HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Product Literature Standard (PLS) 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

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

Mock-ups submitted for regulatory approval, should not deviate from the agreed QRD text ~~or the approved SPC if no QRD text exists for the product~~.

This document includes a list of general labelling requirements, which will assist applicants with the layout and design of their mock-ups submitted for approval and an additional list of national Health Products Regulatory Authority (HPRA) ~~requirements~~ information to be considered for inclusion~~(additional to the agreed QRD texts)~~. ~~Whilst some national specific requirements of the Veterinary Medicines Directorate (VMD) are included in this list, for joint labels, applicants are also advised to consult the as published by the VMD (https://www.gov.uk/guidance) which may include relevant national-specific requirements of the VMD.~~ This document should be read alongside the ~~"~~HPRA 'FAQs on Processing the Labelling and Package Leaflet for Veterinary Medicinal ~~MP~~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. See Appendix I for further information.

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 ~~GB~~ IE and GB~~IE~~, IE and UK (NI)~~ and IE~~, or all three ~~—~~ IE, GB, ~~IE~~ and UK (NI). An application for joint-labelling can be made either at the end of a new ~~Marketing~~ marketing ~~Authorisation~~ authorisation (MA) procedure or, retrospectively, for existing MAs, whether authorised by EU or national procedures.

To obtain joint-labelling, the Summary of Product Characteristics (SPC), ~~and~~ product labelling and package leaflet texts (hereafter referred to as 'product information') must be identical in the relevant territories~~. This can be achieved, for existing MAs, by applying for a harmonisation variation in both countries~~. To maintain joint-labelling, the product information must remain harmonised.

~~To facilitate multi-country packs the 'blue-box' concept allows for administrative country-specific information to be included. National specific information should be included in the country specific box on official joint-labels. This should include any information that is specific to that country only. Any information that applies to both countries should be included in the main~~

~~text outside the box. Information in relation to Northern Ireland should state 'Northern Ireland' in full.~~

See the HPRA 'Guide to Joint labelling for Veterinary Medicinal Products for use in Ireland and the UK' (available on the HPRA website) 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.

~~2.4~~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 ~~and VMD~~ require that all labels and packaging be in English but inclusion of other languages is permissible once the legibility of the English text is not compromised and that the information given is identical in all languages ~~(note that the HPRA/VMD will only review the English text)~~. Multilingual labels require a clear separation between the different languages and all the information provided in each language should be kept together.

~~2.5~~2.3 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 ~~, the mock-ups are~~ 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

TITLE	DESCRIPTION
Font type, style and 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 justification 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
Package Leaflet	9 pt	8 pt

*only in exceptional circumstances and on a case-by-case basis.

TITLE	DESCRIPTION
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').
Use of images and symbols	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.

4 NATIONAL SPECIFIC ~~REQUIREMENTS~~INFORMATION

TITLE	DESCRIPTION
~~The~~ **Marketing Authorisation (MA) Number**	IE - VPA xxxxx/xxx/xxx ~~UK (includes GB and Northern Ireland) - VM xxxxx/xxxx~~ The marketing authorisation (MA) number is required on the package leaflet and~~,~~ outer package.~~ing, immediate packaging, and label (in case of no leaflet). Whilst it is not mandatory, it is strongly encouraged to also include this on the small immediate packaging.~~ For joint-labels, where possible and when space allows, country specific information should appear like this on ~~mock-ups~~the MA Number IE: VPAxxxxx/xxx/xxx UK (NI): VMxxxxx/xxxx **IE** VPA xxxxx/xxx/xxx LP~~O~~M package leaflet: ~~In Ireland, the package leaflet should also state the method of sale and supply in full.~~

TITLE	DESCRIPTION
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. ~~, outer packaging, immediate packaging, and label (in case of no leaflet).~~ ~~Prescription products should include the following statement: 'To be supplied only on veterinary prescription'.~~ ~~For joint-labels:~~ ~~IE only: It is mandatory to include the distribution category on the small immediate packaging.~~ ~~UK only: Whilst it is not mandatory, we strongly encourage you to also include this on the small immediate packaging.~~
Local representative/ distributor	~~A local representative/distributor may also be included, but this is not a legal or national requirement.~~ The listing of a local representative of the marketing authorisation holder (MAH) ~~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. ~~-~~A local representative responsible for pharmacovigilance activities is a specific and important function and where included on the package leaflet should be clearly distinguished 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 unless the design or readability is affected.
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	~~Whilst not a requirement, it is the HPRA's preference that mock-ups of all d~~Dispensing materials intended to be supplied by a ~~marketing~~

TITLE	DESCRIPTION
	authorisation holder (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 benot include any information other than that on the approved label/package leaflet. submitted to the HPRA for review and approval. For new products, mMock-ups of dispensing materials are not reviewed by the HPRA. should be submitted at the time of submission of mock-ups of other product livery (immediate/outer packaging and package leaflet) . For existing products, mock-ups of new or existing dispensing materials should be submitted by way of a variation application (with accompanying fee).
QR codes	A QR code or 2D barcode may be added providing 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. For joint labels with the UK you should also refer to the VMD's Product Literature Standard (https://www.gov.uk/guidance).

APPENDIX I CHECKLIST FOR MOCK-UP SUBMISSION

Prior to submission of mock-ups, please consult the follow checklist:

- Mock-ups contain only the text agreed during the procedure and any additional national information ~~requirements~~ as outlined in the product literature standard.
- Only the mock-ups representing worst case in terms of readability for each label/outer package (usually the smallest pack size) and the package leaflet need be submitted.
- ~~Mock-ups of the smallest pack size must be submitted for assessment. A condition will apply for any smaller pack sizes not submitted.~~
- 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 stated and are in line with the requirements of the product literature standard.
- ~~'For animal treatment only' appears on all components of the packaging.~~
- The method of sale and supply is included. The method of sale and supply on the package leaflet is written in full with each first initial capitalized. For example, POM should be followed by 'Prescription Only Medicine'.
- ~~In the case of POM products, 'To be supplied only on veterinary prescription' is included on the outer and immediate (including small) packaging and on the package leaflet.~~
- The date the package leaflet was last ~~approved~~ revised is included (~~end of procedure date~~as detailed in the QRD guidance and explanatory texts).
- No company websites have been included.
- Confirmation is provided that the batch number and expiry date will be overprinted on the packaging in the format specified in QRD Veterinary Product Information Annotated Template v9.0 if not included on the submitted mock-ups.
- Only pictograms agreed during the procedure and as listed on the agreed QRD texts are included.