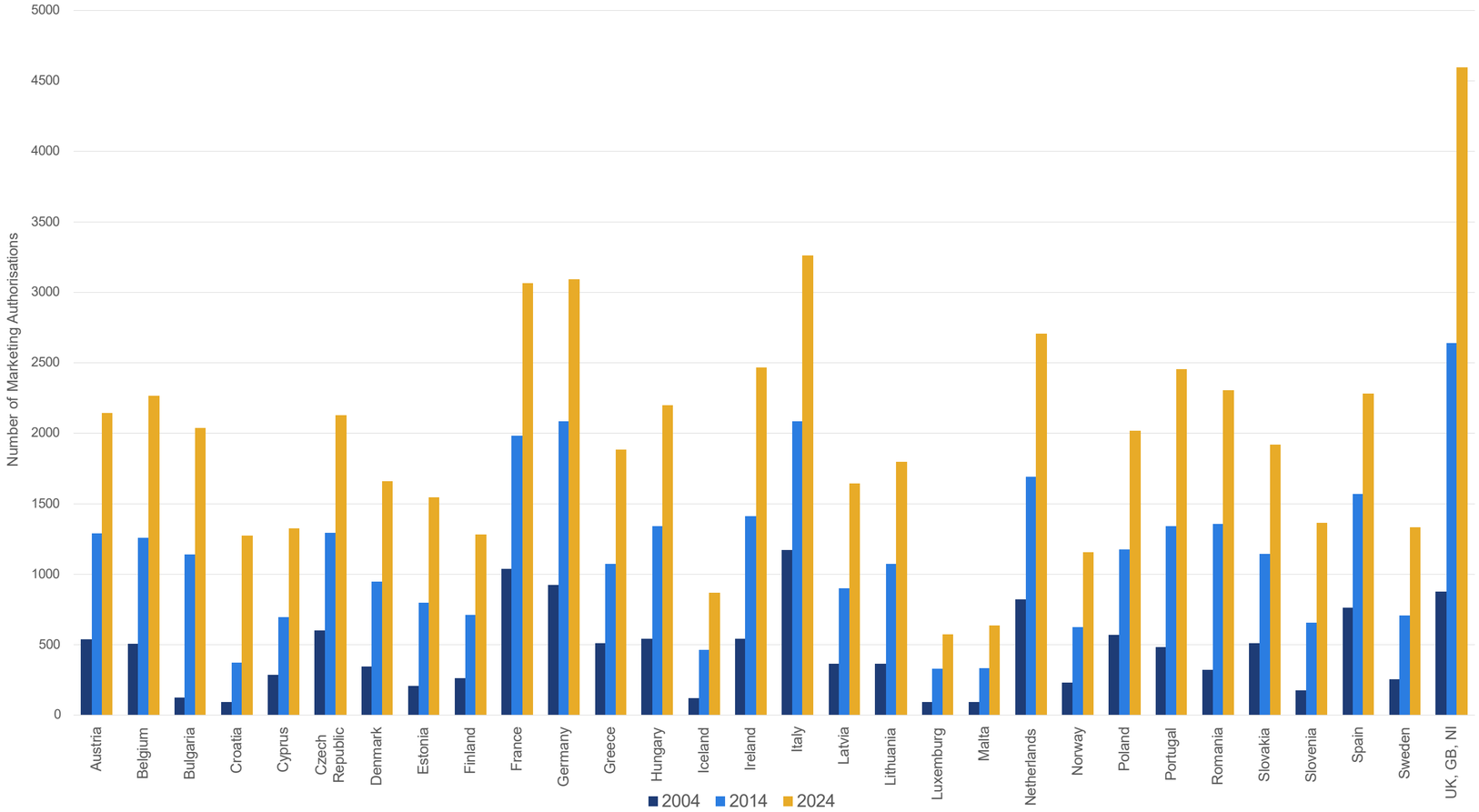


According to **Figure 4**, as of May 2024, 32% of all authorisations and **52% of all veterinary generic authorisations in Europe were contributed by Access VetMed members**, highlighting the role of our members in promoting veterinary generics availability.

05. Access VetMed Data Analytics

Development of Authorizations by Member State

Figure 5: Number of MAs (all type) in each Member State at three time points (2004, 2014 and 2024).



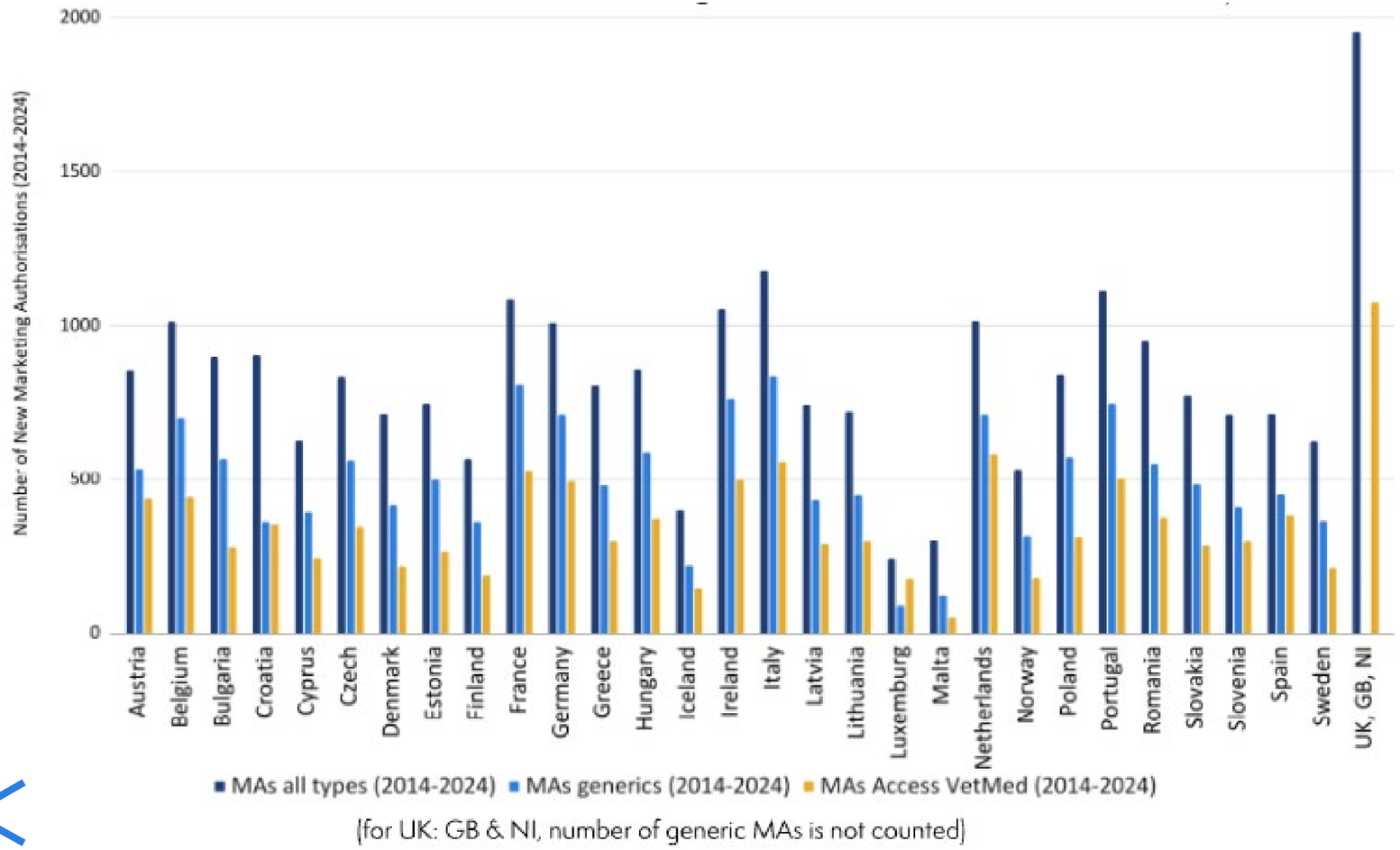
05. Access VetMed Data Analytics

Development of Authorizations by Member State

As per **Figure 5,** some countries have a broader range of authorisations compared to others. The United Kingdom, including both Great Britain and Northern Ireland, stands out as the country with the highest number of authorisations; however this figure includes several duplicates from both regions. Italy, France, and Germany show similar numbersofauthorisations, indicating comparable scales in terms of authorisation volumes. Poland has a significantly lower number of authorisations than expected for its size, even falling behind smaller countries such as Hungary, the Czech Republic, and Romania. Among smaller markets, Bulgaria, Portugal, and Slovakia stand out.

