

Veterinary Medicines Guidance Note

Marketing Authorisations for Veterinary Medicinal Products – Requirements for Product Literature and the Summary of Product Characteristics (SPC)

No 18 *Last updated September 2009*



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE

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INVESTOR IN PEOPLE

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INTRODUCTION

1. This is one of a series of Veterinary Medicines Guidance (VMG) Notes explaining the requirements under the Veterinary Medicines Regulations ('the Regulations'). The Regulations are revoked and replaced every year, so the references to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are not shown in this VMG Note. The VMG Notes will be updated as necessary and the date of the most recent update is shown on the front cover.
2. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. VMG Note 1: *An Introduction to Marketing Controls on Veterinary Medicines* gives basic information about the scope of the Regulations and the requirements for Marketing Authorisations (MAs).
3. The purpose of this note is to:
 - Describe the information required to appear on the product literature of veterinary medicinal products;
 - Outline the procedure for the submission and approval of mock-ups for National applications;
 - Describe the information required to appear on the Summary of Product Characteristics (SPC);
 - Outline the procedure for the submission and approval of SPCs for National applications.
4. Other VMG Notes provide further information on the application procedures including:

VMG Note 2: *Marketing Authorisation for Veterinary Medicinal Products – Applications and Renewals*, and

VMG Note 4: *Marketing Authorisation for Veterinary Medicinal Products – National (Type IA/IB/II) Variation Procedures*.

EXPLANATION OF TERMS

PRODUCT LITERATURE

5. The definition of product literature is as follows:
 - The **product literature** is the immediate packaging, the outer packaging and the package leaflet (if there is one);

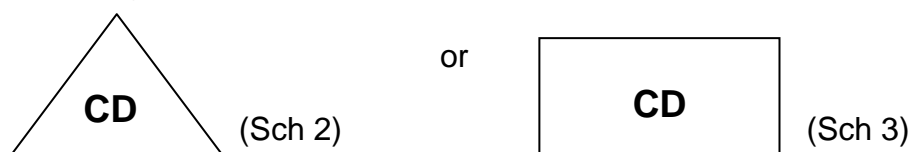
- The **immediate packaging** is the container which immediately encloses the product but does not include capsules which are administered as part of the product;
 - The **outer packaging** is considered to be any box, packet, carton or other article in which one or more immediate containers are enclosed;
 - The **package leaflet** (formerly called a package insert) is a leaflet inserted into the packaging of the product and contains information for the user that accompanies the veterinary medicinal product.
6. Note, however, that applicants should clearly identify the package leaflet as such when submitted for assessment. The package leaflet is different to the data sheet. The VMD does not assess the data sheet because it is not a requirement under legislation; however the information in the datasheet must be the same as the information contained in the approved SPC.

Mock-Ups

7. The term “mock-ups” includes electronic colour versions, or colour print versions, of the artwork or specimens of the product literature as defined in paragraph 4.

GENERAL REQUIREMENTS

8. To ensure that an application for a new MA, a renewal or a variation to an existing MA, satisfies the criteria set out in the Regulations, the product literature is assessed and authorised. The labelling of the cartons in which the product literature is packed for distribution to wholesalers and retailers (shipping packs) is **not** assessed.
9. The MA holder is responsible for the immediate packaging, outer packaging and any package leaflet of an authorised veterinary medicinal product (VMP) as set down in the MA. The VMD must approve all product literature, and any subsequent changes to the text (including its font and layout) may only be made as a variation to the authorisation. However, small changes to the labelling that have no effect on the legally required statements and warnings, or their legibility, may be made without the need for a variation. For example, a change to a barcode would not necessitate a variation.
10. VMPs 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 or a box (see diagrams below) and the relevant schedule detailed on their labels.



PRODUCTS AUTHORISED WITH LIMITED EFFICACY DATA

11. 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 such cases the package leaflet and labels must make it clear to the person prescribing or using the product that, in certain specified respects, the particulars available concerning the medicinal product are incomplete. For further information please refer to VMG Note 5: *Marketing Authorisation for Veterinary Medicinal Products – Provisional Marketing Authorisations*.

