



Revised HPRA policy on requirement for mock-ups

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HPRA Information Day on Implementation of Regulation 2019/6 in Ireland



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What has changed?



When the HPRA want to see mock-ups

Submission of Mock-Ups for Variations to Veterinary Products

2 MOCK-UP REQUIREMENTS

CATEGORY	DESCRIPTION	FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED UNLESS OTHERWISE ADVISED?
A.1	Change in the name and/or address of the marketing authorisation holder	No
A.2(a)	Change in the (invented) name of the medicinal product	No
A.2(b)	Change in the (invented) name of the medicinal product	No
A.3	Change in name of the active substance or of an excipient	No
A.5(a)	Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites): The activities for which the manufacturer/importer is responsible include batch release	No
A.6	Change in ATC Vet Code	No
A.7	Deletion of a manufacturing sites (for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)	No
B.II.a.1(a)	Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking	No
B.II.a.1(b)	Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking	No
B.II.a.2(a)	Change in the shape or dimensions of the pharmaceutical form	No
B.II.a.2(b)	Change in the shape or dimensions of the pharmaceutical form	No
B.II.a.3(a).1	Changes in the composition (excipients) of the finished product	No

CATEGORY	DESCRIPTION	FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED UNLESS OTHERWISE ADVISED?
B.II.a.3(a).2	Changes in the composition (excipients) of the finished product	No
B.II.a.3(a).3	Changes in the composition (excipients) of the finished product	No
B.II.a.3(b).1	Changes in the composition (excipients) of the finished product	No
B.II.a.3(b).2	Changes in the composition (excipients) of the finished product	No
B.II.a.3(b).3	Changes in the composition (excipients) of the finished product	No
B.II.a.3(b).4	Changes in the composition (excipients) of the finished product	No
B.II.a.3(b).5	Changes in the composition (excipients) of the finished product	No
B.II.a.3(b).6	Changes in the composition (excipients) of the finished product	No
B.II.a.5	Change in concentration of a single-dose, total use parenteral product, where the amount of active substance per unit dose (i.e. the strength) remains the same	Yes
B.II.a.6	Deletion of the solvent/diluent container from the pack	Yes
B.II.b.2(b)	Change to importer, batch release arrangements and quality control testing of the finished product	No
B.II.b.2(c).1	Change to importer, batch release arrangements and quality control testing of the finished product	No
B.II.b.2(c).2	Change to importer, batch release arrangements and quality control testing of the finished product	No
B.II.b.2(c).3	Change to importer, batch release arrangements and quality control testing of the finished product	No
B.II.e.4(b)	Change in shape or dimensions of the container or closure (immediate packaging)	No

[illegible]

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What has changed?

- Routine requirement to submit mock-ups during the national phase of variations*
- When changes are required to mock-ups it is the MAH's responsibility that these changes and only these changes are implemented

*The HPRA still reserves the right to request submission of mock-ups following a variation, where it deemed necessary

When is submission of mock-ups required?



When is submission of mock-ups required?

1. Prior to marketing a product for the first time: National phase of a new procedure/ G.I.15 variation
2. When making changes to layout, design or readability: G.I.15 variation
3. During G.I.18 variations to align product information with version 9.0 of the QRD template, if already marketed in IE

Is joint labelling with the UK still feasible?



Is joint labelling with the UK still feasible?

Yes

- However the product information must be aligned
- Where product information texts have been agreed in IE by way of an EU procedure, no changes will be permissible to the agreed EU texts



What if the UK want to see mock-ups and IE do not?


In this case:

- Submit mock-ups to the UK only
- The UK will assess the change related to the variation only
- If changes other than those within the scope of the variation are required, IE will require a G.I.15 variation to review these changes




Where can I find more information?

- Visit our website under
Veterinary > Regulatory
Information > Medicinal
Authorisation
> Labelling Procedure
- Email your queries to
Vetinfo@hpra.ie



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Labelling procedure

FAQs on processing the labelling and package leaflet for veterinary medicinal products

A [FAQ document](#) published by the HPRA answers questions about how the Veterinary Sciences Department will handle and process 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 are outside the scope of the 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.

Product literature standard

The [HPRA Guide to Product Literature Standard \(PLS\) for Veterinary Medicinal Products](#) is a guide for applicants to assist in the creation of mock-ups for regulatory approval.

Mock-ups submitted for regulatory approval should not deviate from the agreed QRD text. The Product Literature Standard includes a list of general labelling requirements, giving guidance on the layout and design of mock-ups and an additional list of national HPRA information to be considered for inclusion.

For joint labels, applicants are also advised to consult the [Product Literature Standard](#) as published by the Veterinary Medicines Directorate (VMD), which may include relevant national-specific requirements of the VMD.

Joint labelling

The joint labelling procedure involves the coordination of approval of final colour mock-ups for veterinary medicines between Ireland and the UK. The procedure enables marketing authorisation holders to create one set of mock-ups for both countries and can be achieved between IE and UK (NI), IE and GB or all three – IE, UK (NI) and GB.

An application for joint labelling can be made either at the end of a new Marketing Authorisation (MA) procedure or retrospectively for existing MAs, whether authorised by EU or national procedures. To obtain joint labelling, the Summary of Product Characteristics (SPC) and product labelling texts must be identical in the relevant territories. To maintain joint labelling, the product information must remain harmonised.

Further information about the use of the procedure is available in the [HPRA Guide to Joint labelling for veterinary medicinal products for use in Ireland and the UK](#) and in the VMD's [Joint labelling for veterinary medicines for use in the UK and Ireland](#).



Thank you