05. Access VetMed Data Analytics

Figure 6: Authorisations in the Member States: Contribution from generics and Access VetMed members (Period 2014-2024).



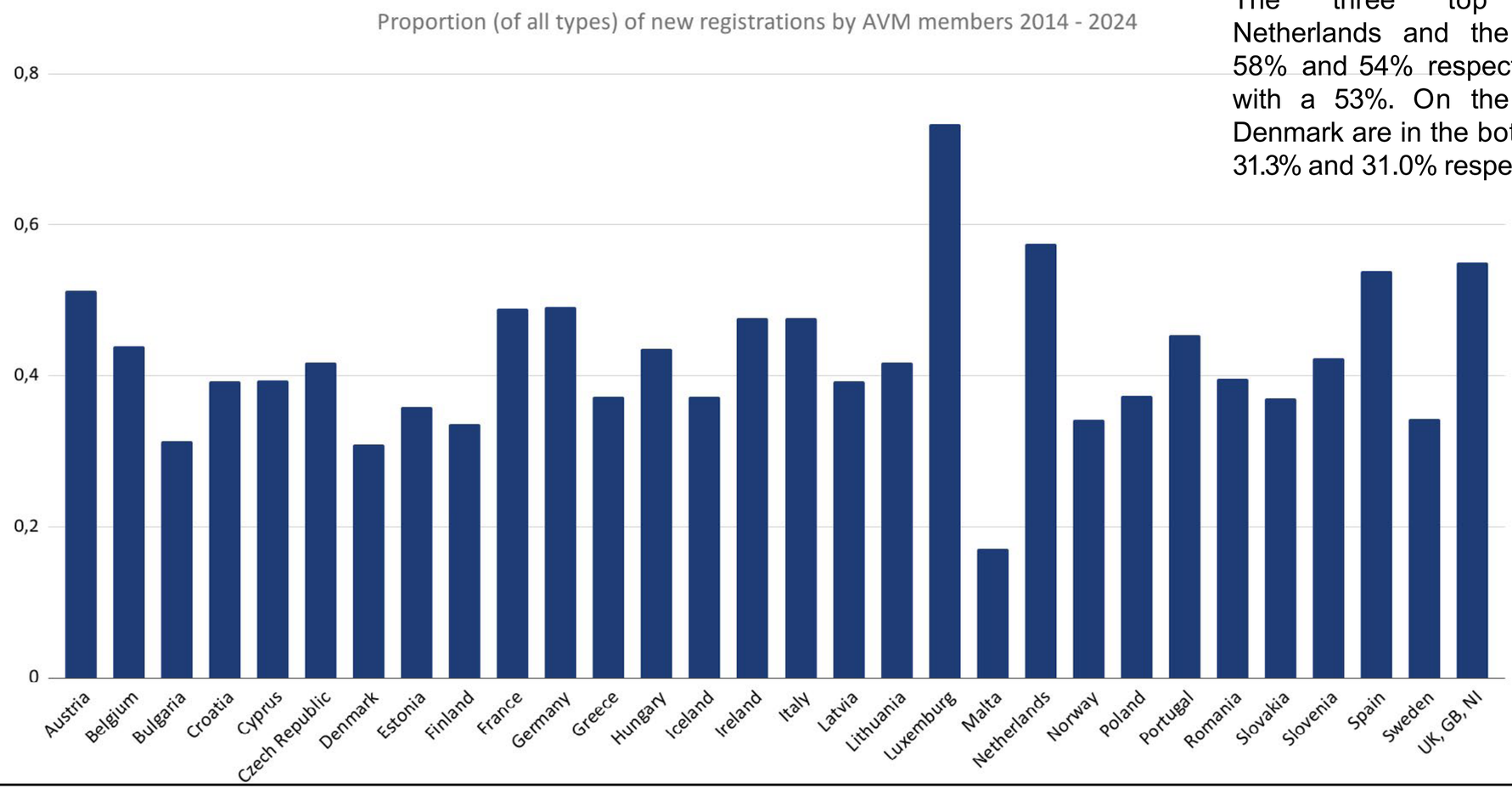
From the analysis of the individual raw data that shapes **Figure 6**, it has been noted that during the period 2014-2024, 62% of the total number of new Authorisations in the EU correspond to generic products, and almost 42% of the total authorisations in that period are contributed by Access VetMed members.

From Figure 6, it can be observed that Spain's growth lagged behind its European counterparts in the last 10 years. As such, while other countries exceeded 1,000 authorisations over the past decade, Spain only recorded around 700, which is 30% lower than its counterparts.

On the other side, Member States such as Portugal, Ireland and The Netherlands show a comparable growth to that from Italy, France, and Germany.

05. Access VetMed Data Analytics

Figure 7: Access VetMed contribution to new authorisations in each Member State (2014-2024).



The three top markets are Luxembourg, Netherlands and the UK with percentages of 73%, 58% and 54% respectively, with Spain following closely with a 53%. On the other side, Malta, Bulgaria and Denmark are in the bottom three with percentages of 17%, 31.3% and 31.0% respectively.

05. Access VetMed Data Analytics

Development of generics by animal species

Figure 8: Development of MAs in major species and horses.

