Veterinary Medicines Directorate

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Product Literature Standard (PLS)

For veterinary medicinal products

Summary: Guidance for industry on the production of mock-ups for use on the UK and Irish markets

This guidance has been produced by the VMD (UK) and HPRA (IE) and was last updated 6th July 2015

Version 1.2

Contents

1. Introduction

The information in the Product Literature Standard (PLS) will assist you in creating your mock-ups, so that you get them right first time.

QRD templates and additional information are available on the EMA website.

Taking note of the following will greatly enhance your chances of getting your mock-ups right first time:

- Follow the approved QRD text (if available) or the approved SPC (if no QRD) and information in this document
- If you wish to deviate from the above, contact the relevant authority BEFORE submitting mock-ups
- Deviating from the above will only be permitted in very exceptional circumstances – it is up to you to agree the wording during the assessment phase of the application procedure and / or before the mock-up review process
- If you are asked to make changes, please make them and do not make any other changes without agreeing it with the relevant authority first.

2. What information should appear on the label

The table below shows the minimum amount of information which should appear on the mock-ups of the package leaflet, outer and immediate packaging.

If it is not practical to include all of the information on the immediate or outer packaging, a package leaflet must be included and the statement 'Read the package leaflet before use' should appear on the outer and immediate packaging.

It is important that the information on a blister pack remains available to the user up to the point when the last dose is removed. Often it is not possible to display all the information over each blister pocket. Random displays of information should appear frequently. It is acceptable to apply the batch number and expiry date at the end of the blister.

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 e.g. MA number, distribution category, MA holder, etc. Any information that applies to both countries should be included in the main text outside the box.

PARTICULARS TO APPEAR ON THE PACKAGING AND PACKAGE LEAFLET	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
The name and address of MAH and manufacturer for batch release						
Name only					X	
Name and address	X	X	X			X
Batch release if different to the MAH	X					X
Where several company names and addresses appear, the role of each should be clear.						
If space is limited the addresses can be shortened; however, it must include the name of the country if outside the UK or Ireland (as applicable).						
A local representative may also be included, but this is not a legal requirement.						
Distributor						
UK: *You may include the details of a named distributor on your labels instead of, or as well as the MAH details.*						
IE: *You may include the details of a named distributor on your labels as well as the MAH details.*						
Name of the veterinary medicinal product, followed by its strength and pharmaceutical form						
The name of the product should match the SPC and should be legible.	X	X	X	X	X	X
The whole product name should appear together.						
Copyright or trademark symbols are allowed.						
The name and quantity of the active substance and the name of any excipient if shown in Section 2 of the SPC.						
The name and quantity of active substance and excipients	X	X	X			X
The name of the active substance and quantity				X		
Active substance					X	

PARTICULARS TO APPEAR ON THE PACKAGING AND PACKAGE LEAFLET	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
Pharmaceutical form Not required if it forms part of product name	X	X				X
Indications <u>*Non-prescription products*</u> <u>*Prescription products*</u>	X X	X	X			X X
Contraindications	X					X
Adverse Reactions *Include the statement "If you notice any serious effects or other effects not mentioned in the package leaflet, please inform your veterinary surgeon."*	X					X
Target Species *For small immediate packaging or blister strips the target species may appear either as part of the product name, separately, or replaced by a clear pictogram.* *Further information and clarification on the use of pictograms has been produced by CMDv which can be found on the EMA website.*	X	X	X			X
Dosage *If there is a package leaflet* *No package leaflet*	X	X	X			X
Method / route of administration *The route of administration should be written as per the SPC. Standard abbreviations (e.g. IV, IM, SC) are acceptable on small immediate packaging or on the outer packaging provided that full terminology is used on the package leaflet. Non-standard routes should be written out in full.*	X	X	X	X		X
Advice on correct administration	X					X

