

## The AEMPS informs on fees for Veterinary Medicinal Products regarding the entry into force of the new Regulation

Fecha de publicación: 28 de enero de 2022  
Categoría: Medicamentos veterinarios  
Referencia: MVET 02/2022

- **On January 28, 2022, Regulation (EU) 2019/6, of December 11 2018, of the European Parliament and Council, on veterinary medicinal products and repealing Directive 2001/82/EC, entry into force**
- **The Spanish Agency of Medicines and Medical Devices, as the competent authority in Spain, must provide a series of services in accordance with such Regulation which that will give rise to the accrual of the corresponding fee**
- **A modification of Royal Legislative Decree 1/2015, of July 24, is in process accordingly, in order to establish the new concepts and amounts of fees applicable to veterinary medicines**

As of January 28, 2022, Regulation (EU) 2019/6, of December 11 2018, of the European Parliament and Council, on veterinary medicinal products and repealing Directive 2001/82/EC, will be applicable. The entry into application of this regulation means that the Spanish Agency of Medicines and Medical Devices (AEMPS), must provide a series of services that will give rise to the accrual of the corresponding fee, in accordance with Royal Legislative Decree 1/2015, of July 24, which approves the consolidated text of the Law on guarantees and rational use of medicines and health products.

Currently, a modification of Royal Legislative Decree 1/2015, of July 24, is in process in order to establish the new concepts and amounts of fees applicable to veterinary medicines after the application of Regulation (EU) 2019/6, of December 11 2018.

According to the foregoing, it is reported that the situation as of January 28, and **until the entry into force of the aforementioned modification**, will be as follows:

- Those services that, in application of Regulation (EU) 2019/6, of December 11 2018, must be provided by the AEMPS and correspond to the concepts specified in the current wording of the Royal Legislative Decree 1/2015, of July 24, will accrue the payment of the corresponding fee, with the amount currently in force.
- The new services that must be provided by this Agency by virtue of Regulation (EU) 2019/6, of December 11, 2018 and do not correspond to any of the concepts included in the current text of Royal Legislative Decree 1/2015, of July 24 will not accrue a fee. These services will not be temporarily reflected in the AEMPS application enabled for the payment of fees. This is the case for example of modifications requiring assessment (VRA) and the annual maintenance in the market, among others.

However, in order not to cause unnecessary inconvenience to applicants, and in compliance with the legislation in force as of January 28, all applications for which there is still no specific fee assigned will be processed normally by the AEMPS.