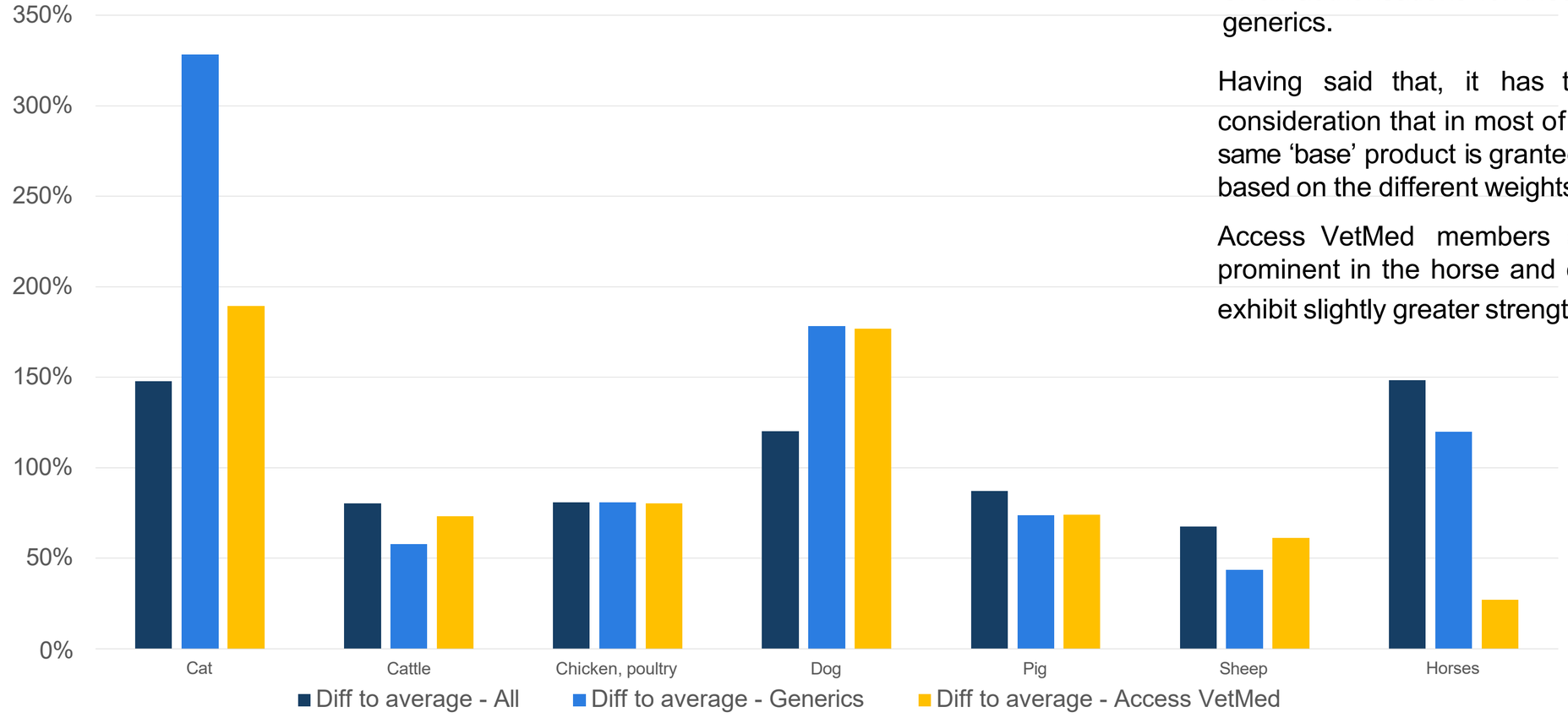


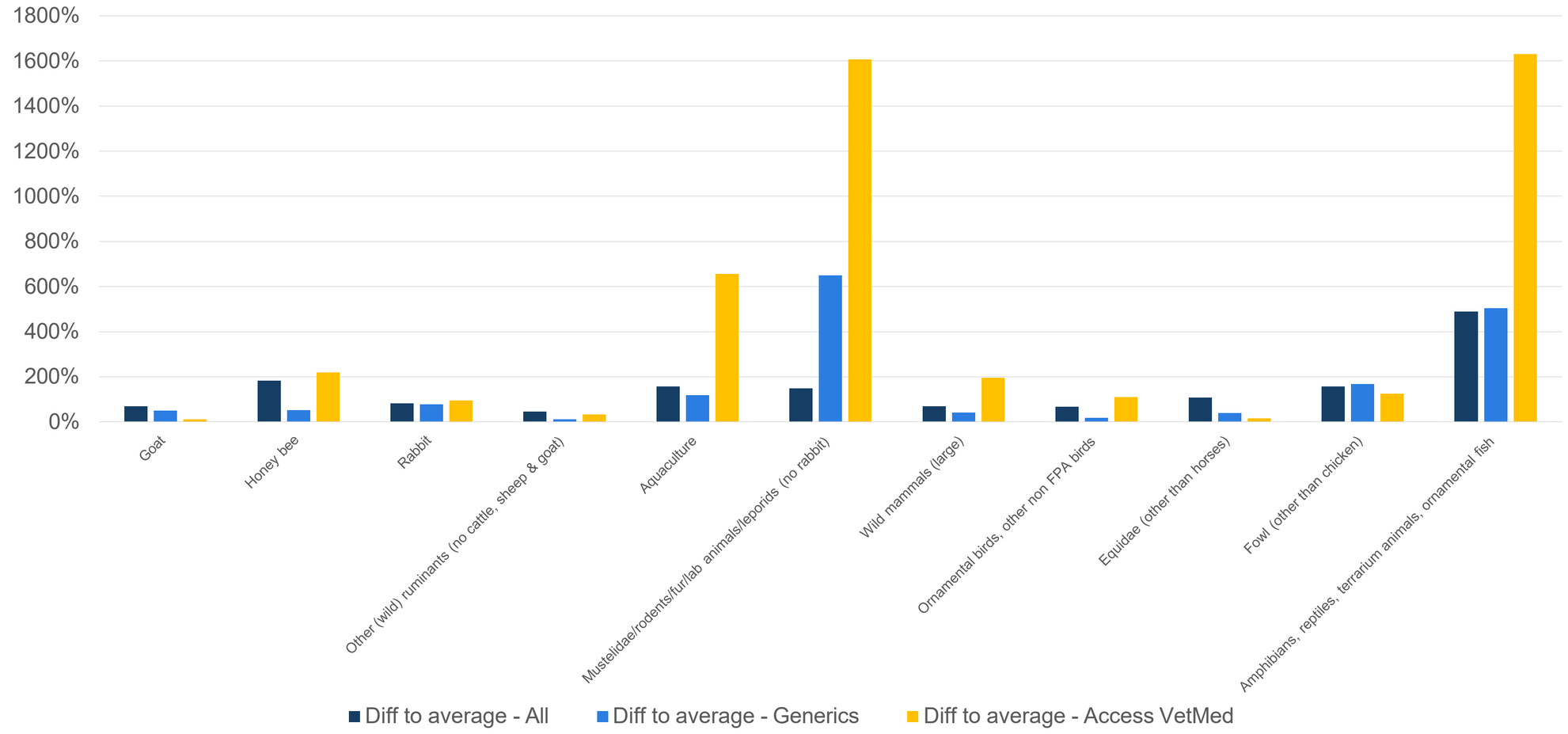
Figure 8 shows the relative growth of authorisations in major species and horses between 2004 and 2024 (100% = base line). Generic medicines show a stronger growth in cats and dogs. Incidentally, data shows that 61% of all authorisations for these two species are generics.

Having said that, it has to be taken into consideration that in most of the occasions, the same ‘base’ product is granted with several MAs based on the different weights of dogs and cats.

Access VetMed members are however less prominent in the horse and cat segments and exhibit slightly greater strength in ruminants.

05. Access VetMed Data Analytics

Figure 9: Development of MAs in minor species (excluding horses).



05. Access VetMed Data Analytics

In **Figure 9** horses have intentionally been excluded to highlight the relative growth in the other minor use/ minor species. From the analysis of the individual raw data that shapes the chart, it has been noted that in absolute numbers, the largest increase in the ornamental fish has come from Access VetMed members, and most significantly, all the growth for ornamental birds and other non-FOA birds has been driven by Access VetMed members. Overall, generics play a crucial role in minor species: As of May 2024, almost 48% of all MAs for minor species (including horses) were for generics. Of these, more than 39% were granted to companies that are members of Access VetMed.