PARTICULARS TO APPEAR ON THE PACKAGING AND PACKAGE LEAFLET	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
Withdrawal period *For food producing species the withdrawal period for the various foodstuffs e.g. meat, offal, eggs, milk etc., should be shown even if it is zero hours / days.*	X	X	X	X		X
Special storage instructions	X	X	X			X
Special warnings *Warnings as per the following sections of the SPC – 4.4, 4.5, 4.7, 4.8, 4.10 and 6.2.*	X	X	X			X
Disposal advice *As written in Section 6.6 of the SPC.* *If agreed during assessment, additional national disposal and environmental warnings may also need to be included on the packaging.*	X	X	X			X
Date package leaflet was last approved *EU Applications – Last day of assessment phase* *National Applications – Date of issue.*	X					X
Other information *Further information required in the MA*	X					X
Batch Number *Shown as e.g. LOT*		X	X	X	X	X
Expiry Date *The expiry date should be written clearly to avoid confusion e.g.* *Exp End of: MM/YYYY or as DD/MM/YYYY* *Dates may be printed, embossed or engraved into the packaging. If this is overprinted onto the final printed mock-up this should be clarified to the competent authority.*		X	X	X	X	X
The words 'For animal treatment only'.	X	X	X	X	X	X

PARTICULARS TO APPEAR ON THE PACKAGING AND PACKAGE LEAFLET	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
Content by weight, by volume or by number of doses	X	X	X	X		X
The marketing authorisation (MA) number *UK Only - Vm xxxxx/xxxx* *IE Only - VPA xxxxx/xxx/xxx* *While it is not mandatory to include this information on the small immediate packaging we strongly encourage you to do so.* ***UK/IE Joint Labelled Products*** *Where possible and when space allows, country specific information should appear on mock-ups as follows:* **UK Only** Vm xxxxx/xxxx POM-V **IE Only** VPA xxxxx/xxx/xxx POM *In Ireland the package leaflet should state the method of sale and supply in full.*	X	X	X			X
Distribution category. The distribution category should appear in a box e.g. **POM-V**, **VPO** Prescription products should include the following statement: "To be supplied only on veterinary prescription". *<u>UK only</u>: While it is not mandatory to include the distribution category on the small immediate packaging, we strongly encourage you to do so.* *<u>IE only</u>: It is mandatory to include the distribution category on the small immediate packaging.*	X	X	X	X (IE only)		X
The words 'Keep out of the sight and reach of children'.	X	X				X

PARTICULARS TO APPEAR ON THE PACKAGING AND PACKAGE LEAFLET	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
The in-use shelf life (if appropriate) should be listed on multidose containers ≥ 50 ml.		X	X	X		X
UK only:						
A suitable space to record the discard date (if relevant).						
The following statement should be included:						
"When the container is broached / opened for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label."	X					X

The table below shows the minimum amount of information which should appear on a diluent label.

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL
Name of diluent *The 'trade' name with a brief description or a more describing way of naming (Solvent /diluent for type of vaccine it can be used with or properties of the diluent).*
Content by weight, by volume or by number of doses *For example: 200 / 400 / 600 / 800 / 1000 ml*
Route(s) of administration *The statement 'Read the package leaflet before use'.*
Storage conditions *E.g. Store below 25ºC*
Batch Number *Lot (number)*
Expiry Date *e.g. Exp End of: MM/YYYY or as DD/MM/YYYY*
The words "For animal treatment only"
Vm/VPA number UK only: While it is not mandatory to include the Vm number on the diluent label, we strongly encourage you to do so. IE only: It is a mandatory requirement to include the MA number on the immediate packaging. While it is not mandatory to include this information on the small immediate packaging, we strongly encourage you to do so.

