VMD Product Literature Standard: Table of mock-up requirements

To appear on the packaging and package leaflet	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
Name and addresses of MAH, site of batch release and distributors						
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 for joint labels). A local representative may also be included, but this is not a legal requirement. You may include the details of a named distributor on your labels instead of, or as well as the MAH details.						
Product name followed by its strength and pharmaceutical form The information must match the SPC/QRD. The whole product name should appear together. Copyright or trademark symbols are allowed.	X	X	X	X	X	X
Name and quantity of the active substance and the name of any excipient						
If shown in Section 2 of the SPC	X	X	X			X
The name of the active substance and quantity				X		
The name of the active substance					X	
Pharmaceutical form Not required if it forms part of product name	X	X				X
Indications						
Non-prescription products	X	X	X			X
Prescription products	X					X
Contraindications	X					X

To appear on the packaging and package leaflet	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
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 HMA website.	X	X	X			X
Dosage *If there is a package leaflet* *No package leaflet*	X	 X	 X			 X
Method / route of administration The method or route of administration should be written as per the SPC. Standard abbreviations 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
Withdrawal period For food producing species the withdrawal period, as per the agreed QRD, 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 unless otherwise agreed in the QRD. If agreed during assessment, additional national disposal and environmental warnings may also need to be included on the packaging.	X	X				X
Date package leaflet was last approved EU Applications – Last day of assessment phase National Applications – Date of issue	X					X

To appear on the packaging and package leaflet	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
GB-national applications completed in parallel with an NI-MRP/DCP/CAP application - Date the EU procedure concluded.						
Other information Further information required in the MA	X					X
Batch Number		X	X	X	X	X
Expiry Date The expiry date should be written clearly to avoid confusion 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
Content by weight, by volume or by number of doses	X	X	X	X		X
The marketing authorisation (MA) number(s) UK (for MAs issue prior to 1st Jan 2021 and valid on a UK-wide basis) - Vm xxxxx/xxxx UK(GB) or GB– Vm xxxxx/xxxx UK(NI) – VM xxxxx/xxxx IE - 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** Vm xxxxx/xxxx POM-V **IE** 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. Prescription products should include the statement: "To be supplied only on veterinary prescription".	X	X	X	X (IE only)		X

To appear on the packaging and package leaflet	Package Leaflet	Outer Packaging	Immediate Packaging	Small Immediate Packaging	Blisters or Strips	Label no leaflet
UK only: While it is not mandatory to include the distribution category on the small immediate packaging, we strongly encourage you to do so. IE only: It is mandatory to include the distribution category on the small immediate packaging.						
The words 'Keep out of the sight and reach of children'	X	X				X
The in-use shelf life (if appropriate) should be listed on multidose containers ≥ 50 ml		X	X			X
Space to record the discard date, if appropriate 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