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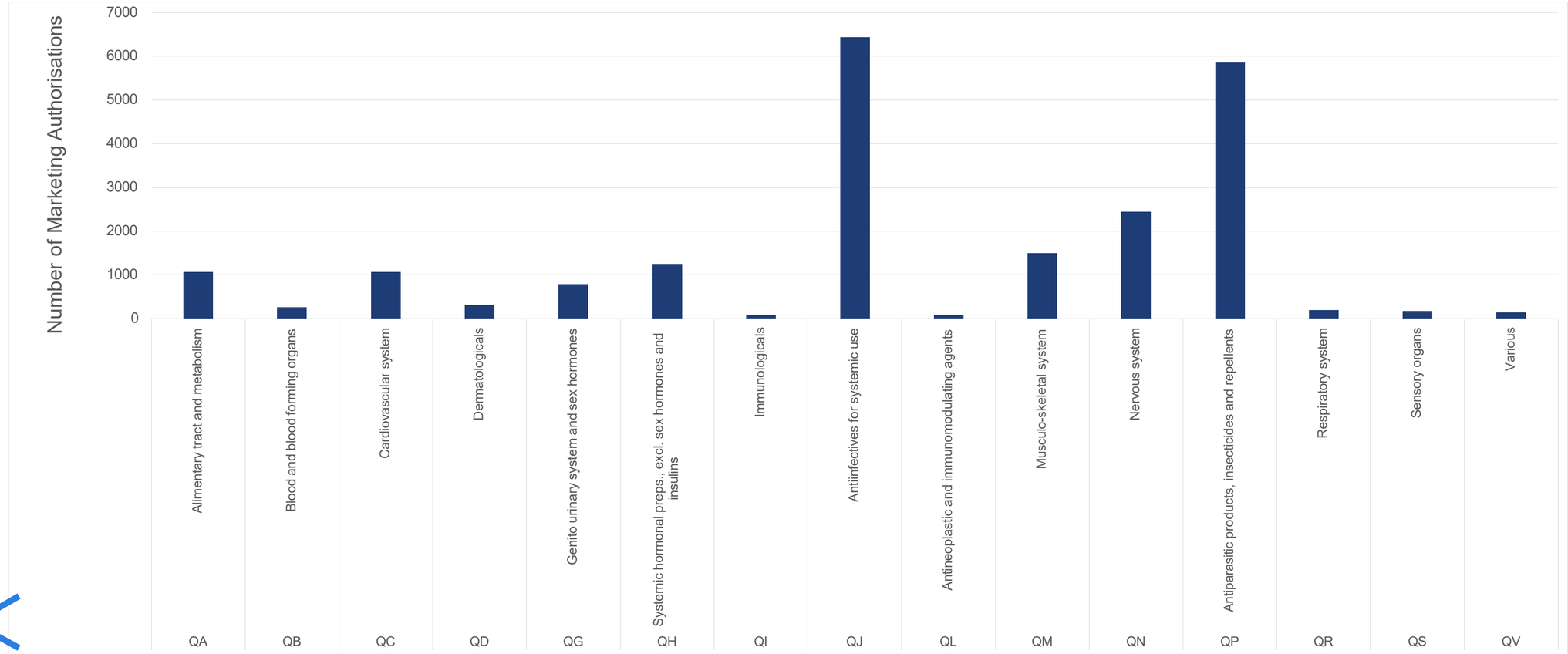
05. Access VetMed Data Analytics

Therapeutic areas covered by generic veterinary medicines

The highest number of authorisations as of 2024 is for anti-infectives and antiparasitics, followed by VMPs for the nervous system and musculo-skeletal system.

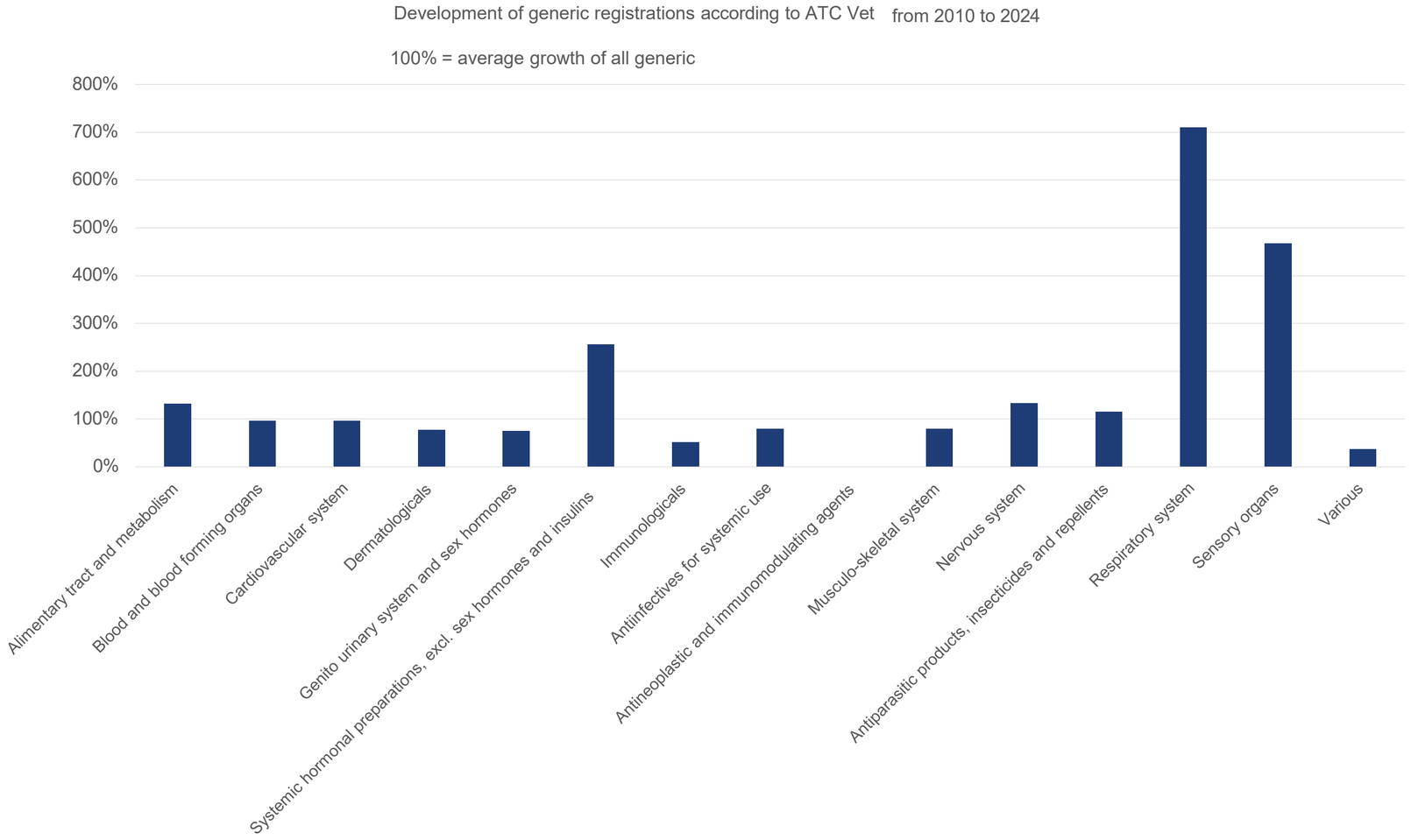
Figure 10: Generic MAs classified by therapeutic groups (ATCvet)*.



*The ATCvet system for classification of veterinary medicines is based on the same overall principles as the ATC (Anatomical Therapeutic Chemical) system for substances used in human Medicine).

05. Access VetMed Data Analytics

Figure 11: Relative growth (2010 – 2024) of generic authorisations according to their therapeutic group.



