NOTA INFORMATIVA

The AEMPS informs about the fees associated with the modification to QRD 9.0 of veterinary medicines

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- **Regulation (UE) 2019/6 establishes a period of five years for veterinary medicines authorized according to the previous legislation, to be in accordance with the aforementioned regulation**
- **To comply with this standard, it is necessary to adapt the summaries of the characteristics, package and labeling of veterinary medicinal products (VMPs) to version 9.0 of the QRD**
- **The AEMPS informs about the fees applicable to these variation procedures**

The entry into force, on January 28, 2022, of Regulation (EU) 2019/6 on veterinary medicinal products requires the adaptation, within a period of five years ending on January 29, 2027, of all the documentation associated with veterinary medicinal products (VMP) authorized in accordance with the previous legislation.

This circumstance, among other procedures, involves updating the templates for the summary of characteristics, the package insert and the labeling. For this reason, the working group of the European Medicines Agency (EMA) *Quality Review of Documents* (QRD) has already carried out the updates corresponding to the 9.0 version.

The variation requiring assessment (VRA) for these procedures is ***G.I.18 "One-off alignment of the product information with version 9.0 (or the latest) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004"***.

This adaptation entails the payment of fee ***9.5. Fee for the modification requiring assessment for already authorized VMPs***, by virtue of the second final provision of Ley 17/2022, de la Ciencia, la Tecnología y la Innovación.

The Spanish Agency of Medicines and Medical Devices (AEMPS), taking into account the provisions of article 121.4 of Real Decreto Legislativo 1/2015, understands that an **exemption of 95%** of the amount of said fee is applicable, as long as this variation does not include another change requiring assessment, which must be requested as a separate variation.

In the event that an applicant has paid the full fee, they may claim the refund of the corresponding amount from the Accounting and Fees Service (Servicio de Contabilidad y Tasas) of the AEMPS, through the following email: sctaemps@aemps.es.

References

1. Reglamento (UE) 2019/6, del Parlamento Europeo y del Consejo, 11 de diciembre, sobre medicamentos veterinarios y por la que se deroga la Directiva 2002/82/CE
2. Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios
3. Ley 17/2022, de 5 de septiembre, por la que se modifica la Ley 14/2011, de 1 de junio, de la Ciencia, la Tecnología y la Innovación