HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Submission of Mock-Ups for Variations to Veterinary Products

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1 SCOPE

Submission of full colour mock-ups is no longer routinely required for all variations which result in changes to the product labelling.

The purpose of this document is to provide guidance on the routine requirements for mock-up submission for individual variation categories. Please note however that submission of mock-ups may be requested by the HPRA for any variation category on a case-by-case basis.

The requirements for the different types and categories of variations are listed below. While most variation categories that potentially result in changes to the mock-ups are listed, it is not an exhaustive list and should changes to mock-ups occur in a variation category not listed in this guide, the applicant should seek clarification from the HPRA regarding the requirements for mock-up submission.

For variations classified as 'z' variations, because of the variety of possible scenarios, it is not possible to state definitively if mock-ups will be required. The requirements for other foreseen variations in the same category will provide an indication as to whether or not mock-ups may be required. Where mock-ups are required for 'z' variations, they will be requested by the HPRA.

2 MOCK-UP REQUIREMENTS

CATEGORY	DESCRIPTION	FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED?
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	Yes
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?
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)	Yes

CATEGORY	DESCRIPTION	FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED?
B.II.e.5(a).1	Change in pack size of the finished product	Yes
B.II.e.5(a).2	Change in pack size of the finished product	Yes
B.II.e.5(b)	Change in pack size of the finished product	No
B.II.e.5(c)	Change in pack size of the finished product	Yes
B.II.e.5(d)	Change in pack size of the finished product	Yes
B.II.e.6(a)	Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used))	No
B.II.f.1(a).2	Change in the shelf-life or storage conditions of the finished product	No
B.II.f.1(a).3	Change in the shelf-life or storage conditions of the finished product	No
B.II.f.1(b).2	Change in the shelf-life or storage conditions of the finished product	No
B.II.f.1(b).3	Change in the shelf-life or storage conditions of the finished product	No
B.II.f.1(c)	Change in the shelf-life or storage conditions of the finished product	No
B.II.f.1(d)	Change in the shelf-life or storage conditions of the finished product	No
B.IV.1(a).1	Change of a measuring or administration device	Yes
B.IV.1(a).2	Change of a measuring or administration device	Yes

CATEGORY	DESCRIPTION	FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED?
B.IV.1(a).3	Change of a measuring or administration device	Yes
B.IV.1(b)	Change of a measuring or administration device	Yes
B.IV.1(c)	Change of a measuring or administration device	Yes
B.V.b.1(a)	Update of the quality dossier intended to implement the outcome of a Union referral procedure	Yes
B.V.b.1(b)	Update of the quality dossier intended to implement the outcome of a Union referral procedure	Yes
C.I.1(a)	Change in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure	Yes
C.I.1(b)	Change in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure	Yes
C.I.1(c)	Change in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure	Yes
C.I.2(a)	Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product.	Yes
C.I.2(b)	Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product.	Yes
C.I.4	Change(s) in the SPC, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data	Yes
C.I.6(a)	Change(s) to therapeutic indication(s)	Yes
C.I.6(b)	Change(s) to therapeutic indication(s)	Yes

CATEGORY	DESCRIPTION	FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED?
C.I.13	Other variations not specifically covered elsewhere in this Annex, which involve the submission of studies to the competent authority	Yes
C.II.1	Variations concerning a change to or addition of a non-food producing target species	Yes
C.II.2(a)	Deletion of a food producing or non-food producing target species.	Yes
C.II.2(b)	Deletion of a food producing or non-food producing target species.	No
C.II.3	Changes to the withdrawal period for a veterinary medicinal product	Yes
C.II.4	Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue	Yes
C.II.5	Variations concerning the replacement of a strain for a veterinary vaccine against equine influenza	Yes
C.II.6(a)	Changes to the labelling, or the package leaflet, which are not connected with the SPC	No
C.II.6(b)	Changes to the labelling, or the package leaflet, which are not connected with the SPC	Yes