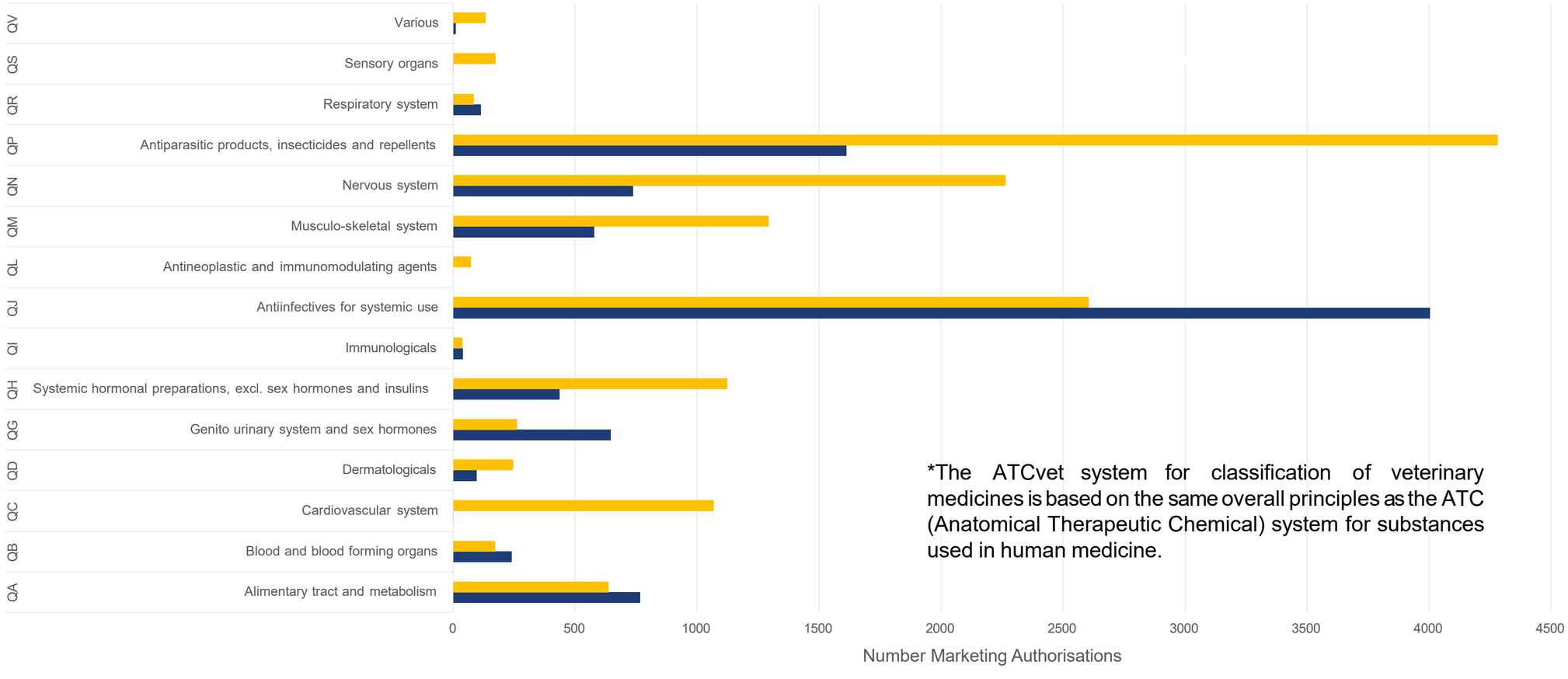
05. Access VetMed Data Analytics

The growth of generic registrations represented in **Figure 11**, it is clearly observed that the main contributors have been those generic VMPs corresponding to the therapeutic areas of respiratory system and sensory organs. However, it is worth noting that this is mainly triggered by the fact that in 2010, the number of generic authorisations in those two categories was only 12, and this has now increased to 351 as of May 2024.

The number of generic VMPs for systemic hormonal preparations has also experienced a significant growth between 2010 and 2024, with a 256% relative growth in comparison with the average growth of all generic VMPs.

05. Access VetMed Data Analytics

Figure 12: Number of generic authorisations for Food Producing Animals (FPA) and Non-Food Producing Animals (Non-FPA) classified by ATCCode (May 2024).



*The ATCvet system for classification of veterinary medicines is based on the same overall principles as the ATC (Anatomical Therapeutic Chemical) system for substances used in human medicine.

05. Access VetMed Data Analytics

From an análysis of the data used to compile **Figure 12**, approximately 60% of all generic authorisations **are in Non-Food Producing Animals,** with antiparasitics, insecticides and repellents (QP) the strongest group in this category (almost 30%). **Anti-infectives are the largest group in Food Producing Animals (43%),** and overall as well (almost 28%). Antiparasitics follow closely, with almost 25% contribution in overall terms. Nervous system (QN) followed by musculo-skeletal system (QM) follow thereafter, together representing a combined total 21% of generic authorisations.

05. Access VetMed Data Analytics

Generics according to the route of administration

Figure 13: Marketing Authorisations (MAs) per Route of Administration.

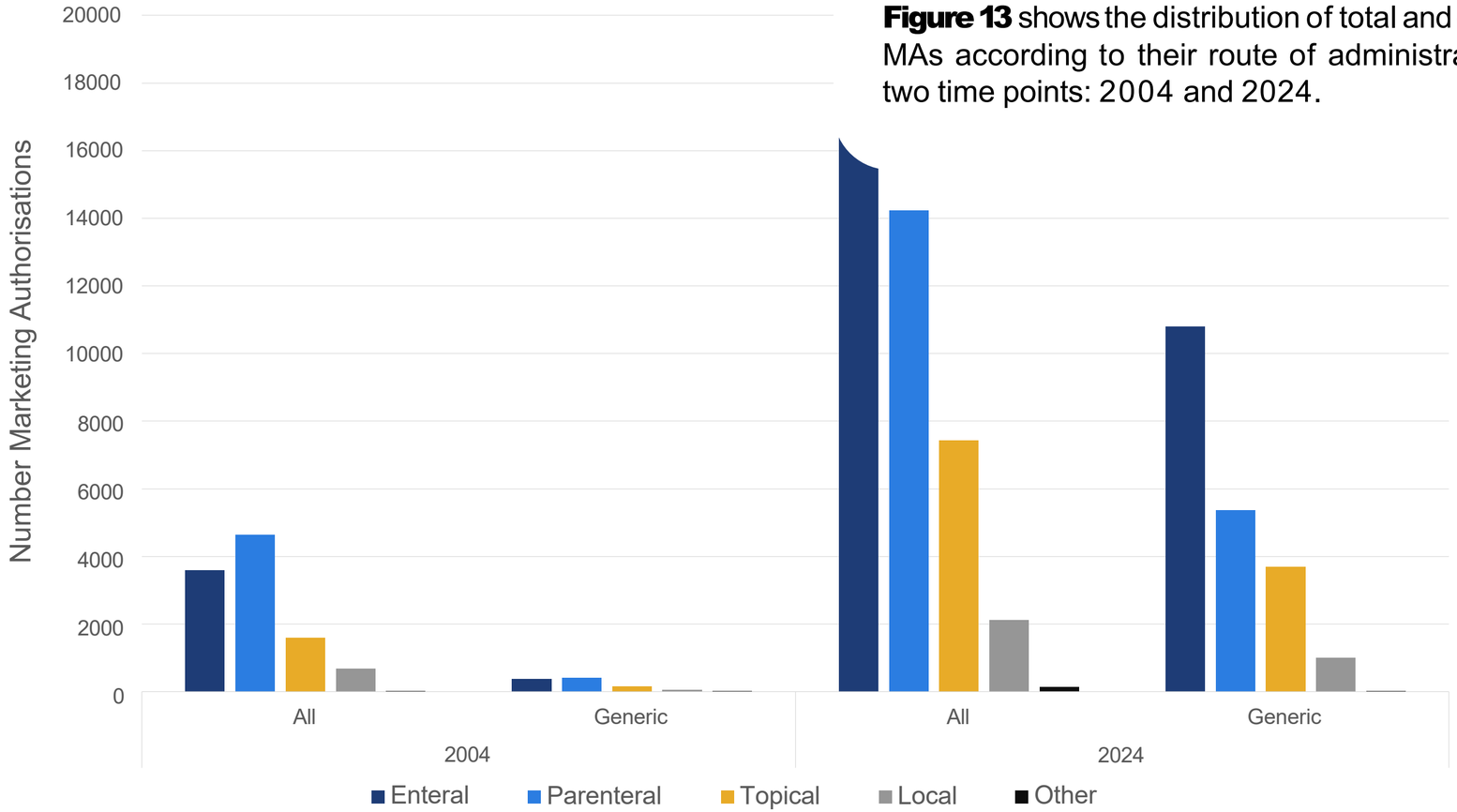
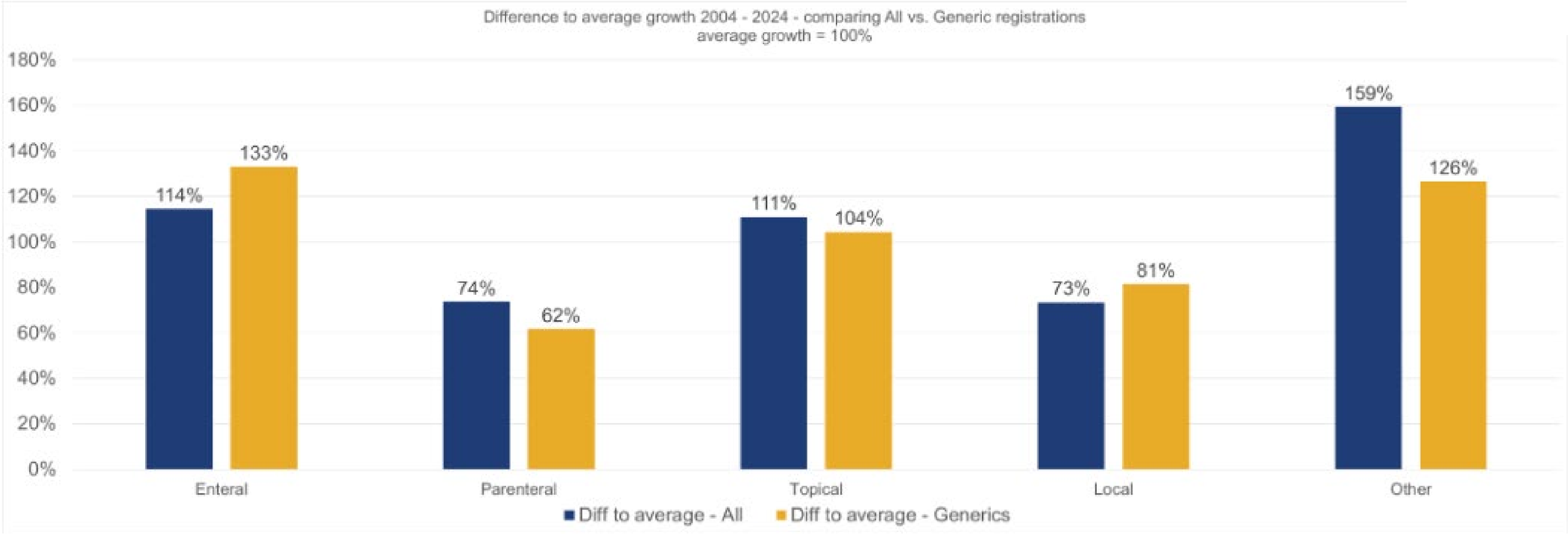