Homeopathics

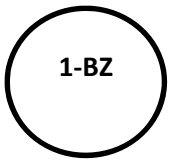
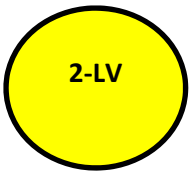
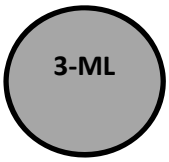
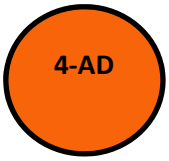
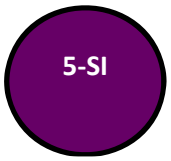
Homeopathic veterinary medical products should include the same information as for most products as well as the extra particulars shown below:

ADDITIONAL PARTICULARS TO APPEAR ON THE VETERINARY HOMOPATHIC REMEDY PACKAGING
Inclusion of the words: "homeopathic medicinal product for veterinary use".
Inclusion of the words "homeopathic medicinal product"
Clear mention of the words "homeopathic veterinary medicinal product without approved therapeutic indications".
Scientific names of the stock(s), followed by degree of dilution using symbols of pharmacopoeia. *If product is composed or more than one stock, the packaging may need to mention an invented name in addition to the scientific names of the stocks.*
Name and address of registration holder and if appropriate manufacturer *The manufacturer does not need to be included on small containers (not more than 50 ml)*
Method and if necessary route of administration *The route of administration should be included on small containers (not more than 50 ml).*
Expiry date
Pharmaceutical form
Contents of sale presentation
Special storage precautions
Withdrawal period or a statement if the product is contraindicated for animals intended for human consumption.
Target species
A special warning if necessary for the product
Manufacturers batch number

ADDITIONAL PARTICULARS TO APPEAR ON THE VETERINARY HOMOPATHIC REMEDY PACKAGING
Registration number **UK** In the UK a registered product will have registration number preceded by the symbol Vh on the labels. **IE** A registered product will have a registered number in the following format: HoVR 01/001. HoVR represents the homeopathic veterinary registration; 01 is the number allocated to the company and 001 is the product number.

3. Labelling Requirements

Multilingual Labels	All labels and packaging must be in English. They may also contain other languages provided that the: - requirements of the VMD and HPRA are respected - English text is kept together - legibility of the English text is not compromised - information given is identical in all languages* * The VMD or HPRA will only assess the English text on the label
Strength and total content	Sometimes packaging may need to include both quantity per unit volume and total quantity per total volume. Different strengths of the same product should be expressed in the same format e.g. 100 mg, 500 mg, 1000 mg. Unless space is limited micrograms should be spelt out in full, not abbreviated. Trailing zeros should not be used e.g. 2.5 mg not 2.50 mg. The use of decimal points or commas should be avoided where possible.
Space availability on packaging	This should be considered during the assessment process and **before** the mock-up review process. The amount of text included on the QRD must reflect the size of the label.
Company Websites	You can't refer to company websites. You can include an email address and / or telephone number.
Anthelmintics	A voluntary labelling scheme has been introduced for the inclusion of chemical group symbols on sheep anthelmintic. You may use the scheme for other species. This is for easy identification of the chemical group through the use of approved symbols and to facilitate efforts to delay the development of anthelmintic resistance. The symbols consist of a circular design with a designated colour (although can be in monochrome) and the anthelmintic group code. The symbol should be located in a prominent position on the outer carton, immediate label and package leaflet. A minimum diameter of 10 mm is suggested for the symbol on the outer carton, which can be scaled up for larger presentations. No symbol is required for narrow spectrum anthelmintics e.g. closantel.

	 Benzimidazoles  Levamisoles  Macrocyclic Lactones  Amino-acetonitrile Derivatives  Spiroindoles
QR Codes	A Quick Response (QR) code is a 2D barcode which can be scanned with an internet enabled device to link to a website. The website content must be accurate and suitable for the intended audience. The addition of a QR code or 2D barcode to product labelling or package leaflets is permissible provided that: QR code or 2D barcode intended for internal manufacturing processing, stock control or anti-counterfeit measures that cannot be accessed by the public and do not affect the legibility of the packaging can be used without approval. If any additional information in the QR code or 2D barcode can be read by members of the public it must conform to the information approved by the HPRA and VMD i.e. Summary of Product Characteristics, label or package leaflet for that product. **UK only:** The inclusion of or addition of information in the QR code or 2D barcode, which can be read by members of the public, must be submitted for approval as a Type IB variation. The variation must include a detailed account of information to which this code links. Further significant changes to this information, would require the submission of a further variation.

