HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Dossier requirements; Labelling & package information for products to be registered under Article 5(6) of Regulation 2019/6

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14 May 2021

How to apply for registration

- An application form together with supporting documentation and fee should be submitted to the HPRA
- Electronic submission to Receipts and Validation section (submissions@hpra.ie)
- A regulatory check will be in place to ensure that all required information/documentation has been provided
- The data provided or product attributes will not be assessed

Registration requirements

Applicant details

- Name and address of the applicant
- Confirmation that the applicant is legally established in an EU Member State, and presuming so, the name and address of the EU address for the applicant (if different from above).
- Contact details for correspondence with the HPRA (name, email address).
- Location and contact details for the Qualified Person for Pharmacovigilance.

Registration requirements (2)

Product details

- Qualitative and quantitative composition of the product
- Pharmaceutical form
- Pack size(s) being offered for sale
- Route of administration
- Target species and indication(s) for use
- Dosage
- Any warnings or precautions considered necessary to ensure correct and safe use of the product

Registration requirements (3)

- Pharmacovigilance requirements
- GMP certificate for the manufacturing site
- Manufacturing/importation requirements
- Declaration that a batch recall procedure is in operation
- Declaration that information on any significant quality defects associated with batches of the product supplied in Ireland will be reported to the HPRA (Market Compliance). See the following link for information.
- Product specification
- Text of the product labelling and package leaflet

Product specification

The product specification shall consist of:

1. Assay for active substance(s) with a limit of +/- 5.0 % using an analytical method validated in-line with VICH GL 2: Validation of analytical procedures: methodology
2. Those parameters included on the relevant Ph. Eur. dosage form monograph

The specification for an oral solution shall contain:

- active content +/- 5 %
- the relevant uniformity of dose test (there are 5 listed in the Ph. Eur. depending on the type of product)

The specification for a tablet shall contain:

- active content +/- 5 %
- the relevant uniformity of dose test (there are 3 listed in the Ph. Eur. depending on the type of product)

Labelling and product information requirements

Requirements vary depending on immediate/outer packaging or package leaflet:

- Name of the veterinary medicinal product
- Name and strength of the active substance(s)
- Target species
- Indications
- Contraindications
- Dosage for each species, route and method of administration
- Any necessary warnings/precautions for the safe use
- Disposal of unused product or waste materials, if any

Labelling and product information requirements (2)

- Expiry date
- General storage precautions
- Shelf life after immediate packaging has been opened
- Pack sizes
- The words “For animal treatment only”
- The words “Keep out of sight and reach of children”
- “Read the package leaflet before use”
- Name of the registration holder
- Registration number
- Batch number

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Thank you

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