Figure 13 shows the distribution of total and generic MAs according to their route of administration at two time points: 2004 and 2024.

05. Access VetMed Data Analytics

Figure 14: Relative growth (2004-2024) of Marketing Authorisations (MAs) based on the Route of Administration. Average growth = 100%.



05. Access VetMed Data Analytics

Figure 14 illustrates the growth differences (2004-2024) between all authorisations and generic authorisations, categorised by routes of administration (e.g., oral, intravenous, topical). The horizontal axis represents the various routes of administration, while the vertical axis shows the relative growth difference compared to an average growth benchmark of 100%.

The enteral and local routes of administration show significantly higher growth rates for generic authorisations compared to the overall average, with the enteral route exhibiting much stronger growth between 2004 and 2024. In contrast, parenteral authorisations grew more slowly in the generic side compared to all authorisations.

The analysis of growth differences by route of administration highlights the importance of generic authorisations in more accessible and widely used categories, such as enteral and topic administrations. However, the variability across routes suggests untapped potential in certain specialized markets.

06 Evaluation of the impact of Regulation (EU) 2019/6

06. Evaluation of the impact of Regulation (EU) 2019/6

Access VetMed has identified a priority to monitor, measure, and address the provisions of Regulation 2019/6 to ensure they are utilized and effectively applied, particularly in order to achieve the objective of reducing administrative burdens. To assess the impact of the regulation, Access VetMed launched a quantitative survey among its members to evaluate how the regulation affects their operations (in terms of finance and staffing) and to better understand what the increase in administrative burden truly means for Access VetMed members.

The quantitative survey identified several challenges related to registration management, regulatory compliance, and additional costs associated with the new regulations. Regulation (EU) 2019/6 has led to a greater standardisation in administrative processes but has also imposed a significant financial burden on companies in the veterinary sector.

06. Evaluation of the impact of Regulation (EU) 2019/6

Administrative Burden Evolution

Human Resources, Regulatory and Pharmacovigilance departments

One key question in the questionnaire focused on the Full Time Equivalent (FTE*) staffing levels in the Regulatory and Pharmacovigilance departments from 2018-2023. The cumulative results are presented in the graph below, which illustrates the change in the number of FTEs required to perform the work compared to the previous year. Small and medium-size enterprises (SMEs) are shown separately, as the impact on these businesses has been greater than on larger enterprises.

