Veterinary Medicines Directorate

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Joint HPRA/VMD Guide to
Acceptable Texts for Joint Labelling for Veterinary Medicinal Products for use in Ireland and the UK

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1 INTRODUCTION

The Health Products Regulatory Authority (HPRA) and the Veterinary Medicines Directorate (VMD) have successfully operated a bilateral joint labelling procedure for in excess of 20 years. This has been challenged in recent years with the United Kingdom's (UK's) withdrawal from the European Union (EU) and the subsequent implementation of Regulation (EU) 2019/6 which has resulted in significant changes to requirements in terms of the labelling and package leaflets for veterinary medicinal products authorised in the EU. The Veterinary Medicines Regulation (2013), which applies in Great Britain (GB), requires the inclusion of additional text on the labelling and package leaflet of veterinary medicinal products to be marketed in GB. Whilst the UK legislation is undergoing a review process, and ahead of the publication of this anticipated revised legislation, an interim position has been agreed by the HPRA and VMD with respect to the current divergent labelling requirements. This position has been agreed, following communication with our respective stakeholders, in the interest of ensuring the continued availability of veterinary medicinal products on both the Irish and UK markets.

The information in this guide has been drafted by both the HPRA and VMD and it aims to clarify the acceptable text for joint-labelled mock-ups where the agreed labelling and package leaflet texts have been approved in IE in line with Regulation (EU) 2019/6 requirements, that is, texts align with version 9 of the annotated QRD templates and where a shared label/package leaflet with GB is sought. Mock-ups should include both the agreed QRD text, as well as the additional labelling and package leaflet texts specific to GB that are specified below. According to Article 13 of Regulation 2019/6, additional information may be allowed on the immediate or outer package, where the information is compatible with the SPC.

The document includes two appendices with a tabulated list of additional GB information for inclusion on the mock-ups along with a list of those elements of the labelling and package leaflet to be identified as "IE only" or "UK only" (or "UK (NI) only" or "GB only" if only one territory is affected), that is, national-specific information.

This document should be read alongside the HPRA 'FAQs on Processing the Labelling and Package Leaflet for Veterinary Medicinal Products', 'Guide to Joint labelling for Veterinary Medicinal Products for use in Ireland and the UK' and 'Guide to Product Literature Standard (PLS) for Veterinary Medicinal Products' as well as the VMD's guidance on joint-labelling for veterinary medicines for use in the UK and Ireland and Product Literature Standard.

2 JOINT LABELLING WHERE QRD TEXTS ARE APPROVED IN LINE WITH REGULATION (EU) 2019/6

For new MA applications submitted in parallel to IE (via NAP/MRP/DCP/SRP), UK (NI) (via NAP/MRP/DCP) and GB (via NAP), pursuant to HPRA guidance referenced above, mock-ups should be provided simultaneously to the HPRA and VMD and should include the agreed end of procedure QRD texts along with all GB additional information and national-specific

information as listed in the appendices below. Thereafter, the assessment timelines applied will be as listed in the respective joint labelling guidance documents.

For existing MAs (with approved version 9 QRD texts), which have never been subject to the joint-labelling procedure, but where a joint-label is now desired, MAHs should simultaneously submit a G.I.15.z VRA to the HPRA and the VMD to facilitate the joint labelling procedure. The mock-ups provided as part of the variation submission, should include the agreed end of procedure QRD texts along with all GB additional information and national-specific information as listed in the appendices below. Thereafter, the assessment timelines applied will be as listed in the respective joint labelling guidance documents.

At the end of a G.I.18 VRA for QRD alignment, and for those products already joint-labelled, the HPRA do GB not routinely request mock-ups for review. Instead, the MAH should implement changes to the mock-ups in accordance with the changes agreed during the G.I.18 VRA and in accordance with the GB additional information and national-specific information as listed in the appendices below. This also applies to products where the G.I.18 VRA has already concluded and where the applicant now wishes to re-introduce the GB additional information. Conversely, the VMD continue to require submission of mock-ups for national assessment at the end of a G.I.18 VRA.

The HPRA reminds MAHs that in addition to the review of 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, being the approved QRD texts and only the additional GB information as identified in the appendices below.

