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Reporting Obligations for Veterinary Medicinal Products: Implementation of Regulation (EU) 2019/6 and EOF's Recent Announcement

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I. Introduction

In the context of aligning Greek law with the European regulatory framework on veterinary medicinal products, the Hellenic National Organization for Medicines (EOF) recently issued an announcement regarding the submission of sales data for veterinary medicinal products from 2025 onwards. This development complements the implementation of Ministerial Decision No. 410185 (Government Gazette B' 7562/31.12.2024) on the wholesale and distance retail sale of veterinary medicinal products and forms part of Greece's broader compliance with Regulation (EU) 2019/6 on veterinary medicinal products (hereinafter, "Regulation").

II. The European Framework: Overview of Regulation (EU) 2019/6

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 established a comprehensive and modernised legal framework for the sale, manufacture, import, export, supply, distribution, control and use of veterinary medicinal products within the European Union.

Its overarching objectives are to:

- Update and streamline EU legislation on veterinary pharmaceuticals,
- Encourage innovation and ensure the availability of veterinary medicinal products across Member States, and
- Strengthen the EU's action against antimicrobial resistance (AMR).

The Regulation applies directly in all Member States and replaces Directive 2001/82/EC. It introduces harmonised rules for marketing authorisations, pharmacovigilance, manufacturing standards, and controls on antimicrobial use. It also establishes a common framework for collecting data on the sales and use of antimicrobial products to ensure greater transparency and evidence-based policymaking in animal health.

III. National Implementation in Greece: Ministerial Decision no. 410185/2024

In order to operationalise the Regulation within the Greek legal framework, Ministerial Decision No. 410185 (Government Gazette B' 7562/31.12.2024) established detailed rules on the wholesale and distance retail sale of veterinary medicinal products.

The Ministerial Decision regulates, inter alia:

- The conditions under which wholesalers may distribute veterinary medicinal products in Greece, including licensing, record-keeping, and traceability requirements.

- The terms for distance retail sales, aligning national practice with EU rules on e-commerce and veterinary prescription control.
- The obligation of wholesale licence holders to maintain accurate and timely data on transactions and sales volumes of veterinary medicinal products.

These provisions aim to ensure market integrity, traceability, and public and animal health protection, while contributing to the EU-wide monitoring of antimicrobial usage envisaged under the Regulation.

IV. Reminder on Sales Data Submission (October 2025)

On its official website, the EOF recently published an announcement reminding all relevant stakeholders (including marketing authorisation holders, wholesalers, and distributors) of their duty to submit annual sales data for veterinary medicinal products for the year 2025 and onwards.

According to the EOF, data must be submitted electronically through the dedicated EOF platform in accordance with the procedures and deadlines that will be communicated separately. The collected data will feed into both national monitoring and the EU's pharmacovigilance and antimicrobial resistance databases, ensuring compliance with Article 57 of the Regulation. Stakeholders are therefore advised to ensure that their internal reporting systems are capable of capturing all relevant data on veterinary medicinal product sales **as of 1 January 2025**, covering both wholesale transactions and retail operations. EOF's announcement underscores that the submission of accurate data is a regulatory obligation, and non-compliance may entail administrative sanctions under the applicable national framework.

The announcement therefore serves as a critical step in aligning Greek practice with the European data-collection framework and safeguarding the reliability of national records.

This development marks another step toward full alignment of Greek veterinary legislation with the EU framework. Stakeholders are encouraged to review their internal reporting and compliance systems early to ensure readiness ahead of the 2025 reporting cycle.

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