**Medicines for veterinary use: harmonisation of translations of summaries of product characteristics (SPCs), labelling and package leaflets**

**Within the context of the closure of a marketing authorisation procedure, its renewal, or variation with changes made to the SPC, package leaflet or labelling of a medicine for veterinary use, translations of the SPC, labelling and package leaflet must be submitted. In order to respond to growing demand in the pharmaceutical industry for a common labelling/package leaflet and to facilitate the harmonisation of texts, new national Belgian rules will come into effect from 11.12.2017 for medicines for veterinary use.**

Within the context of the national phase of closure of a marketing authorisation procedure, its renewal or variation (with changes made to the SPC, package leaflet or labelling) of a medicine for veterinary use, translations of the French and Dutch texts of the SPC, and texts in French, Dutch and German of the labelling and package leaflet must be submitted.

**For decentralised procedures (DCP)** and **mutual recognition procedures (MRP)**, as laid down respectively in articles 14 and 1, paragraphs 27 and 28 of the European directive 2001/82/EC and in article 6, sections 1d and 6f of the Law of 25 March 1964 on medicinal products, the translation must be accurate and correct with respect to the content of the English documents concerned which have been approved pursuant to article 32 of this directive for a MRP or DCP, in accordance with the provisions laid down in the Notice to Applicants, Volume 6A, Chapter 2.

**For national procedures**, such as those laid down respectively in article 6, sections 1d and 6f of the Law of 25 March 1964 on medicinal products, the translation must be accurate and correct with respect to the content of the French or Dutch documents concerned which have been approved under article 6, sections 1d and 6f of the Law of 25 March 1964 on medicinal products for a national procedure, in accordance with the provisions laid down in the Notice to Applicants, Volume 6A, Chapter 2.

**General harmonisation**

When submitting these documents to the authorities, the marketing authorisation holder/applicant may request harmonisation between Belgium and other countries, such as the Netherlands for Dutch texts, France and Luxembourg for French texts, and Germany, Austria and Luxembourg for German texts.

Currently, three conditions must be met to approve labelling/a package leaflet used in both Belgium and other countries:

* the product’s full name must be identical;
* its legal classification (method of delivery: prescription only medicines - POM or over-the-counter - OTC) must also be identical;
* all information on the labelling and the package leaflet must be the same, except for the blue box requirements and each country’s national requirements.

**New Belgian rules**

In order to respond to growing demand in the pharmaceutical industry for a common labelling/package leaflet and to facilitate the harmonisation of texts, new national Belgian rules will come into effect from 11 December 2017.

* The legal classification (method of delivery) will no longer have to be identical for the countries concerned by the harmonisation request. In this case, you will find only the method of delivery for Belgium in the harmonised texts approved by the Belgian authorities, but the **delivery method** for the other countries as well as Belgium **must appear on the common packaging/package leaflet in a visible and clearly identifiable manner.**
* The national information of the other countries concerned by the harmonisation will no longer be included in the harmonised texts approved by the Belgian authorities. Consequently, only the national Belgian information will be included. In this case, the marketing authorisation holder will be responsible for the compliance of the labelling/package leaflet published on the national market and of the approved harmonised translations.

It is also important to inform all countries concerned by the harmonisation of the translations **at the time of submission of the closure documents** so that the different countries can easily put in place a collaboration. In the case where the collaboration between the countries is not directly implemented, it is important to send us any comments from these countries which may be received by the marketing authorisation holder/applicant to ensure that they do not approve their texts before we can accept their comments/send our additional comments, thereby allowing for common approval of the harmonised text.

As a reminder, texts must be harmonised with the English version approved at European level (for European procedures), using the currently valid QRD template and the EDQM standard terms.

If the text harmonisation request is not submitted when submitting the closure documents, **the FAMHP will no longer accept the harmonisation request after the linguistic role’s review of the text during the closure phase**.Harmonisation will still be possible at this point, on condition that a type IA administrative national variation is submitted.