HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Product Literature Standard (PLS) for Veterinary Medicinal Products

AUT-G0163-~~34~~ 2
~~**14 NOVEMBER 2022**~~
2 MAY 2024
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 INTRODUCTION

The information in this guide aims to assist applicants with the creation of mock-ups.

Mock-ups should not deviate from the agreed QRD text.[1]. Mock-ups should always be submitted for approval via a G.I.15z variation either immediately after the close of a new marketing authorisation procedure (where the product is to be marketed immediately) or a later stage (before marketing). Mock-ups are not routinely required in support of variation applications which result in changes to the product information, and this applies to G.I.18 variations to align the product information with version 9.0 of the QRD templates.

This document includes a list of general labelling requirements, which will assist applicants with the layout and design of their mock-ups and an additional list of national Health Products Regulatory Authority (HPRA) information to be considered for inclusion. This document should be read alongside the HPRA ~~'FAQs on Processing the Labelling and Package Leaflet for Veterinary Medicinal Products''~~FAQs on Processing the Labelling and Package Leaflet for Veterinary Medicinal Products'.

Applicants are advised that the HPRA does not assess shipping packs, datasheets (including Material Safety Data Sheets (MSDSs)), packaging for wholesalers that do not include any labels, display packaging or promotional material.

2 MULTI-COUNTRY PACKS

Multi-country packs are medicinal products that are labelled to allow their placing on the market in several Member States with the same packaging.

2.1 Joint-labels

Joint-labelling can be achieved between IE and GB, IE and UK (NI), or all three – IE, GB, and UK (NI). ~~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.~~

[1] An exception applies where a shared label/package leaflet with GB is sought and where an interim position has been agreed by the Health Products Regulatory Authority (HPRA) and Veterinary Medicines Directorate (VMD) (cf. Joint HPRA/VMD Guide to Acceptable Texts for Joint Labelling for Veterinary Medicinal Products for use in Ireland and the UK)

~~To obtain joint-labelling, the Summary of Product Characteristics (SPC), product labelling and package leaflet texts (hereafter referred to as 'product information') must be identical in the relevant territories. To maintain joint-labelling, the product information must remain harmonised.~~

~~See the HPRA 'Guide to Joint labelling for Veterinary Medicinal Products for use in Ireland and the UK' (available on the HPRA website)~~For further details, see the HPRA 'Guide to Joint labelling for Veterinary Medicinal Products for use in Ireland and the UK'~~.~~ and the Veterinary Medicines Directorate's (VMD) 'Joint labelling for veterinary medicines for use in the UK and Ireland' (https://www.gov.uk/guidance). ~~For joint labels, applicants are also advised to consult the Product Literature Standard as published by the VMD, which may include relevant national-specific requirements of the VMD.~~

~~2.3~~2.2 Multilingual labels

'Multilingual packaging' refers to the use of two or more languages for at least one component of the packaging material for a medicinal product. The HPRA ~~require~~requires that all labels and packaging be in English, but inclusion of ~~other~~additional languages is permissible ~~once~~if the legibility of the English text is not compromised and ~~that~~ the information given is identical in all languages. Multilingual labels require a clear separation between the different languages and all the information provided in each language should be kept together.

~~2.4 Dual labels~~

~~Whilst dual labels between the IE and the UK are permissible without a formal joint-labelling procedure, in these situations the product information is assessed independently by the respective competent authorities. All national requirements are applicable. The responsibility of maintaining a harmonised dual label/leaflet lies completely with the applicant.~~

3 GENERAL LABELLING REQUIREMENTS

Font type, style, and size

The font size should be as large as possible and should be measured against Times New Roman.

~~TITLE~~	~~DESCRIPTION~~	
Type of Packaging	Recommended Font ~~type, style, and size~~Size	~~The font size should be as large as possible and should be measured against Times New Roman. If the recommended font size cannot be used, a G.I.15 variation should be submitted for approval of the mock-ups and a justification regarding font size should be provided upon submission.~~

~~Type of Packaging~~	~~Recommended Font Size~~	~~Minimum Font Size~~
~~Small Immediate Pack Sizes~~	~~7 pt~~	~~4.75 pt*~~
~~Immediate Packaging~~	~~7 pt~~	~~6 pt~~
~~Outer packaging~~	~~7 pt~~	~~7 pt~~

Inserted Cells

		~~Package Leaflet 9 pt 8 pt~~ ~~*only in exceptional circumstances and on a case-by-case basis. Requires approval via a G.I.15 variation.~~ **Minimum Font Size**
~~**Headings**~~Small Immediate Pack Sizes	~~Use of QRD headings on the immediate and outer packaging is not obligatory, but you must include headings that clearly convey meaning (such as 'withdrawal period').~~ 7 pt	4.75 pt*
~~**Use of images and symbols**~~Immediate Packaging	~~You may include clear diagrams and images in addition to wording, provided they are not misleading or cause confusion. Symbols and images can be useful provided the meaning is clear and that the size of the image is legible. Pictograms used should be as per those of the approved QRD text.~~ 7 pt	6 pt
Outer Packaging	7 pt	7 pt
Package Leaflet	9 pt	8 pt

*Only in exceptional circumstances and on a case-by-case basis. Requires approval via a G.I.15z variation.

Headings

Inserted Cells

Use of QRD headings on the immediate and outer packaging is not obligatory, but you must include headings that clearly convey meaning (such as 'withdrawal period').