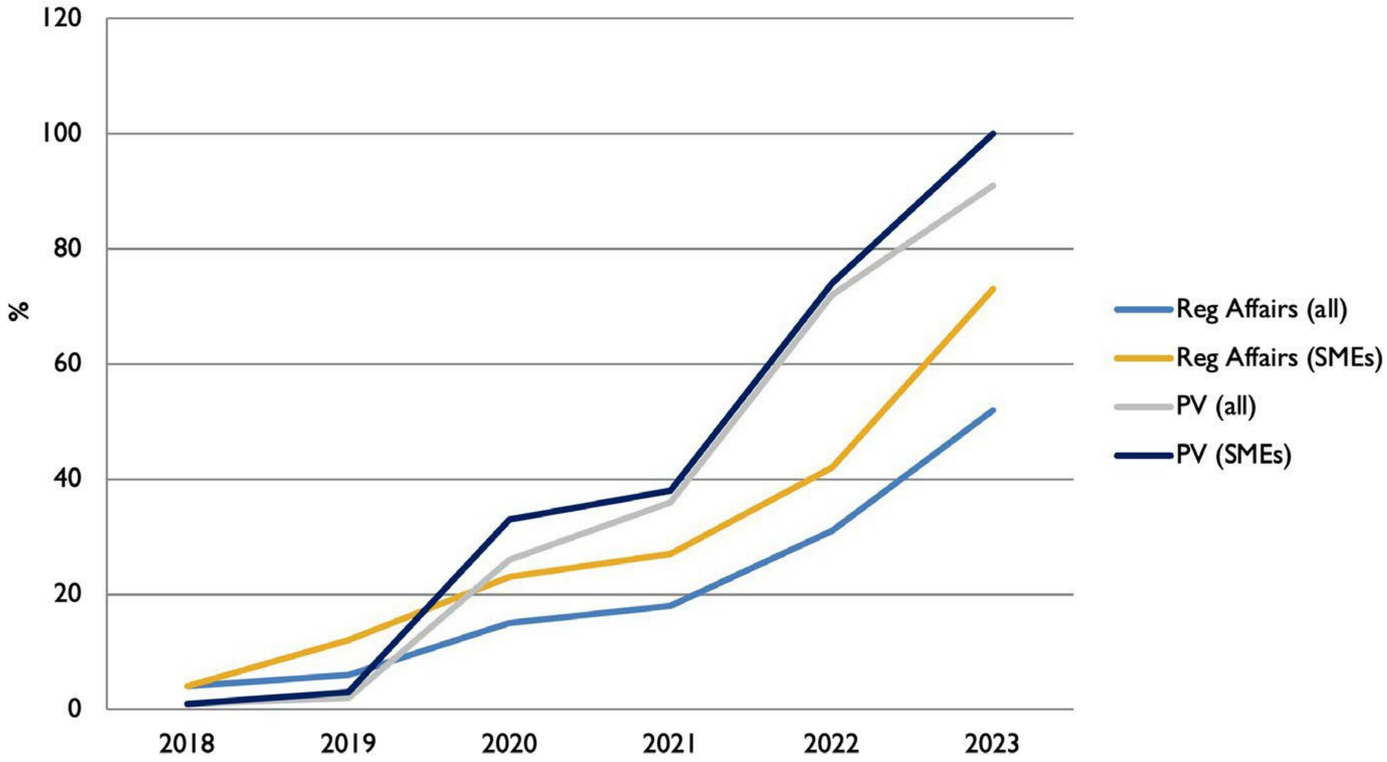


Figure 15 : Cumulative percentage evolution of Human Resources in Regulatory Affairs and Pharmacovigilance (PV) departments (2018-2023).

* Full-Time Equivalent (FTE). It's a measure used to standardize the amount of work done, helping to quantify the workforce based on the number of full-time hours worked. An FTE represents one full-time employee, typically working 40 hours a week (though this may vary by country or organization).

06. Evaluation of the impact of Regulation (EU) 2019/6

Main Conclusions and Remarks

1. There is a significant increase in administrative burden, reflected by an increase in the number of FTEs* needed to perform the work.
2. There is a significant increase in financial burden. This started in 2019 (once the current Regulation 2019/6 was published), and increased exponentially after 2021 on all fronts (in line with the immediate year prior to implementation of the Regulation).
3. Quality Review Documents (QRD) update workload will become less. Consequently, variations costs and regulatory resources shall also reduce. However, there are still concerns arising from upcoming procedures such as the Summary of Product Characteristics (SPC) harmonisation and others.
4. There are concerns regarding the consequential variations after QRD, such as additions of local representatives, delayed product transfers, delayed market expansions. In this particular area, another issue of concern is the still lack of major harmonisation at national level.

* Full-Time Equivalent (FET). It's a measure used to standardize the amount of work done, helping to quantify the workforce based on the number of full-time hours worked. An FTE represents one full-time employee, typically working 40 hours a week (though this may vary by country or organization)

06. Evaluation of the impact of Regulation (EU) 2019/6

Main Conclusions and Remarks

5 It is anticipated that in the near future, all Information Technologies (IT) related issues and 'bugs' from the recently launched Union Product Database (UPD) shall be resolved, so more routine will come in working with UPD, uploading sales data, availability and Pharmacovigilance database. In that instance, any efforts from the European Medicines Agency (EMA) and National Competent Authorities to resolve these issues will be very much appreciated.

6 Duplication of the reporting of sales figures (almost 3 years after entrance of Regulation 2019/6) is another additional and unnecessary burden.

7 In general, system improvements for Regulatory affairs and Pharmacovigilance are required (at all different layers) and avoiding disconnections between National databases and Union Product Database (UPD).

8 Ultimately, a vast majority of Access VetMed members are small to medium size companies (even if they may not be "ticking all the boxes" as per Small and Medium Enterprises definition), so a significant number of employees from our associates are currently "wearing multiple hats" to face and address all the changes from the recent Regulation 2019/6. Therefore, and once again, all efforts from European Medicines Agency (EMA) and national competent authorities to streamline administrative burden and have proportionate fees will be very much appreciated.

* Full-Time Equivalent (FET). It's a measure used to standardize the amount of work done, helping to quantify the workforce based on the number of full-time hours worked. An FTE represents one full-time employee, typically working 40 hours a week (though this may vary by country or organization)

07 Business Aspects

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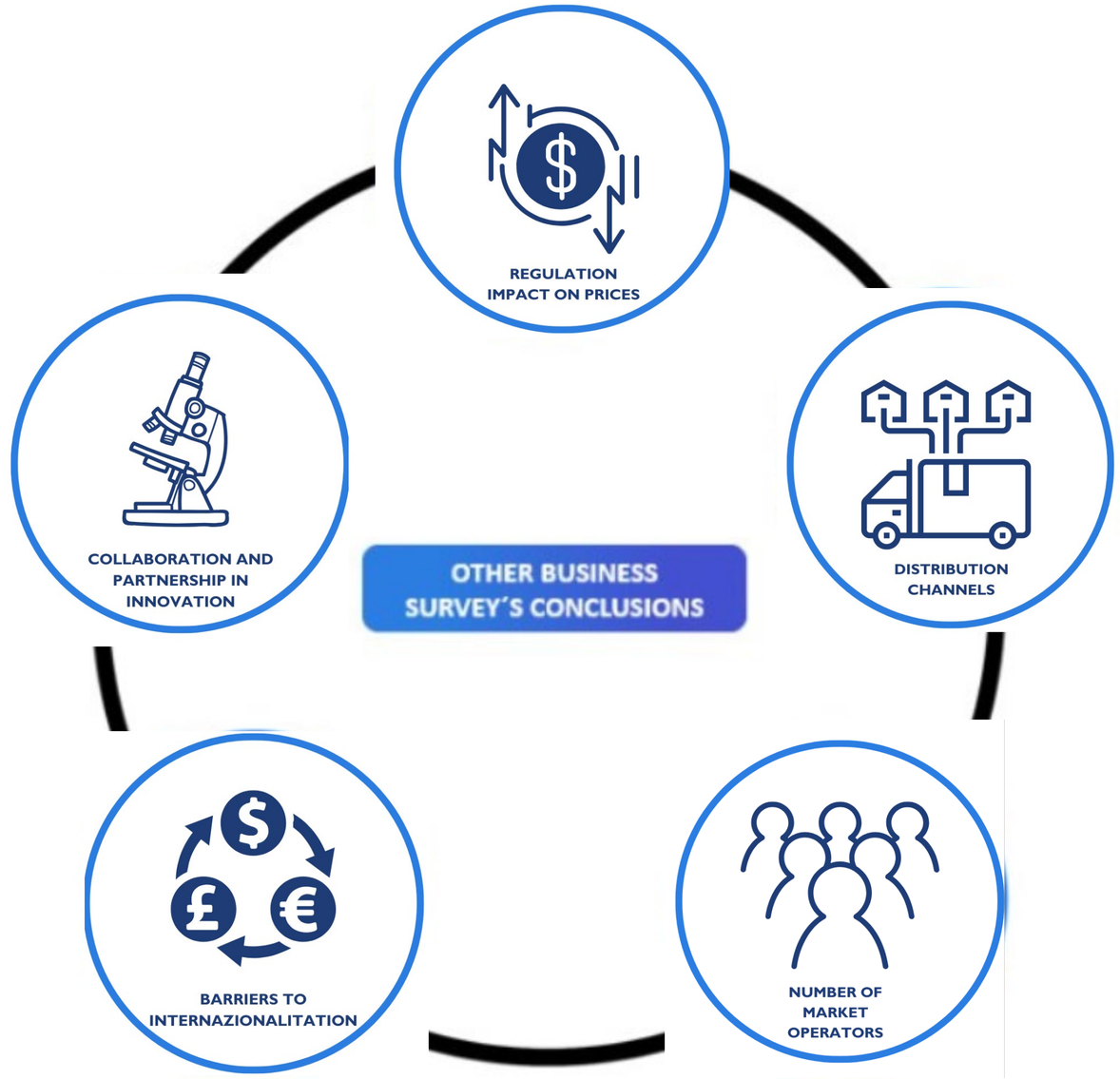
Qualitative surveys conducted among Access VetMed member companies reveal that despite regulatory challenges, there are clear growth opportunities for marketing authorisation holders of generics. **These opportunities are mainly found in new niche markets such as emerging therapeutic areas, and in countries where the veterinary medicine market is not yet fully developed.**

