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Veterinary Medicines Division

Mock-ups checklist - Guidance for checking mock-ups

This guidance should be read in conjunction with:

- the applicable Quality Review of Documents (QRD) veterinary product-information annotated templates (English)
- Veterinary Medicines Regulation (Regulation (EU) 2019/6) and Commission Delegated Regulation (EU) 2021/805

Please note that all elements on the approved product information (PI) attached to the CVMP opinion should be taken into account when preparing mock-ups.

The checks mentioned in this guidance are standard checks and instructions to guide applicants in the preparation of the mock-ups.

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READABILITY

A. OUTER PACKAGE		***Comments***
Critical labelling elements ☐	• **(Invented) name of the veterinary medicinal product** • **Strength** (if applicable) • **Pharmaceutical form** • **Active substance(s)** • **Package size** • **Target species** • **Routes of administration** • **Withdrawal period** (if applicable) • Indications (Only for products not subject to veterinary prescription, and if so, when space allows) • Expiry date (mm/yyyy) preceded by the abbreviation "Exp." and followed by the appropriate space to insert the date. • Special precautions for storage, if any • The words "Read the package leaflet before use" • The words "For animal treatment only" • The words "Keep out of the sight and reach of children" • Name of the marketing authorisation holder (MAH) (name or company name or logo name of the MAH) • Marketing authorisation numbers • Batch number preceded by the word "Lot" and followed by the appropriate space to insert the number. **The elements mentioned in bold** should be **prominent** on the packaging, e.g. in larger font size, and it is recommended to mention them on the front panel of the packaging. **This requirement is optional for multilingual packs**.	
Name of the product ☐	• The name should be stated as per the respective sections of the QRD product information template. • Format of the product name can differ from the format used in the PI.	
Print size, quality and type ☐	• Minimum 8 pt. • The text should be easily readable (print type, size and space between lines) for the healthcare professionals, farmers or animal owners.	

A. OUTER PACKAGE		***Comments***
Print colour ☐	• **Distinguishable** colours from the background for print of characters should be used. • Use of background colour should not adversely impact on readability of the text. • Do not use green on red or red on green, as these pose problems for people who are colour blind.	
Pictograms/Logo ☐	• The applicant/ MAH should refer to the guidance on pictograms until this is superseded by the Implementing Act providing a list of abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3) of Regulation (EU) 2019/6.	
Layout of text ☐	• Multilingual packs should be clearly legible and, where practical, grouping of text elements for each language is recommended. • The use of language abbreviation may also be used to distinguish grouped languages.	
Barcode ☐	• A barcode is allowed on the labelling.	
QR (Quick response) code ☐	• The applicant/MAH should refer to the QR code guidance	

B. IMMEDIATE PACKAGE		***Comments***
Critical labelling elements ☐	• **(Invented) name of the veterinary medicinal product** • **Strength** (if applicable) • **Pharmaceutical form** • **Active substance(s)** • **Target species** • **Routes of administration** • **Withdrawal period** (if applicable) • Expiry date (mm/yyyy) preceded by the abbreviation "Exp." and followed by the appropriate space to insert the date. • Special storage precautions, if any • Name of the MAH (name or company name or logo name of the MAH) • Batch number preceded by the word "Lot" and followed by the appropriate space to insert the number. **The elements mentioned in bold** should be **prominent** on the packaging, e.g. in larger font size, and it is recommended to mention them on the front of the packaging. **This requirement is optional for multilingual packs**.	
Name of the product ☐	• The name should be stated as per the respective sections of the QRD product information template. • Format of the product name can differ from the format used in the PI.	
Print size, quality and type ☐	• Minimum 8 pt. • The text should be easily readable (print type, size and space between lines) for the healthcare professionals, farmers or animal owners. •	
Print colour ☐	• Distinguishable colours from the background for print of characters should be used. • Use of background colour should not adversely impact on readability of the text. • Do not use green on red or red on green, as these pose problems for people who are colour blind.	
Pictograms/Logo ☐	• The applicant/ MAH should refer to the guidance on pictograms until this is superseded by the Implementing Act providing a list of abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3) of Regulation (EU) 2019/6..	

B. IMMEDIATE PACKAGE		***Comments***
Layout of text ☐	• Multilingual packs should be clearly legible and, where practical, grouping of text elements for each language is recommended. • The use of language abbreviation may also be used to distinguish grouped languages.	
Barcode ☐	• A barcode is allowed on the labelling.	
QR (Quick response) code ☐	• The applicant/MAH should refer to the QR code guidance	

B. SMALL IMMEDIATE PACKAGING UNITS including blisters, strips and ampoules		***Comments***
Critical labelling elements ☐	• **(Invented) name of the veterinary medicinal product** • **Active substance** • Batch number preceded by the word "Lot" followed by the appropriate space to insert the number. • Expiry date (mm/yyyy) preceded by the abbreviation "Exp." and followed by the appropriate space to insert the date. • **Pictograms:** (It is strongly recommended to include at least an (approved) pictogram of the target species e.g. for spot-ons where there is risk of confusion between dog and cat presentations.) • **The bold elements** to be in larger font size, where feasible.	
Name of the product ☐	The name should be stated as per the respective sections of the QRD product information template • Format of the product name can differ from the format used in the PI.	
Print size, quality and type ☐	• Minimum 8 pt. With regard to multi-lingual packaging and very small bottles/vial sizes, e.g. 2 or 10 ml, 8 pt. is in most cases not achievable, but the closest font size should be sought. • The text should be easily readable (print type, size and space between lines) for the healthcare professionals, farmers or animal owners. •	

B. SMALL IMMEDIATE PACKAGING UNITS including blisters, strips and ampoules		***Comments***
Print colour ☐	• **Distinguishable** colours from the background for print of characters should be used. • Use of background colour should not adversely impact on readability of the text. • Do not use green on red or red on green, as these pose problems for people who are colour blind.	
Layout of text ☐	• Multilingual packs should be clearly legible and where practical, grouping of text elements for each language may be done.	
Barcode ☐	• A barcode is allowed on the labelling.	
QR (Quick response) code ☐	• The applicant/MAH should refer to the QR code guidance	

D. PACKAGE LEAFLET		***Comments***
Critical elements ☐	• It is advisable that all elements should follow the order of Annex III.B of the current QRD template and the approved package leaflet.	
Name of the product ☐	• The name should be stated as per the SPC; • In case of multilingual package leaflets the information above should appear at the beginning of each language. • The use of language abbreviations may also be used to distinguish multilingual package leaflets.	
Print size, quality and type ☐	• Minimum 8 pt. • The text should be easily readable (print type, size and space between lines) for the healthcare professionals, farmers or animal owners. • The readability should be acceptable e.g. font size, layout and paper quality. • The pictures explaining the use of the medicinal product should be clearly printed.	
Print colour ☐	• **Distinguishable** colours from the background for print of characters should be used.	

D. PACKAGE LEAFLET		***Comments***
Local representatives ☐	• Listing of local representatives is not a requirement, but if included in the product information annexes, the full list for all Member States must be stated. However, a representative may be designated for more than one country and may also be the MAH where no other local representative is indicated. In cases where the same representative is designated for more than one country, the representative's details may be listed only once below the names of the countries concerned. • In the **printed package leaflet**, only the concerned local representative can be mentioned provided the whole list has been included in the product information annexes.	
QR (Quick response) code ☐	• The applicant/MAH should refer to the QR code guidance	