FEDERATION OF VETERINARIANS OF EUROPE

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FVE STATEMENT

Tailored prescription and use of veterinary medicinal products by veterinarians, a prerequisite for animal health and welfare

Veterinarians know, care and contribute

Veterinarians possess a unique blend of scientific knowledge, clinical experience, and professional judgment that equips them to make informed, prudent decisions about the use of veterinary medicinal products (VMPs).

Balancing Regulatory Compliance and Veterinary Prescribing Flexibility

VMPs are only placed on the market after approval of their patient safety and treatment efficacy. However, the Veterinary Medicines Regulation (EU) 2019/6 lays down that veterinarians must strictly follow the summaries of product characteristics (SPCs) and that VMPs always must be used in accordance with the terms of the marketing authorisation in each country (Article 106(1)). Unfortunately, when this is strictly enforced in practice, this means that veterinarians can no longer prescribe VMPs in doses, for durations and/or administration routes that deviate from those specified in the SPC.

While veterinarians always seek to fully comply with the terms of marketing authorisations, through the application of evidence-based veterinary medicine (EBVM)[1], they sometimes need to prescribe medications for the target species and target indications but in doses, durations and/or administration routes which deviate from the SPC ('off-label') to tailor treatment to ensure proper treatment efficacy and to avoid suffering[2].

Veterinary Caution in Off-Label Prescribing: An evidence-led and Science-Based Approach

This EBVM is underpinned by professional knowledge and experience on drug behaviour and effects in the animals, existing responsible use guidelines in each Member State; the latest scientific publications; specific acquaintance of the animals' health status and or laboratory information on the pathogen and resistances affecting the animal(s) will therefore require the responsible

[1] Evidence-based veterinary medicine – RCVS Knowledge. Evidence-based veterinary medicine is about combining clinical expertise with the most relevant and best available scientific evidence, while taking into account patient and owner/keeper circumstances. An evidence-based approach can be applied to all aspects of the delivery of veterinary care, from diagnosis to treatment and beyond.

[2]This is different to the well-established 'cascade use', in which there is no authorised VMP available for the target species and target indication.

veterinarian to prudently deviate from the SPC. Simply put, this means that veterinarians may need to use, prescribe and apply a veterinary medicinal product in a different dosage, duration and/or administration route, not specified in the SPC, if it is in the best interest of the animal(s).

When prescribing 'off-label', there are important safeguards to support decision-making. Veterinarians have extensive accredited initial and continuous education and apply clinical judgment on risks and benefits for the individual patient and public health, scientific evidence and guidelines, and the animal's specific circumstances. The responsible veterinarian will inform animal caretakers about the reasoning and any potential risks or benefits and ensure required documentation.

Veterinarians recognise that some parts of the SPCs are outdated or not harmonised. Regulation (EU) 2019/6 established in 2022 the **SPC harmonisation procedure** under the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) to align and standardise the SPC of nationally authorised VMPs that are essentially the same across EU Member States, aiming to reduce unnecessary differences in key product information (e.g., dosage, indications, warnings). By January 2026, **seven products had completed SPC harmonisation**.

In 2024, the **ADRA (Dosage Review and Adjustment of selected veterinary Antibiotics) project** was also launched to update and refine dosage recommendations for established veterinary antibiotics. By January 2026, the first antibiotic was being reviewed. While these initiatives are fully supported, **it will take many years before all SPCs will be fully updated** and they **will never be able to address all practical challenges veterinarians face** to ensure effective treatment in support of animal health and welfare as well as public health.

This means that there will be a long period during which veterinarians must sometimes continue to deviate from the SPC, placing them in the unacceptable position of requiring off-label use despite it being legally prohibited.

For this reason, some countries have now taken national initiatives such as the Spanish ministries' explanation note **clarifying the conditions under which** a clinician can adapt treatments or others who led responsible use guidelines prevail over Article 106.1.

The Need for Veterinary Flexibility

Veterinarians need to have the flexibility to prescribe off-label doses, durations and/or administration routes **when clinically justified based on the risk assessment and in the best interest of the patient and public health. This flexibility is grounded in our professional judgment, clinical experience, initial and ongoing education, to tailor the use of VMPs to meet the needs of safety, health and well-being of the animals we treat.**

The Federation of Veterinarians of Europe calls on Policymakers to

1. Work together and adopt a common approach that empowers veterinarians—as highly educated professionals—to make informed, judicious decisions for their patients and for public health, in line with the principles of responsible veterinary medicinal product use. This approach should provide veterinarians with the necessary flexibility to adapt doses, durations, and routes of administration when clinically justified and based on evidence that this is necessary to protect animal health, welfare and public health.

2. Accelerate and prioritise the harmonisation and updating of SPCs to safeguard older products without adding more administrative burdens and to move towards a pragmatic, more future-proof SPC establishment and revision protocols which reflect the complexity of an evolving evidence landscape.