	Links to company website are considered promotional and cannot be included. The addition of the QR code should not affect any other aspect of the label and should not affect the legibility of the approved label or leaflet text. Once a QR code has been approved the MAH is responsible for ensuring that the information included in the QR code is in line with the approved SPC.
Product ranges	There should be a separate SPC and product literature for each strength and pharmaceutical form of a veterinary medicinal product. You may be able to combine package leaflets for products that are different strengths and / or different pharmaceutical forms e.g. for a range of tablet strengths. If a combined package leaflet is required, this should be raised during the assessment phase when the QRD text is being agreed and **before** the mock-up review process. A combined package leaflet will only be agreed if the following conditions are met: 1. Package leaflets are completely identical; except for a few strength specific details. 2. A combined package leaflet does not cause confusion for the user of the product.

4. Readability

The following should be taken into consideration during the design of mock-ups:

<table>
<tr>
<td>Type Style and Size</td>
<td>
The type of font should be easy to read. Stylised fonts which are difficult to read should not be used.

Choose a font that clearly distinguishes between similar characters e.g. “i”, “l” and “1”.

Capitals should be avoided, but can be used to emphasis words.

Italics should be used for Latin terms e.g. citing correct nomenclature and microorganisms.

The font size should be as large as possible and, as a minimum, must be clearly legible and understood by the end user.
<table>
<tr><th>Type of Packaging</th><th>Recommended Font Size</th><th>Minimum Font Size</th></tr>
<tr><td>Small Immediate Pack Sizes</td><td>7 pt</td><td>4.75 pt*</td></tr>
<tr><td>Immediate Packaging</td><td>7 pt</td><td>6 pt</td></tr>
<tr><td>Outer packaging</td><td>7 pt</td><td>7 pt</td></tr>
<tr><td>Package Leaflet</td><td>9pt</td><td>8 pt</td></tr>
</table>
If you can’t use the recommended font size, please include a justification for this when submitting mock-ups.

* This is only applicable in exceptional circumstances and on a case by case basis.
</td>
</tr>
<tr>
<td>Colour</td>
<td>
Colours should have a good contrast between the text and the background.

The legibility of information should not be compromised by the colours chosen such as the use of similar colours being used for the text and background, use of different colours that makes the product name more difficult to identify.

Preferably, dark text should be printed on a light background, but the reverse may also be applied in certain circumstances e.g. when highlighting a particular warning.
</td>
</tr>
</table>

The following should be taken into consideration by the applicant when generating mock-ups:

Design and Layout	Legibility of information should not be compromised by design. When designing mock-ups you should consider whether the layout, font size, legibility etc. have been fully optimised. Where possible line spaces should be kept clear. Space between lines enhances clarity. Column format of text is acceptable. The margin between columns should be large enough to separate the text. If space is limited a vertical line may be used to separate text. Related information should be kept together so that information flows from one column to the next. Multilingual labels should have a clear separation between the different languages. All the information provided in each language should be kept together.
Headings	Headings can help users navigate the text. Bold type and different colours can help this information stand out. Spacing above and below the headings should be consistent throughout the packaging. The use of multiple headings should be considered carefully as the use of more than two levels may cause confusion. Use of QRD headings on the immediate and outer packaging is not obligatory, but you must include headings that clearly convey meaning (e.g. 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.

5. Mock-up Review Process

Mock-ups are assessed against:

- the agreed QRD text (if available) or the agreed SPC (if no QRD)
- the PLS
- any other information provided by or discussed with you.

Mock-up submitted should not deviate from the agreed QRD text and / or SPC.

In exceptional cases, you may be allowed to deviate from the above, but you MUST contact the relevant authority to discuss this before submitting your mock-ups. Not doing so will greatly delay the approval of your mock-ups, which will then delay issue of the application.

Submission of Mock-Ups

You must:

- submit mock-ups electronically
- make sure they are legible
- include a scale that shows what the real size will be
- say what the font size will be on the marketed labels

The following are not assessed by the VMD or HPRA and, therefore should not be submitted with applications:

- Labelling of cartons where product literature is packaged for distribution to wholesalers and retailers (shipping packs)
- Datasheets, including Material Safety DATA Sheets (MSDSs)
- Packaging for wholesalers that do not include any labels

Timescales

Mock-ups will be assessed and signed-off within 20 days of receipt of correct versions*.

