An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to ~~Product Literature Standard (PLS)~~Preparation of Mock-ups for Veterinary Medicinal Products

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 INTRODUCTION

Mock-ups in support of Veterinary Medicinal Product (VMP) applications are not routinely required for assessment by the Health Products Regulatory Authority (HPRA). Instead, the Marketing Authorisation Holder (MAH) is responsible for ensuring that all mock-ups accurately reflect the approved Quality Review of Documents (QRD) texts and comply with the applicable national requirements. This obligation applies both to new marketing authorisation applications prior to first placing the product on the market and to variation applications where the approved variation has an impact on the mock-up design or readability.

The information in this guide aims to assist applicants with the creation or update 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 in Appendix 1, which will assist applicants with the layout and design of their mock-ups ~~and an~~. An additional list of national ~~Health Products Regulatory Authority (HPRA)~~HPRA specific information to be considered for inclusion~~.~~ may be found in section 3 and Appendix 2 of this guide. 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' which can be found on the HPRA website.

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

~~[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)~~

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). ~~For further details, see the HPRA 'Guide to Joint labelling for Veterinary Medicinal Products for use in Ireland and the UK'~~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' ~~(available on the UK Government website at https://www.gov.uk/guidance).~~ www.gov.uk/guidance.

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 requires that all labels and packaging be in English, but inclusion of additional languages is permissible if the legibility of the English text is not compromised and 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.

2.3 Centrally authorised products

Mock-ups for centrally authorised products (CAPs) are not assessed by national competent authorities.

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.

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
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
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'~~).~~) must be used.

Abbreviations and Pictograms
~~Pictograms~~ Abbreviations and pictograms used should be as per those of the approved QRD guidance on the use of ~~approved~~adopted abbreviations and pictograms on the packaging of veterinary~~-~~ medicinal products~~-~~ authorised via the centralised (CP),~~-~~ mutual recognition ~~(MR) and~~ (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures ~~(DCP).~~and as per the Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products.

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.

The text of mock-ups of dispensing materials is not reviewed by the HPRA.

4 NATIONAL SPECIFIC INFORMATION

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/route of sale and supply 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.

National reporting system

The national reporting system in IE should be displayed under the package leaflet section titled Adverse events (Section 7):
HPRA Pharmacovigilance
Website: www.hpra.ie.

~~**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~~. The QR code can allow access to information intended for internal manufacturing, processing, stock control or anti-counterfeit measures ~~that cannot~~but this internal information should not be ~~accessed by~~accessible to the public ~~or~~. Access to public information~~, which conforms to~~ must comply with 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-~~1 MOCK-UP ~~PREPARATION~~

~~WHEN PREPARING MOCK-UPS, PLEASE CONSULT THE FOLLOW~~INSPECTION READINESS 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, 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".~~

Item	Requirements
QRD information	Mock-ups should contain only the text agreed during the procedure and any additional agreed national-specific information.
Presentation	The name of the VMP appears as an integrated unit in the user's field of vision. Target species should appear close to the product name on the outer packaging.

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Item	Requirements
Font sizes	The applicant is requested to ensure mock-ups templates conform to the following recommended and minimum font sizes specified below in Times New Roman: Small Immediate Packaging: Recommended font size - 7 pt Minimum font size – 4.75 pt (Only in exceptional circumstances and on a case-by-case basis. Requires approval via a G.I.15z variation) Immediate Packaging: Recommended font size - 7 pt Minimum font size – 6 pt Combined Label-Leaflet: Recommended font size - 7 pt Outer Packaging: Recommended font size - 7 pt Minimum font size – 7 pt Package Leaflet: Recommended font size - 9 pt Minimum font size – 8 pt
Readability	Allow for appropriate spacing between sections and sub-headings to improve readability.

Item	Requirements
Abbreviations and pictograms	Abbreviations and pictograms used should be as per those of the approved QRD guidance on the use of adopted abbreviations and pictograms on the packaging of VMPs authorised via the centralised (CP), mutual recognition (MR) and decentralised (DCP), subsequent recognition (SRP) and national procedures, and as per Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of VMPs. The addition of pictograms not agreed as part of the approved QRD texts is not authorised on mock-ups. Pictograms denoting the pharmaceutical form are not permitted.
Headings	Use of QRD headings on the immediate and outer packaging is not obligatory, but headings that clearly convey meaning (such as 'withdrawal period') should be used. Headings (bolded) and sub-headings (under-lined) are obligatory on the package leaflet, section numbering is not required.
Links and QR codes	Under the provisions of Article 13 of Regulation 2019/6, a QR code may be added, provided the legibility is not affected. The QR code can allow access to information intended for internal manufacturing, processing, stock control or anti-counterfeit measures but this internal information should not be accessible to the public. Access to public information must comply with the product information approved by the HPRA. Links to website addresses and/or company websites are considered promotional and cannot be included.
LOT & EXP	The batch number and expiry date need to be overprinted on the packaging in the format specified in QRD.
IE ONLY	For joint-labels, all national-specific information should be identified as "IE only".
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 VMPs 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.

APPENDIX 2 NATIONAL PARTICULARS REQUIRED TO APPEAR ON MOCK-UPS

Particulars to appear on mock-ups	Information required	Outer Package required? Yes/No	Immediate required? Yes/No	Small immediate packaging units required? Yes/No	Blisters required? Yes/No	Package Leaflet required? Yes/No
Distribution category	The distribution category in IE is only required on the **package leaflet** as follows with the abbreviation in **bold (not in a box)** followed by the corresponding explanatory text in brackets. For example: **POM** (Prescription Only) **POM(E)** (Prescription Only Exempt) **CAM** (Companion Animal Medicine) **LR** (Licensed Retailer)	No	No	No	No	Yes
National reporting system	The national reporting system in IE should be displayed under the **package leaflet** section titled Adverse events (section 7) as: HPRA Pharmacovigilance Website: www.hpra.ie	No	No	No	No	Yes

Particulars to appear on mock-ups	**Information required**	**Outer Package required? Yes/No**	**Immediate required? Yes/No**	**Small immediate packaging units required? Yes/No**	**Blisters required? Yes/No**	**Package Leaflet required? Yes/No**
Marketing Authorisation Number	Marketing authorisation numbers are only required on the **outer packaging** and **package leaflet** (section 14) in the format: IE - VPA xxxxx/xxx/xxx.	Yes	No	No	No	Yes
Local representative (responsible for receiving reports of suspected adverse reactions)	Local representative is only required on the **package leaflet** (section 16).	No	No	No	No	Yes
National special restrictions for use	Where national specific warnings have been introduced into section 3.11 of the SPC, these should be replicated in section 6 of the package leaflet.	No	No	No	No	Yes
Date of leaflet revision	The date the package leaflet was last revised should be included under section 15 of the **package leaflet.**	No	No	No	No	Yes