07. Business Aspects



07. Business Aspects

Regulation 2019/6 is expected to significantly impact prices, with increased fees and administrative burdens driving up costs, particularly for generics. Rising technical constraints, such as stricter requirements for sterile products, and the lack of harmonization between countries on local regulations, will further contribute to price increases. The increased frequency of pharmacovigilance reporting and additional regulatory requirements (e.g. UPD, QRD 9.0) are seen as adding complexity without clear added value. While production costs are expected to rise (by 20-50%+), the competitive pressure from low-cost producers in India and China may limit price increases. National regulatory inconsistencies and the complexity of complying with diverse laws add additional burdens. Despite these challenges, the competitiveness of the market may keep final price increases in check, especially given the lack of new molecules in the generics sector.

Some of our members do not generally expect major changes to distribution channels in the short term, as current regulations are newly implemented and well-defined. However, the lack of harmonisation across EU countries, particularly in the definition of a distributor, remains a significant issue. There is speculation that wholesalers may struggle to survive due to low margins, leading some businesses to consider direct sales models. The rise of online sales and easier cross-border distribution under the EU license is anticipated to impact traditional channels. Additionally, stricter GDP requirements are expected to increase distribution costs. Some companies might explore establishing subsidiaries in specific countries to overcome margin challenges and support long-term growth.

07. Business Aspects

The increasing number of corporate veterinary clinics is putting significant pressure on the animal health industry. Centralized purchasing and the bargaining power of large clinic chains are driving down prices and eroding profit margins, with some members reporting a loss of 2-3% in margin annually. This trend is particularly impactful in both companion animal and livestock sectors. The rise in private label demand and cross-border tenders further intensifies competition. To adapt, companies need more key account managers focused on corporate clients and should innovate their products and services. There is also concern about the impact on veterinarians' prescribing freedom and the potential shift of customers back to independent clinics due to high consultation costs. Finding a balanced, mutually beneficial way to collaborate with corporate clinic chains is becoming increasingly important.

Members identified several key hurdles in expanding geographically, both within the EU and beyond. In the EU, bureaucracy and regulatory complexity are significant obstacles, with varying national requirements for marketing authorisations, regulatory fees, dossier evaluation times, and distribution rules. These discrepancies make it difficult to navigate the regulatory landscape, and the high costs associated with yearly fees and the need to hold marketing authorisations for export contribute to financial strain, especially for smaller companies. Outside the EU, delays in obtaining marketing authorisations and the lack of recognition of EU GMP standards are major challenges. Some third countries also prefer API material from China, which can undermine EU-produced veterinary products. These issues, combined with the increasing time required for regulatory processes and the lack of harmonised procedures for generics, make international expansion difficult and less attractive to potential partners.

07. Business Aspects

In general, members expect future partnerships for new product development to be more beneficial with EU companies due to the shared costs of development and easier navigation of national regulations and procedures. EU partnerships offer advantages in streamlining marketing authorisations and improving speed to market within the EU. However, some members see potential in partnering with non-EU companies for product introduction, as these partnerships may face fewer regulatory hurdles and offer more flexibility. While production must still adhere to EU standards, non-EU partners may help reduce manufacturing and shipment costs, influencing decisions on where to collaborate. Overall, partnerships with EU companies are favored for product development, but non-EU partners may be more attractive for market entry and cost considerations.

08 Final conclusions of the Market study

08. Final conclusions of the market study

1. The study shows that the generic veterinary medicines industry in Europe is strong and continuously growing. In fact, **60% of all European MAHs hold generic licenses,** and **50% of all veterinary medicines authorisations in Europe are generics.**

2. The slower growth on MAs noted since 2020-2021 will have to be closely monitored.

3. 64% of MAHs holding more than 500 generic authorisations are Access VetMed members, and collectively account for **52% of the total of generic authorisations.** This means that Access VetMed, as a group, is a strong and growing player in the European veterinary medicines industry, driving the sector forward with the ongoing technical consultancy provided by its working groups, which include Pharmacovigilance, Labelling and Packaging, Antimicrobials and Antimicrobials Resistance, Immunological and Novel Therapies, Safety and Efficacy, Variations, Telematics, Bioequivalence, Quality and Environmental Risk Assessment.

4. Regarding the activity of the association across different species, Access VetMed members' generics lag behind the horse and cat segment compared to other generics, while they are stronger in ruminants.

08. Final conclusions of the market study

5 Data analysis shows that generic medicines are strong in dogs and cats, accounting for **61% of all authorisations for these two species.**

6 In relation to generic products per ATC (Anatomical Therapeutic Chemical) VetCodes, anti-infectives and antiparasitics represent the largest group, accounting for a 57% of the total number of generic MAs.

7 Enteral and local routes of administration experienced higher growth between 2010 and 2024 compared to overall authorisations.

8 Finally, the study indicates that the veterinary generics sector in Europe is still strong, has a promising future with significant opportunities for expansion and growing consolidation in the regulatory field (e.g. in emerging markets and some therapeutic areas). However, attention should be drawn to coming challenges due to higher costs, administrative burden, and the decrease in the number of new active ingredients and brand-new products being authorised at present.

09 Acknowledgements

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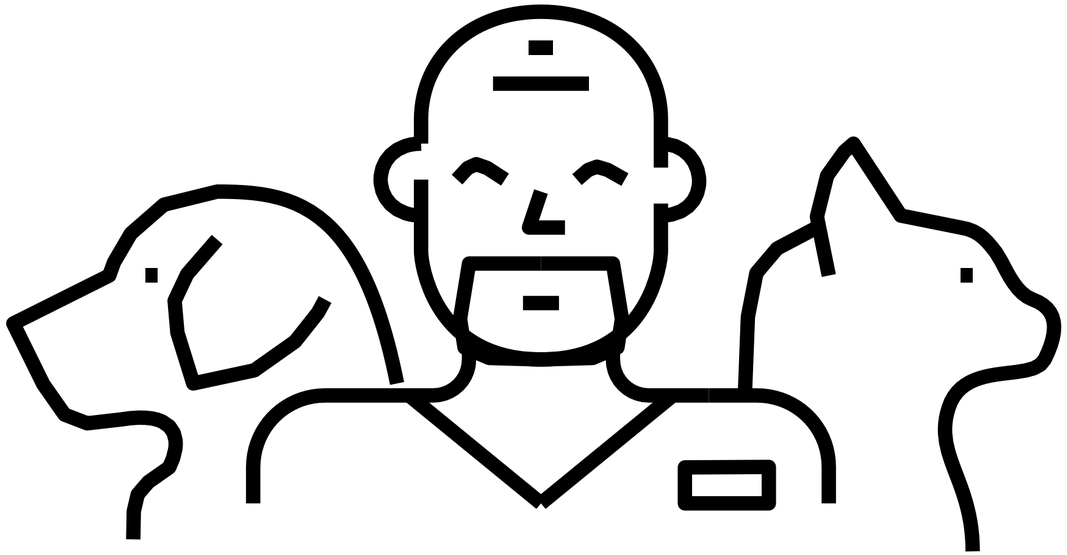

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