3 IMPLEMENTATION OF APPROVED MOCK-UPS

MAHs have up to 12-months from the date of approval to implement labelling changes, of existing MAs in accordance with the outcome of a G.I.18 VRA. This extension is only applicable to changes agreed under a G.I.18 VRA. This extension does not apply in instances where the G.I.18 VRA is grouped with additional changes to the product literature.

4 IMPLEMENTATION OF APPROVED MOCK-UPS

All queries should be sent to vetinfo@hpra.ie or postmaster@vmd.gov.uk.

APPENDIX I: THE FOLLOWING TABLE LISTS GB INFORMATION ADDITIONAL TO QRD VERSION 9 THAT MAY BE INCLUDED ON JOINT-LABELLED MOCK-UPS (WHERE RELEVANT):

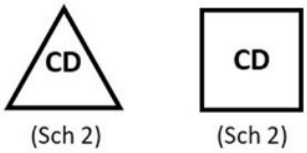
PARTICULARS TO APPEAR ON THE LABELLING AND PACKAGE LEAFLET	***Information required:*** ***[text]: Guidance and explanatory notes.*** ***{text}: Information to be filled in.*** ***<text>: Text to be selected or deleted as appropriate.***	Outer Package	Immediate Package	Small immediate packaging units	Blisters	Package Leaflet
Qualitative and Quantitative composition	*[Qualitative and quantitative composition of the excipients and other constituents (e.g., adjuvants), knowledge of which is essential for proper administration of the veterinary medicinal product i.e., those listed quantitatively in section 2 of the SPC should be stated here.]*	x	x			
	Qualitative expression of the active substance(s)			x	x	
Special storage precautions	Keep the {container}**** in the outer carton *[This is a national requirement and ensures all packaging elements are kept together.]*		x			
Special warnings, if necessary	*[Indicate any particulars essential for safety or health protection, including any special precautions relating to use and any other warnings.]* *[For certain veterinary medicinal products e.g., injectables containing mineral oil, the following statement should be included:]* <Accidental administration> <Contact with the mucosa> is dangerous. >	x	x			
Specific precautions for the disposal of unused products or waste materials	Disposal: Read package leaflet.	x	x			
	Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment. IE: Medicines should not be disposed of via wastewater or household waste. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with					x

	local requirements and with any applicable national collection systems. UK: Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.					
Route(s) of administration	*[According to "Standard terms".]*			x		
The words "For animal treatment only".	For animal treatment only.		x	x	x	x
Anthelmintics – chemical group symbols		x	x			x
*QR codes		x	x			x

*Inclusion of QR codes are permissible in both IE and GB.

APPENDIX II: THE FOLLOWING TABLE LISTS INFORMATION TO BE INCLUDED ON THE LABELLING AND PACKAGE LEAFLET WHICH MUST BE IDENTIFIED UNDER AN "IE ONLY" OR "UK ONLY" HEADING.

PARTICULARS TO APPEAR ON THE LABELLING AND PACKAGE LEAFLET	***Information required:*** ***[text]: Guidance and explanatory notes.*** ***{text}: Information to be filled in.*** ***<text>: Text to be selected or deleted as appropriate.***	Outer Package	Immediate Package	Small immediate packaging units	Blisters	Package Leaflet
Name of the Marketing authorisation holder	{Name or company name or logo name of the marketing authorisation holder}	IE& UK	IE& UK			IE& UK
Address of the Marketing Authorisation Holder	Address *[Including town, postal code (if available)]* Country}*[Country name in the language of the text.]* <{Tel}> <{Fax}> <{E-mail}> *[no website addresses or e-mails linking to websites are allowed.]*					IE& UK
Marketing Authorisation Number		IE& UK				IE& UK
Distribution category	UK POM-VPS ('Veterinary medicinal product subject to prescription') POM-V ('Veterinary medicinal product subject to prescription') AVM-GSL NFA-VPS	UK	UK	UK (recom-mended)		UK

	IE POM (prescription only) POM(E) (prescription only exempt) CAM (companion animal medicine) LM (licensed retailer)					IE
Contact details	Contact details for marketing authorisation holder/local representatives/manufacturer responsible for batch release/ contact details to report suspected adverse reactions.					IE& UK
A reference to product database where additional product information is located	Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).					IE
	Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk *[This information is only mandatory for the UK where reference to the UPD is also included on joint labels.]*					UK
Controlled Drugs		UK	UK			UK