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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Revised HPRA policy on requirement for mock-ups

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

Content

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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

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	(invented) name of the medicinal prod	
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	e of the active substance or of an excipient	
	me and/or address of a orter of the finished product (including batch ontrol testing sites): The activities for which porter is responsible include batch release	No
		No
A	sites (for an active substance, ct, packaging site, manufacturer where batch control takes l, reagent or excipient	No
B.II.a.1(a)	er markings oduct	No
B.II.a.1(b)		
B.II.a.2(a)	Change in t	
B.II.a.2(b)	Change in the shape	
B.II.a.3(a).1	Changes in the composition (excipi	

CATEGORY	DESCRIPTION		FULL COLOUR MOCK-UPS TO BE ROUTINELY SUBMITTED UNLESS OTHERWISE ADVISED?
B.II.a.3(a).2	Changes in the com	duct	No
B.II.a.3(a).3	Changes in the compo	uct	No
B.II.a.3(b).1	Changes in the compos	ct	No
B.II.a.3(b).2	Changes in the compos	ct	No
(b).3	Changes in the compo	uct	No
	Changes in the com	duct	No
	n the	roduct	No
		product	No
		parenteral r unit dose	Yes
		n the pack	Yes
		gements and quality ct	No
		se arrangements and quality product	No
		tch release arrangements and quality he finished product	No
		importer, batch release arrangements and quality ol testing of the finished product	No
.4(b)	Change in shape or dimensions of the container or closure (immediate packaging)		No

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

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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

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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

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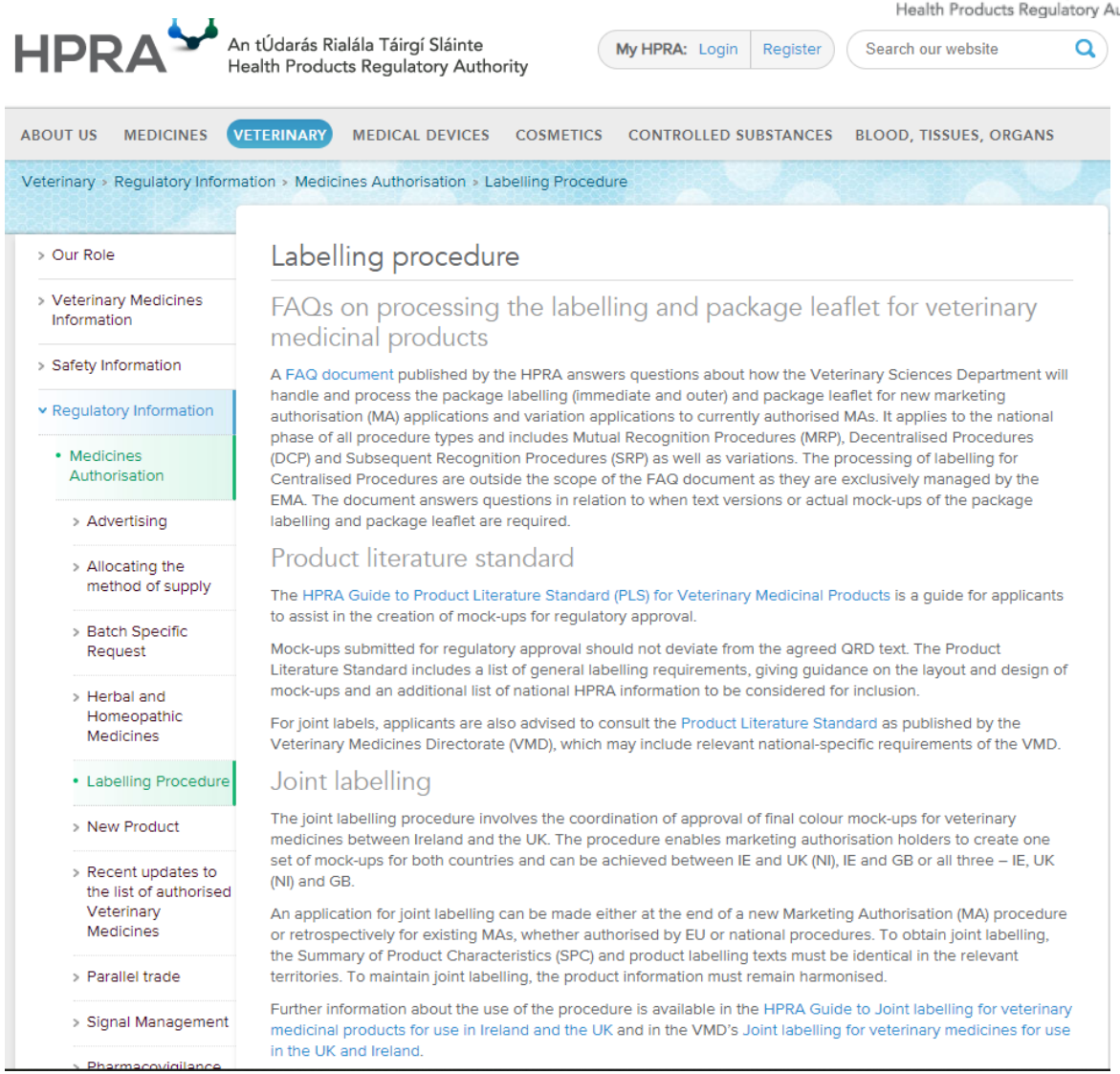
Where can I find more information?

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



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Thank you