

MANIFESTO:

ADVANCING ACCESS TO VETERINARY
MEDICINES IN EUROPE
BY STREAMLINING PROCESSES



Access
VETMED



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The European animal health industry -vital to animal health, food safety, and human well-being- is at a critical crossroads. Recent data from Access VetMed's market study on generic veterinary medicines reveal a troubling imbalance: between May 2024 and May 2025, new authorisations declined while product withdrawals surged, with 638 approvals compared to compared to 1, 027 withdrawals. This negative trend points to a structural problem that threatens the sustainability of the sector.

The challenge extends beyond scientific or commercial factors. Surveys conducted among Access VetMed members show growing pressure stemming from administrative complexity and financial burden. Since 2018, regulatory affairs and pharmacovigilance requirements demands have increased steadily, disproportionately affecting small and medium-sized enterprises, which face relative regulatory burdens 15–20% higher than those of larger companies. These pressures translate into higher costs, reduced operational flexibility, and an increased risk of market exit, particularly in countries with excessive regulatory fees.

Rising regulatory requirements also drive exponential cost growth, eroding margins and constraining investment in research, innovation, and workforce development. As a result, the industry is caught in a vicious cycle of increasing obligations and a diminishing capacity to grow or to ensure a stable supply of veterinary medicines across Europe.

In response, Access VetMed presents this Manifesto, "Advancing access to veterinary medicines in Europe by streamlining processes". Built on robust evidence drawn from a database of more than 46,000 EU and UK regulatory records, the Manifesto sets out a package of urgent measures to address these challenges. Its objectives include better integration of animal, human, and environmental health policies; ensuring access to veterinary medicines; harmonising regulatory frameworks; and improving transparency, while fostering dialogue among European and national authorities, industry, and other stakeholders.

The urgency is clear. Ongoing product withdrawals, particularly in the food-producing animal sector, undermine industry competitiveness and limit veterinarians' access to essential medicines, placing herd health and food security at risk. At the same time, regulatory overcosts accelerate market concentration, threatening diversity, innovation, and Europe's technological independence.

Animal health is a cornerstone of the One Health approach and of public health more broadly. Europe must act decisively. Without immediate and coordinated action, the consequences for animal health, food safety, and strategic autonomy may soon become irreversible.

The European veterinary generic and added-value medicines sector is facing increasing challenges that threaten both product availability and business sustainability. An extensive analysis of over 46,600 marketing authorisations (MAs) in public databases demonstrates a continuous erosion of MAs in the EU and the UK. Between May 2024 and May 2025, the industry registered 638 new MAs, but lost 1,027 MAs - withdrawals or expirations - leading for the first time in over 20 years to a net negative balance of MAs.

Beyond the registration dynamics, surveys conducted among Access VetMed members, representing 52% of the total generic licenses in Europe, provide a clear evidence of the increasing regulatory and financial burden:

➤ **Administrative burden:** Since 2018, companies have reported a near-doubling of staff allocation in Regulatory Affairs (RA) and Pharmacovigilance (PV). The effect is particularly acute among Small and Medium Enterprises (SMEs), which face 15–20% higher workloads compared to larger organisations.

Figure 1.- Administrative burden. Cumulative Evolution (%) of FTEs in Regulatory Affairs (RA) and Pharmacovigilance (PV) (2018-2024).

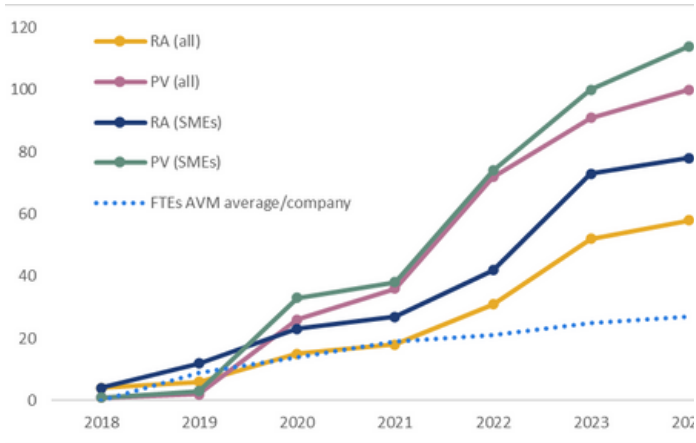
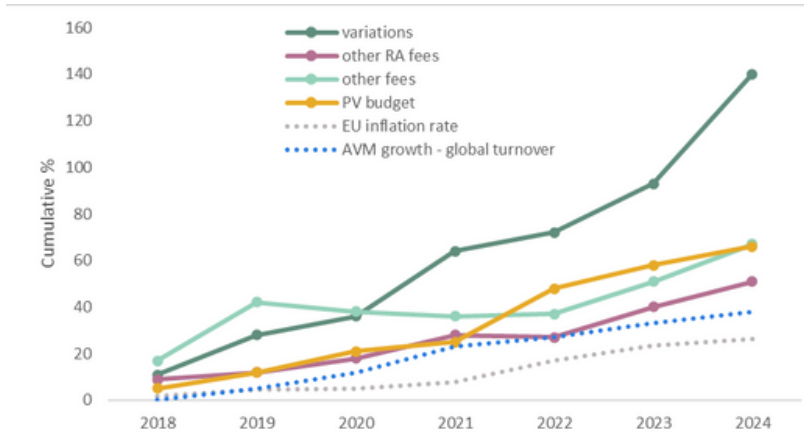


Figure 2.- Financial burden. Cumulative Evolution (%) budgets allocated to RA and PV activities (2018-2024).