*The above does not apply for national variations and renewals, because mock-ups are reviewed during the assessment process; there is not separate ‘mock-up’ phase.

Review

If / once the mock-ups are correct, they will be approved at the end of the application procedure.

If the mock-ups contain errors, or are not suitable, you will receive a comments document listing any proposed changes. You should update the mock-ups to incorporate the proposed changes and return revised versions as soon as possible.

For joint labelled products, the UK and IE will agree the proposed changes before sending them to you. The UK and IE will not communicate about unofficial dual-labelled products, and will simply assess the mock-ups as suitable for marketing in their own country.

Further information about joint labelling is available on the VMD (GOV.UK) and HPRA websites.

UK only: Where only minor amendments are needed, annotated mock-ups rather than clean versions will be approved.

IE only: It is recommended to submit clean versions of the mock ups. Annotated mock-ups should only be submitted in exceptional circumstances where the annotations are very minor.

No Mock-Ups

If you do not want to submit mock-ups (or certain pack sizes), or mock-ups are not submitted within the deadlines set, your application can be issued on the condition that mock-ups will be submitted for assessment under cover of a national C.II.6(b) Type IB variation category.

6. What Changes Require Variations

Any change that may affect the legibility of the mock-up must be approved by way of a variation, e.g.

- Changes to the colouring of the product literature, use of different colours etc.
- New corporate design of packaging
- New container type / size
- Changes to the layout of the package
- Introduction of multilingual packs for an already approved authorised product

Changes that do not affect the font size, layout, legibility etc., do not require a variation. For example, a change to the barcode, logo (assuming same size) etc.

If you are in doubt about whether a variation is needed, please contact a member of the General Assessment Team at the VMD or vetinfo@hpra.ie at the HPRA.

UK Only - If you submit a revised mock-up showing the proposed change and the VMD agrees that no variation is required, we will confirm this with you. This does not mean the VMD has assessed or approved the mock-up provided; simply that the proposed change can be made without the need for a variation. You are not required to submit revised mock-ups to the VMD once the change has been made.

Joint-Labelling

If you make any changes to country specific information only, you do not need to submit the variation to the country not affected. Neither country requires copies of revised labels showing changes to the other countries information.

ANNEX A: VMD Requirements

A.1 Packaging

If you cannot fit all of the required information on the relevant packaging, you should include the following statements on all product literature if an outer carton is used:

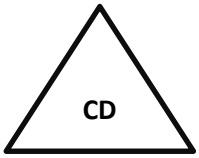
- The words “Keep the container in the outer carton”.

If space is available, you may be asked to include extra information especially in the case of Provisional Marketing Authorisations (PMAs) and Limited Marketing Authorisations (LMAs).

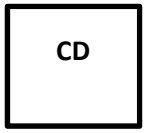
A.2 Controlled Drugs

Products containing controlled drugs are authorised as POM-V.

Products containing controlled drugs in Schedule 2 or 3 of the Misuse of Drugs Regulations 2001 will be clearly identified with “CD” either in a triangle (preferably) or in a box and the relevant schedule detailed on the label – see below.



(Sch 2)



(Sch 2)

The CD symbol should be included on labels (where space permits), outer packaging and on the package leaflet. This does not need to be included on blister packs or small immediate labels.

A.3 Warnings for Horse Products

Warnings such as the following are not considered necessary on the SPC or product literature of VMPs and should be removed at the next opportunity:

> “Horses intended for racing and competition should be prevented from racing or competing when in need of treatment and horses which have been recently treated should be dealt with according to local requirements. Appropriate precautions must be taken to ensure compliance with competition regulations”

It is the veterinary surgeons responsibility to ensure the horse treated with the product complies with competition rules.

