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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CONTENTS

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 and includes 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 FAQ document as they are exclusively managed by the EMA. The document answers questions in relation to when text versions or actual mock-ups of the package labelling and package leaflet are required.

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 (sometimes referred to as the '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 BY THE END OF PROCEDURE?

If the product is to be marketed immediately, the mock-ups of the labelling and package leaflet must be provided (to review the readability and design) before close of the procedure.

If the product is not to be marketed immediately, mock-ups of the labelling and package leaflet are not required at this stage and the procedure will be closed based on the agreed labelling and package leaflet text. See question 4 below regarding when mock-ups will be required in these cases.

The above requirements for new applications will also apply to applications that are submitted as a variation application but result in a new stand-alone marketing authorisation (e.g. I.II.1I, I.II.1(d), I.III.1(a)).

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 unless the design or readability is significantly affected. Nevertheless, the HPRA reserves the right to request submission of mock-ups during a variation procedure, where it is deemed necessary (see question 10 below).

Q4: ARE MOCK-UPS OF THE LABELLING AND PACKAGE LEAFLET REQUIRED TO BE SUBMITTED TO THE HPRA BEFORE MARKETING?

Before marketing, and if not previously reviewed and approved by the HPRA, the marketing authorisation holder (MAH) is required to submit the proposed mock-ups of the labelling and package leaflet. Only the mock-ups representing worst case in terms of readability for each label/outer package (usually the smallest pack size) and the package leaflet need be submitted. The mock-ups should be submitted as a G.I.15 variation (changes to the labelling or the package leaflet which are not connected with the summary of product characteristics).

Q5: DOES THE HPRA NEED TO SEE MOCK-UPS OF THE LABELLING AND PACKAGE LEAFLET FOR A G.I.15 VARIATION?

A G.I.15 variation is submitted when a change is made to the text registered for the labelling and package leaflet that is unrelated to the SPC. If there is no associated significant change to the design or layout of the labelling and leaflet, then mock-ups are not required to be submitted.

Q6: DOES THE HPRA NEED TO SEE MOCK-UPS FOR A G.I.18 VARIATION?

A G.I.18 variation is a one-off alignment of the product information with version 9.0 of the QRD templates, i.e. 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.

Given that:

- this variation is intended to be administrative in nature and no new/additional information will be included in the revision of the labelling and package leaflet text,

- there is a reduction in the text required to be included on the immediate and outer labelling and legibility should not therefore be negatively impacted,

mock-ups of the labelling and package leaflet are not required to be submitted for review with this variation. 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 Guide to Product Literature Standard (PLS) for Veterinary Medicinal Products available on the HPRA website.

Q7: WHEN DOES THE HPRA WANT TO SEE MOCK-UPS OF THE LABELLING AND PACKAGE LEAFLET THAT WILL APPEAR IN THE MARKET?

To confirm that there are no readability issues with labelling and package leaflet, the HPRA needs to review labelling and package leaflet mock-ups before initially marketing the product, either at the time of the initial marketing authorisation approval or prior to marketing via a G.I.15 variation.

Q8: 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 will have been provided with (through the appropriate submission as indicated in question 7 above) mock-ups reflecting the current (on the market) labelling and package leaflet designs and layouts. The HPRA does not require the submission of revised mock-ups during a procedure where only text changes have been implemented in the labelling or package leaflet (as the HPRA will always have the current registered national/EU harmonised text on file).

Q9: ARE THE REQUIREMENTS FOR MOCK-UPS DIFFERENT IF MY PRODUCT IS JOINT-LABELLED AS IE/UK LABELS?

No, the requirements at time of authorisation and for variations are the same for joint-labelled products. If a variation results in changes to the labelling and/or package leaflet texts and a review of mock-ups is required by the UK's Veterinary Medicines Directorate (VMD), mock-ups are not required to be submitted to the HPRA unless the layout and design is impacted by the change.

For new product applications, if the product is to be marketed immediately, the mock-ups of the labelling and package leaflet (to review the readability and design) must be provided and the joint-labelling procedure will be conducted during the national phase of the new product assessment.

For new product applications, if the product is not to be marketed immediately, the approved text versions of the labelling and package leaflet, or the EU harmonised text versions must be submitted. Mock-ups of the labelling and package leaflet can be submitted at this time for review of the readability and design, but they are not required at this stage and may instead be submitted before marketing the product in Ireland. If submitted, the joint-labelling procedure will be conducted during the national phase of the new product assessment. If not submitted in the national phase of the new product application, the MAH should submit a G.I.15 variation to facilitate the joint-labelling procedure prior to marketing the product.

For variations that do not significantly impact on the layout or design of the labelling and package leaflet, no mock-ups are required to accompany the submission and the submission of national or EU harmonised text versions is sufficient.
This applies irrespective of whether or not the mock-ups are required by the UK's VMD.

Q10: WILL THE HPRA EXERCISE DISCRETION ON THE REQUIREMENTS FOR MOCK-UPS?

Assessors can always decide on a case-by-case basis during a variation if they consider that the overall design or readability could be affected and that mock-ups should be submitted. If this is the case, the variation will be completed on the basis of the national or EU harmonised text versions, the HPRA case will be closed and an additional case, a G.I.15 variation, will be opened to review the mock-ups. No fee will be charged for this additional case and review of the mock ups.

Q11: 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. Reviews the labelling and package leaflet mock-ups for readability and design considerations prior to first marketing of a product (either in the context of an application for a new marketing authorisation or, subsequently, in the context of a G.I.15 variation), or prior to completion of a variation application when the overall design or layout is affected.

In addition to the review of the labelling and package leaflet text/mock-ups during regulatory procedures as detailed above, the HPRA will, as part of their routine sample and analysis programme, undertake compliance checks of product labelling from the marketplace to ensure compliance with agreed texts.

Q12: WHAT ARE THE MAH RESPONSIBILITIES IN RELATION TO THE LABELLING AND PACKAGE LEAFLET?

The MAH:

1. Ensures that 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. Provides mock-ups of the labelling and package leaflet to support a new application for a product to be marketed or subsequently by way of a G.I.15 variation when the mock-ups have not been provided at time of initial authorisation.