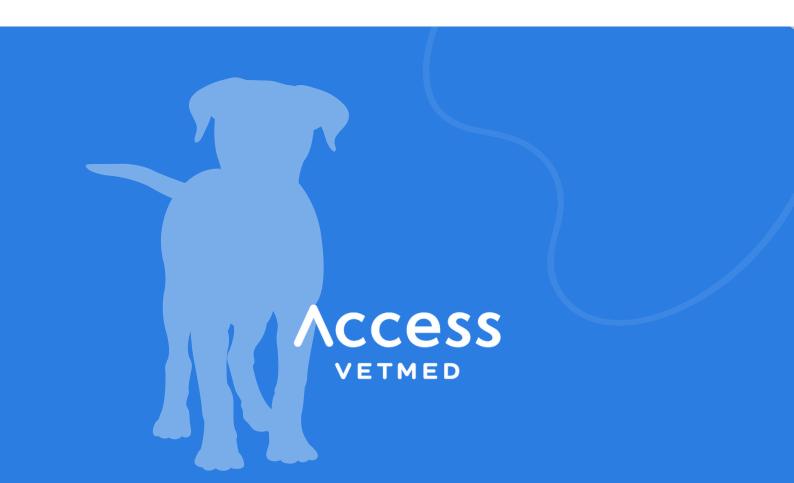
MANIFESTO:

ADVANCING ACCESS TO VETERINARY MEDICINES IN EUROPE
BY STREAMLINING PROCESSES



BACKGROUND

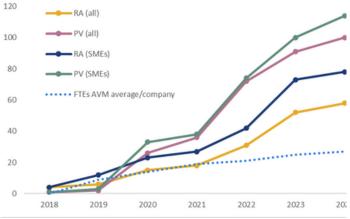
The European veterinary generic and added-value medicines sector is facing increasing challenges that threaten both product availability and business sustainability. An extensive analysis of over 46,600 marketing authorisations (MAs) in public databases demonstrates a continuous erosion of MAs in the 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 I.- Administrative burden. Cumulative Evolution (%) of FTEs in Regulatory Affairs (RA) and Pharmacovigilance (PV) (2018-2024).





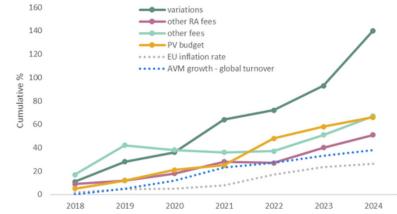


Figure 2.- Financial burden. Cumulative

${\bf *I}$ 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.



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

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





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





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



ONE HEALTH



MISATION PREDICT



AVAILABILITY



HARMONISATION

Issues

- 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.
- 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.
- 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.
- Regulation 2019/6's complex implementation risks veterinary medicine access.
- Vague rules on reference products, excessive paperwork and disproportionate fees.
- Misaligned GMP standards between human and animal health and divergent interpretation create duplication, additional costs, and uncertainty.
- Conflicting horizontal laws.
- Misalignment of certain processes between regions, i.e. EEA vs UK.

Priorities

Calls to

Actions

- 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.
- Streamline and harmonise regulatory systems to eliminate duplication of work.
- Removal of national requirements
- Removal of extremely disproportionate regulatory fees in some Member States
- 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.
- 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.
- Achieve a full alignement and harmonisation across all Member States regarding the interpretation /definitions of Regulation 2019/6, and related guidelines and secondary legislation.

- 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 ergencies for animal health stakeholders.

- 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.
- 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.
- 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
- 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.

- 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.



Committed to animal well-being in Europe



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