*1 FTE means one person working full-time.

➤ **Financial Burden:** Companies continue to face exponential growth in costs, particularly linked to regulatory fees, translation requirements, and IT system updates. These financial pressures are further reducing profit margins and constraining the ability to invest in R&D and workforce expansion. Regulation 2019/6, contrary to its intended purpose, has introduced greater administrative complexity, higher fees, procedural delays, and reduced product availability within the generic and added-value veterinary medicines industry. In conclusion, the European Generic and Added-Value veterinary industry faces a dual challenge: ensuring continued market availability through resilient registrations, while addressing growing regulatory and financial pressures that threaten its sustainability.

As an industry we seek a unified response to promote efficient and equitable regulatory practices through this Manifesto divided into five different pillars.

1

ONE HEALTH

BALANCED ONE HEALTH DECISION-MAKING FOR HUMAN AND ANIMAL HEALTH ALIKE

SMARTER REGULATION: ENHANCE EFFICIENCY, REDUCE RED TAPE AND ELIMINATE DUPLICATION OF WORK

OPTIMISATION
2

3

PREDICTABILITY

TRANSPARENCY FOR GENERIC PLAYERS TO BUILD TRUST AND CREATE A RELIABLE REGULATORY ENVIRONMENT AND ENHANCE COMPETITION

REMOVING BARRIERS: PRAGMATIC SOLUTIONS TO KEEP VETERINARY MEDICINES ON THE MARKET

AVAILABILITY
4

CONSISTENCY, ALIGNED STANDARDS AND COLLABORATION FOR A COHERENT ONE HEALTH FRAMEWORK

5

HARMONISATION



ONE HEALTH



OPTIMISATION



PREDICTABILITY



AVAILABILITY



HARMONISATION

	ONE HEALTH	OPTIMISATION	PREDICTABILITY	AVAILABILITY	HARMONISATION
Issues	<ul style="list-style-type: none"> Coordination between human and animal health stakeholders is essential to address shared challenges. Fragmented policies and fragile supply chains risk shortages of critical APIs for veterinary use. 	<ul style="list-style-type: none"> Regulatory processes remain disharmonised across Member States. Divergent and duplicate IT systems, delays in procedures, and uneven application of BPGs create inefficiency and burden without added value. 	<ul style="list-style-type: none"> Uncertainty in the interpretation of Regulation (EU) 2019/6, secondary legislation and guidance, hinder generic business planning and access the market in a timely manner. 	<ul style="list-style-type: none"> Regulation 2019/6's complex implementation risks veterinary medicine access. Vague rules on reference products, excessive paperwork and disproportionate fees. 	<ul style="list-style-type: none"> Misaligned interpretation of GMP standards between human and animal health create duplication, additional costs, and uncertainty. Conflicting horizontal laws. Misalignment of certain processes between regions, i.e. EEA vs UK.
Priorities	<ul style="list-style-type: none"> Balanced One Health policies for human and animal health alike to ensure access to veterinary medicines. Resources to prevent supply disruptions to safeguard animal welfare. 	<ul style="list-style-type: none"> Streamline and harmonise regulatory systems to eliminate duplication of work. Removal of national requirements Removal of extremely disproportionate regulatory fees in some Member States 	<ul style="list-style-type: none"> Increase clarity and transparency in the protection of technical documentation, enabling timely market entry of generic and added-value medicines and a competitive EU market. 	<ul style="list-style-type: none"> Pragmatic solutions — including on reference products and documentation requirements for limited markets - as well as fair and harmonised fees . Continuous monitoring to ensure Regulation 2019/6 delivers what was intended to. 	<ul style="list-style-type: none"> Achieve a full alignment and harmonisation across all Member States regarding the interpretation /definitions of Regulation 2019/6, and related guidelines and secondary legislation.
Calls to Actions	<ul style="list-style-type: none"> Ensure that decisions for human health (i.e. critical human medicines) do not jeopardise the continued availability of critical veterinary medicines. Effective involvement of animal health actors through transparent communication and adequate consultation opportunities on horizontal legislative initiatives. Equitable treatment in cases of global health emergencies for animal health stakeholders. 	<ul style="list-style-type: none"> Limit the scope of procedures to what is strictly covered in BPGs. Make the UPD the single point of truth. Strengthen its use and functionality to end double reporting / stop duplicate reporting via national systems. Adequate resources allocation at NCAs to ensure regulatory procedures are initiated and completed in a timely manner. 	<ul style="list-style-type: none"> Competent Authorities publishing public assessment reports on a timely fashion, regularly updated, and containing information relevant to any periods of exclusivity/ protection. Enforce timely and uniform implementation across all Member States, as fragmented national practices and requirements continue to cause uncertainty and delays in market access. 	<ul style="list-style-type: none"> Develop clear guidance on the designation of reference products, including pragmatic solutions when the original product is no longer available, and allowing broader use of UK reference products. Ensure proportionate and pragmatic application of Art 23 of Regulation 2019/6, enabling reduced documentation requirements where scientifically justified. To amend the relevant secondary legislation based on continuous engagement with industry and other stakeholders. Ensure fair and proportionate fees, particularly in smaller markets, to ensure the sustainability of medicines availability and support SMEs. 	<ul style="list-style-type: none"> Avoid duplication of GMP inspections (human and veterinary), these bring administrative burden, and unnecessary costs for both authorities and industry. Definition of local Representative to be clarified and harmonized. More uniform interpretation of the Regulation by Member States, as requirements (documentation, studies, etc.), may often differ. Approach/acceptance of future e-label must be the same in all Member States for this initiative becoming workable.

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