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~~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~~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 ~~FAQ~~ document as they are exclusively managed by the ~~EMA. The~~European Medicines Agency. This document answers questions in relation to ~~when text versions or actual mock-ups of the~~ the approved package labelling and package leaflet ~~are required.~~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 (~~sometimes referred to as the '~~common English ~~texts'~~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. ~~However,~~The HPRA does not routinely require the ~~marketing authorisation holder (MAH) is required to submit the proposed mock-ups of the labelling and package leaflet for~~ 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.

~~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) immediately after the close of a new marketing authorisation procedure by way of a G.I.15z variation.~~

~~If the product is not to be marketed immediately, mock-ups of the labelling and package leaflet may be submitted for review by way of a G.I.15z variation at any time before first marketing. See also question 4.~~

~~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)).~~

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 ~~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 MAH is required to submit the proposed mock-ups of the labelling and package leaflet via a G.I.15z variation for review. 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.~~

~~Q5: APART FROM WHEN SUBMITTED FOR THE SPECIFIC PURPOSE OF MOCK-UP APPROVAL (SEE Q2 AND Q4 ABOVE), DOES THE HPRA NEED TO SEE MOCK-UPS OF THE LABELLING AND PACKAGE LEAFLET FOR A G.I.15z VARIATION?~~

~~A G.I.15z variation is~~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). 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~~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.

~~**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 quality review of documents (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~~HPRA 'Guide to Preparation of Mock-ups for Veterinary Medicinal Products' available on the HPRA website.

~~Q7~~Q4: 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. This review is made either immediately after the initial marketing authorisation approval or prior to marketing (at a later stage) and both via a G.I.15z variation.~~

~~Q8~~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 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~~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 ~~at time of authorisation and for variations~~ are the same for joint-labelled products. ~~If~~ For products eligible for 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),~~joint-label, mock-ups are not required by the HPRA. However, mock-ups should continue to be submitted to the ~~HPRA unless the layout and design is impacted by~~ 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 ~~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 immediately after the procedure closes by way of a G.I.15z variation and the joint-labelling procedure will commence. For further information please refer to the Guide to Joint labelling for Veterinary Medicinal Products for use in Ireland and the UK~~UK' available on the HPRA website~~.~~

~~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, by way of a G.I.15z variation, 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 assessment of the G.I.15z variation.~~

~~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.15z variation, will be opened to review the mock-ups.~~

~~Q11~~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. ~~1.~~ Approves the national or the EU harmonised text versions of the labelling and package leaflet during the relevant procedure.

2. ~~Reviews the~~As part of a risk-based surveillance programme, the HPRA undertakes review of labelling and package ~~leaflet mock-ups for readability and design considerations, via a G.I.15z variation, prior to first marketing of a product or after completion of a variation application when the overall design or layout is affected.~~

2. ~~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~~leaflets from the marketplace to ensure compliance with agreed texts.

~~Q12~~Q9: WHAT ARE THE MAH RESPONSIBILITIES IN RELATION TO THE LABELLING AND PACKAGE LEAFLET?

The MAH~~:~~

~~1. Ensures~~ ensures that ~~the~~:

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. ~~Provides mock-ups of the labelling and package leaflet for review and approval following a new marketing authorisation application and prior to first marketing of a product in Ireland or following a variation application when the variation impacts on overall design or readability. Mock-up review is always handled by way of a G.I.15z variation.~~

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.