A.4 Exceptional Marketing Authorisations (MAs)

All of the required particulars must appear on either the container or the package. There are also additional labelling requirements depending on the type of product.

The package leaflet and labels must make it clear to the person prescribing or using the product that, the particulars available concerning the medicinal product are incomplete.

Exceptional MAs are subject to normal labelling requirements, but are also required to include the following information on the packaging:

- A clear statement that the product does not have a full Marketing Authorisation and to highlight areas of 'weakness'. For example: "*This is a Limited Marketing Authorisation. A full set of supporting efficacy data is not available for the product*".
- The statement "All suspected adverse reactions and any suspected lack of efficacy should be reported to <company pharmacovigilance phone number and address>"
- The statement "Further information on this product and its supporting data can be found on http://www.vmd.defra.gov.uk/ProductInformationDatabase/"

A.5 Animal Test Certificates (ATCs)

ATCs are subject to the normal labelling requirements. There are also additional labelling requirements depending on the type of product.

Where trials are being conducted according to a blind study, the labelling requirements may be relaxed to the extent necessary to allow for this.

For authorised veterinary medicinal products, the approved labelling may be used provided it is in English, but a small over-label should be included which indicates:

- any amendment to directions / warnings
- the ATC number
- the words "Veterinary Clinical Trial Use Only" to ensure accountability in line with GCP requirements

Any deviations from this should be discussed with the VMD.

Type A and B ATCs

- Labelling and package leaflet text should be submitted for approval.
- The approved labels and package leaflet must be used for the trial.

Type S ATCs

- The applicant will be required to submit a statement of user and target species safety warnings to appear on the label / package leaflet.
- It is the responsibility of the ATC holder to ensure that the labelling / package leaflet conforms to the requirements.

EXPECTED MINIMUM PARTICULARS TO APPEAR ON THE ANIMAL TEST CERTIFICATE PACKAGING
The words “For veterinary Clinical Trial Use Only”.
Name or other designation of the product
Quantity of product
Any restrictions on use
Expiry date, and if appropriate in-use expiry date
Directions for use specified to the trial including: o dosage o frequency o duration o method and route of administration
Contraindications, warnings and precautions
Special instructions for handling and storing of the product
Instructions for disposal – in most cases these should state that any unused product and containers should be returned to the trial sponsor.
If used in a food producing species (including horses, rabbits and pigeons) the withdrawal period should be included or the words: “Not to be Used in Animals for Human Consumption”.
Name and address of ATC holder and ATC number
The manufacturer’s **batch number**
A unique code / number identifying the individual container, where appropriate e.g. when the identity of the product used in the trial are blinded.

A.6 Dedicated Dispensing Containers

Authorised packaging of a product usually consists of immediate, outer packaging and a package leaflet. In addition to this, some distributors provide an empty, partly labelled pack such as an envelope, wallet or cartons for use with specific products.

This type of packaging is intended to be used by the veterinary surgeon to supply the dispensed medicine. Dispensing of the medicine into these containers is the responsibility of the veterinary surgeon.

The dispensing containers are not subject to the same labelling requirements as the authorised immediate and outer packaging. However if they are submitted to the VMD with the authorised packaging, they are considered to form part of the authorised packaging and will be subject to the same level of mock-up assessment.

ANNEX B: HPRA Requirements

Submission of mock-ups for different pack sizes

The HPRA does not require the submission of mock-ups for all pack sizes. It is sufficient to submit the smallest and largest pack sizes for review. Should the MAH not wish to market the smallest/largest pack size at time of assessment, a condition will be placed on the marketing authorisation to state that mock-ups for these pack sizes must be approved by the HPRA prior to marketing via a C.II.6 (b) variation.

For Nationally Authorised 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".

Exceptional Marketing Authorisations

The Regulations allow a product to be authorised in specific and restricted circumstances, without all the comprehensive data on therapeutic effects, which is normally required. In Ireland, the Department of Agriculture, Food and the Marine (DAFM) is responsible for authorisation under this provision. Information on labelling requirements for products authorised under exceptional circumstances can be obtained from DAFM.

