HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

FAQs on
Processing the Labelling and Package Leaflet for Veterinary Medicinal Products

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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INTRODUCTION

This document answers frequently asked questions on how the Veterinary Sciences Department of the Health Products Regulatory Authority (HPRA) handles and processes the package labelling (immediate and outer) and package leaflet for new marketing authorisation (MA) applications and variation applications to currently authorised MAs. It applies to the national phase of all procedure types including mutual recognition procedures (MRP), decentralised procedures (DCP) and subsequent recognition procedures (SRP) as well as variations. The processing of labelling for centralised procedures is outside the scope of this document as they are exclusively managed by the European Medicines Agency. This document answers questions in relation to the approved package labelling and package leaflet and the responsibilities of the marketing authorisation holder (MAH).

Q1: WHAT ARE THE REGISTERED LABELLING AND PACKAGE LEAFLET?

The registered labelling and package leaflet are the text versions of the labelling and package leaflet that have been approved by the HPRA during a regulatory procedure.

For products assessed through MRP/DCP or SRP, the registered labelling and package leaflet is the EU harmonised text versions (common English texts) agreed at the end of the EU assessment procedure.

For products that have been submitted only in Ireland, there is only a national text and this is the registered labelling and package leaflet.

Q2: WHAT LABELLING AND PACKAGE LEAFLET INFORMATION DOES THE HPRA NEED TO SEE FOR NEW APPLICATIONS AND BEFORE FIRST MARKETING?

The new marketing authorisation application procedure will be closed based on the agreed labelling and package leaflet text at the end of procedure. The HPRA does not routinely require the review and approval of mock-ups before first marketing of the product in Ireland for new applications. All new marketing authorisation procedures will be closed based on the agreed labelling and package leaflet text at the end of the procedure.

Nevertheless, the HPRA reserves the right to request submission of mock-ups where it is deemed necessary.

Q3: WHAT LABELLING AND PACKAGE LEAFLET INFORMATION DOES THE HPRA NEED TO SEE FOR VARIATIONS?

Where a variation results in changes to the labelling or package leaflet, revised national or EU harmonised text versions of the labelling and package leaflet must be submitted as part of the submission data package.

Mock-ups of the labelling and package leaflet are not routinely required. Nevertheless, the HPRA reserves the right to request submission of mock-ups where it is deemed necessary.

This also applies to G.I.15.z variations submitted when a change is made to the text registered for the labelling and package leaflet that is unrelated to the Summary of Product Characteristics (SPC), and G.I.18 variations submitted as a one-off alignments of the product information with version 9.0 of the quality review documents (QRD) templates.

The MAH should ensure that the changes to the labelling do not negatively impact on legibility and that the mock-ups are in compliance with the HPRA 'Guide to Preparation of Mock-ups for Veterinary Medicinal Products' available on the HPRA website.

Q4: WHEN DOES THE HPRA WANT TO SEE MOCK-UPS OF THE LABELLING AND PACKAGE LEAFLET THAT WILL APPEAR IN THE MARKET?

The HPRA does not routinely review and approve mock-ups. Review of mock-ups is conducted within a risk-based mock-up surveillance programme operated by the HPRA. The surveillance programme is operated by authorised officers who collect samples from any point in the Irish supply chain. Samples are examined for compliance with their registered product information, readability and determining if they can be used as per instructions in the package leaflet.

Mock-ups may also be requested in the event of non-compliance issues such as quality defects and recalls.

Q5: DOES THE HPRA NEED TO HAVE ON FILE A MOCK-UP OF THE VERSION OF THE LABELLING AND PACKAGE LEAFLET CURRENTLY ON THE MARKET?

The HPRA does not require to have on file the mock-up of the version of the labelling and package leaflet currently on the market.

Q6: ARE THE REQUIREMENTS FOR MOCK-UPS DIFFERENT IF MY PRODUCT IS JOINT-LABELLED AS IE/UK LABELS?

No, the requirements are the same for joint-labelled products. For products eligible for a joint-label, mock-ups are not required by the HPRA. However, mock-ups should continue to be submitted to the VMD according to the VMD policy for mock-up submission. See the HPRA 'Guide to Joint-Labelling for Veterinary Medicinal Products for use in Ireland and the UK' available on the HPRA website

Q7: CAN AN MAH REQUEST REVIEW AND APPROVAL OF MOCK-UPS?

Yes. A MAH may, on a voluntary basis, submit a G.I.15z VRA, for review and approval of mock-ups if they wish the HPRA to conduct an assessment of their mock-ups for a product.

Q8: WHAT ARE THE HPRA RESPONSIBILITIES IN RELATION TO THE LABELLING AND PACKAGE LEAFLET?

The HPRA:

1. Approves the national or the EU harmonised text versions of the labelling and package leaflet during the relevant procedure.
2. As part of a risk-based surveillance programme, the HPRA undertakes review of labelling and package leaflets from the marketplace to ensure compliance with agreed texts.

Q9: WHAT ARE THE MAH RESPONSIBILITIES IN RELATION TO THE LABELLING AND PACKAGE LEAFLET?

The MAH ensures that:

1. The national texts of the labelling and package leaflet that have been approved by the HPRA are implemented correctly for product in the marketplace.
2. The font size used is appropriate and that all elements of the mock-ups are legible.
3. The mock-ups are in compliance with the HPRA 'Guide to Preparation of Mock-ups for Veterinary Medicinal Products' available on the HPRA website.