NOTA INFORMATIVA

The AEMPS provides additional information on the adaptation of veterinary medicinal products to QRD v.9.0

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- **Regulation (UE) 2019/6 establishes a period of five years for veterinary medicinal products (VMPs) authorized in accordance with the former legislation to be in compliance with the aforementioned regulation**
- **It makes necessary to adapt the summary of product characteristics, the leaflet and the labelling of the VMPs to version 9.0 of the QRD**
- **The AEMPS informs applicants about some additional considerations regarding the leaflet and the labelling of VMPs subject to this variation**

Regulation (EU) 2019/6 has set a period of five years for VMPs authorized under the former legislation to comply with this regulation. Consequently, it is necessary to adapt the summary of product characteristics, package leaflet and labelling of VMPs to version 9.0 of the Quality Review of Documents (QRD).

On October 21, 2022, the AEMPS published a note on the fees applicable to the variation procedure **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".**

In order to facilitate the development and harmonization of these procedures, and taking into account the actions carried out in the centralized procedures, the AEMPS has agreed on the following:

- **Make the implementation time of the variation more flexible**

  It will be possible for nationally authorized medicines (including decentralized and mutual recognition procedures) to implement changes in the leaflet and labelling in a maximum period of 12 months if the following conditions are met:

  1. The variation G.I.18 must be single (it will not be applied for as a group together with other variations). If a grouping application is made, the implementation date will correspond to that established in the group's authorization resolution.

     Moreover, if during the 12 months period other variations involving the leaflet and labelling are authorized, the implementation dates will be those established in their resolutions, and the texts will be in accordance to the previously authorized version QRD v.9.

2. In the electronic application form (eAF) of this variation G.I.18, the applicant must declare the intent of implementing such changes in a máximum period of 12 months.

- **Avoid administrative burden**

  Applicants must ensure that the texts sent with the application, as well as those sent as responses to the AEMPS assessment, are correctly adapted to the QRD v.9 template.

References

1. Regulation (EU) 2019/6, of the European Parliament and the Council, of 11 December 2018, on veterinary medicinal products and repealing Directive 2002/82/EC.
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.