Dedicated Dispensing Containers

Whilst not a requirement, it is the HPRA's preference that mock-ups of all dispensing materials intended to be supplied by a marketing 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 be submitted to the HPRA for review and approval.

For new products, mock-ups of dispensing materials 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).

Note that in the case of joint labelling procedures between the HPRA and the VMD where dispensing materials are not enclosed within the authorised packaging but are to be supplied independently of the authorised packaging, such mock-ups will be assessed independently by the HPRA only.

The following points should be considered by the MAH before submitting mock-ups of dispensing materials to the HPRA for review and approval.

- Dedicated dispensing materials are considered as 'supplementary packaging materials' and are not to be used as a replacement for official packaging materials.
- The choice of whether or not to use dispensing materials (wallets/cartons etc.) rests with the prescribing veterinarian, the pharmacist or the responsible/registered person dispensing the product and who is responsible for ensuring that all relevant information concerning the product being dispensed is provided to the animal owner.
- Responsibility for the assessment of the suitability/adequacy of any form of dispensing material (in terms of child resistance/user safety, manufacturing materials etc.) rests with the person dispensing the product and will not be considered by the HPRA in the context of assessing such mock-ups.
- All text must be of an adequate font size to ensure legibility (as for all other product literature).
- Only approved information (i.e. information included in the SPC and/or labelling/leaflet texts) agreed during the product application procedure may be included on the dispensing materials.
- Promotional or marketing statements will not be approved and therefore should not be included.
- Space requirements for dispensing information (such as name & address of veterinary practice, date of dispensing, client details etc.) should be considered by the applicant.
- The legal category of route of sale/supply and VPA number must be included.
- The text to be included on the dispensing material should normally include the QRD text approved for immediate packaging units as a minimum.

Definitions

Immediate Packaging	The container or any other form of packaging that is in direct contact with the Veterinary Medicinal Product (VMP) e.g. vials, ampoules, bottles, blister packs, etc. The immediate packaging does not include capsules which are administered as part of the product.
Outer Carton	The packaging into which the immediate packaging is placed e.g. cartons, boxes, packets, etc.
Label	Information on the immediate or outer packaging.
Package Leaflet	The leaflet that contains information for the user which accompanies the VMP.
Product Literature	Consists of labelling for the immediate packaging, outer packaging and package leaflet.
Summary of Product Characteristics (SPC)	Contains information on the VMP as agreed during the course of the assessment process
Mock-up	A flat artwork design in full colour, presented so that it provides a full size replica of both the immediate, outer packaging and package leaflet so that the three dimensional presentation of the label text is clear.
Specimen	A sample of the actual printed immediate and outer packaging materials and the package leaflet.

Legal Requirements

Labelling of VMPs has a legal basis in EU Directive 2001/82/EU as amended by 2004/28/EC and 2009/9/EC ("The Directive"). Some of the product literature related extracts from this directive are listed below with an explanation of their meaning. This is not a comprehensive list of requirements relating to product literature.

Article 12(3) point (l) ***"The file shall be submitted in accordance with Annex I and shall contain, in particular the following information:***

….. a summary in accordance with Article 14 of the product characteristics, a mock-up of the immediate packaging and the outer packaging of the veterinary medicinal product, together with the packaging leaflet, in accordance with Articles 58 to 61…."

This sets out the requirements to submit a draft SPC and mock-ups of the product literature with the submission of an application for a marketing authorisation (MA).

Article 25(2) ***"The competent authority shall take all the necessary measure to ensure that information concerning the veterinary medicinal product, and in particular the labelling and packaging leaflet, is in conformity with the summary of product characteristics approved when the marketing authorisation was granted or subsequently."***

This requires that the competent authority assess and approve the product literature to be in accordance with the approved SPC.

Article 30 point (e) ***"The authorisation shall also be refused if, after examination of the documents and particulars listed in Article 12 and 13(1), it is clear that:***

…. the labelling or the packaging leaflet proposed by the applicant does not comply with this Directive…"

This sets out that an MA can be refused if the product literature is not in accordance with The Directive.