Pictograms

Pictograms used should be as per those of the approved QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MR) and decentralised procedures (DCP).

4 4 NATIONAL SPECIFIC INFORMATION

~~TITLE~~	~~DESCRIPTION~~
~~Marketing Authorisation (MA) Number~~	~~IE - VPA xxxxx/xxx/xxx~~ ~~The marketing authorisation (MA) number is required on the package leaflet and outer package.~~ ~~For joint-labels, where possible and when space allows, country specific information should appear like this on the package leaflet:~~ ~~MA Number~~ ~~IE: VPAxxxxx/xxx/xxx~~ ~~UK (NI): VMxxxxx/xxxx~~
~~Distribution category~~	~~The distribution category should appear in a box on the package leaflet. In Ireland, the package leaflet should also state the method of sale and supply in full.~~
~~Local representative/ distributor~~	~~The listing of a local representative of the marketing authorisation holder (MAH) or of an entity that functions to physically distribute the product ('a distributor') may be introduced on the package leaflet by the MAH but is not a national requirement.~~ ~~However, if a local representative is responsible for receiving reports of suspected adverse reactions, then the local representative and their contact details must be included on the package leaflet, clearly identifying them as performing that task.~~

~~TITLE~~	~~DESCRIPTION~~
	~~To introduce, and subsequently amend, local representative/ distributor details on the package leaflet, submission of a C.10.a Variation Not Requiring Assessment 'Changes to the labelling or the package leaflet which shall not be connected with the SPC – administrative information concerning the holder's representative' is required. Mock-ups of the labelling and package leaflet are not routinely required.~~
~~**Immunological products only**~~	~~If a product is classified as 'LM', the following warning is required:~~ ~~'Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary practitioner is sought'.~~
~~**Dedicated dispensing containers**~~	~~Dispensing materials intended to be supplied by a MAH to facilitate the dispensing of their product by a registered veterinary practitioner, pharmacist, the holder of an animal remedies merchant's licence (responsible person), or a person entered in the 'companion animal medicine sellers register' (registered person), should not include any information other than that on the approved label/package leaflet.~~ ~~Mock-ups of dispensing materials are not reviewed by the HPRA.~~
~~**QR codes**~~	~~A QR code or 2D barcode may be added provided legibility is not affected, and accesses information intended for internal manufacturing, processing, stock control or anti-counterfeit measures that cannot be accessed by the public or public information, which conforms to the product information approved by the HPRA.~~ ~~Links to website addresses and/or company websites are considered promotional and cannot be included.~~

Marketing Authorisation (MA) Number

The marketing authorisation (MA) number is required on the package leaflet and outer package in the format: IE - VPA xxxxx/xxx/xxx.

Distribution category

The distribution category should only be included on the package leaflet as follows with the abbreviation in bold (not in a box) followed by the corresponding explanatory text in brackets:

POM (Prescription Only)

POM(E) (Prescription Only Exempt)

CAM (Companion Animal Medicine)

LR (Licensed Retailer)

Local representative/ distributor

The listing of a local representative of the marketing authorisation holder (MAH) or of an entity that functions to physically distribute the product ('a distributor') may be introduced on the package leaflet by the MAH but is not a national requirement.

However, if a local representative is responsible for receiving reports of suspected adverse reactions, then the local representative and their contact details (including telephone number) must be included on the package leaflet, clearly identifying them as performing that task.

To introduce and subsequently amend local representative/ distributor details on the package leaflet, submission of a C.10.a Variation Not Requiring Assessment 'Changes to the labelling or the package leaflet which shall not be connected with the SPC - administrative information concerning the holder's representative' is required. Mock-ups of the labelling and package leaflet are not routinely required.

Dedicated dispensing containers

Dispensing materials intended to be supplied by an MAH to facilitate the dispensing of their product by a registered veterinary practitioner, pharmacist, the holder of veterinary medicinal product retailer's licence (retail responsible person), or a person entered in the 'Companion Animal Medicine Retailers' Register' (registered person), should not include any information other than that on the approved label/package leaflet.

Mock-ups of dispensing materials are not reviewed by the HPRA.

QR codes

Under the provisions of Article 13 of Regulation 2019/6, a QR code may be added, provided the legibility is not affected, and accesses information intended for internal manufacturing, processing, stock control or anti-counterfeit measures that cannot be accessed by the public or public information, which conforms to the product information approved by the HPRA.

Links to website addresses and/or company websites are considered promotional and cannot be included.

APPENDIX I CHECKLIST FOR MOCK-UP PREPARATION

When preparing mock-ups, please consult the follow checklist:

- Mock-ups contain only the text agreed during the procedure and any additional agreed national-specific information.
- The name of the VMP appears as an integrated unit in the user's field of vision.
- Product specific VPA number is included on the package leaflet and the outer package.
- Font sizes are in line with the requirements as detailed in section 3 above.
- The method of sale and supply is included on the package leaflet denoted by the appropriate abbreviation ~~(e.g. POM) and then written in full, with each first initial capitalized. For example, POM should be followed by 'Prescription Only Medicine'~~, as detailed in section 4 above.
- The date the package leaflet was last revised is included (as detailed in the QRD guidance and explanatory texts).
- No company websites have been included.
- Note that the batch number and expiry date will need to be overprinted on the packaging in the format specified in QRD Veterinary Product Information Annotated Template v9.0.
- Only pictograms agreed during the procedure and as listed on the agreed QRD texts are included.
- For joint-labels, all national-specific information should be identified as "IE only" or "UK only".