REQUIREMENTS FOR THE SUMMARY OF PRODUCT CHARACTERISTICS

12. The requirements for SPCs are detailed in the Regulations. MA Holders should also refer to the following Notice to Applicants (Volume 6C) Guidelines, which are available on the EMEA website (www.emea.eu.int), when producing their SPCs.
 - [Guideline on Summary of Product Characteristics SPC - Pharmaceuticals](#) for VMPs (volume 6C: Regulatory Guidelines)
 - [Guideline on Summary of Product Characteristics SPC - Immunologicals](#) for VMPs (volume 6C: Regulatory Guidelines)
13. We have produced SPC templates to help guide applicants and recommend that they be used. They can be found on our website (www.vmd.gov.uk), under Industry Information / Applications Page / Guidance Documents.

SECTIONS 1, 9 AND 11 OF THE SPC

14. However, the VMD is aware that it is not totally clear what is required in Sections 1, 9 and 11 of the SPC. Therefore, we are providing the following information to ensure a consistent approach.
15. The following will apply to new applications and applications where SPC changes are required. It will only apply to SPCs of nationally authorised MAs. It will not apply to SPCs authorised through the MRP or DCP routes and will not be applied retrospectively.
 - [Section 1 \(Product name\)](#)

Pharmaceutical products:	Name + strength + pharmaceutical form Target species only if necessary
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Immunological products: Name
 Vaccine strain only if necessary/relevant
 Target species only if necessary/relevant

- Section 9 (Date of first authorisation/date of the renewal of the authorisation)

Date of first authorisation: This applies to both pharmaceutical and immunological products.

- Section 11 (Further information)

This is a national requirement only.

The text 'Section 11' will not be included in the SPC. The VMD (not the applicant) will add 'Section 11', plus the relevant information, in exceptional circumstances only.

This applies to both pharmaceutical and immunological products.

The following are examples of what the VMD would consider appropriate:

1. Reference to specific requirements relevant to the PET Travel Scheme;
2. Restrictions to the supply of the product subject to national or EU control measures.

REQUIREMENTS FOR PRODUCT LITERATURE

16. The Regulations detail the requirements for information that must be on your product literature. All labels and package leaflets must be in English, and may contain in legible characters the words “UK authorised veterinary medicinal product” or, if specified in the MA, other suitable wording.
17. This logo may also be used, either in blue or in greyscale. It can be downloaded from the VMD website (www.vmd.gov.uk) and is sizable so it can fit a convenient space; however it must remain legible.



18. It should be noted that inclusion of the statement, in whatever format, is not a mandatory requirement. However, the VMD encourages MA holders to include some suitable approved wording on their product literature.
19. The labelling requirements apply to the immediate packaging, outer packaging and the package leaflet of the retail product literature.
20. All packaging must be presented in a legible manner that is understood by those involved in the supply and administration of the product. The critical information should appear in as large a font as is possible to maximise legibility.
21. In order that the user of the medicine can easily see all the necessary information in one place, all information should be placed on either the immediate or outer packaging or package leaflet.

LABELLING

22. The label must provide all the following information on the immediate packaging if practical to do so. The information is listed as a guide to the normal order of priority, in which it must appear on the container. However for certain products the order of priority may need to be modified to ensure that the most important warnings for those products are immediately apparent.
 - a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;
 - b) the name and proportion of each active substance and of any excipient if this is specified in the marketing authorisation;
 - c) the route of administration (if not immediately apparent);
 - d) the batch number;
 - e) the expiry date;
 - f) the words “For animal treatment only” and for POM-V and POM-VPS products also the words, “To be supplied only on veterinary prescription”;
 - g) the contents by weight, volume or number of dose units;
 - h) the marketing authorisation number;
 - i) the marketing authorisation holder or distributor name and address;
 - j) a suitably labelled space to record discard date (if relevant);
 - k) the target species;
 - l) the distribution category;**
 - m) the words “Keep out of reach of children” or Keep out of reach and sight of children”;**
 - n) storage instructions;
 - o) the in-use shelf-life (if appropriate);
 - p) for food-producing species, the withdrawal period for each species or animal product concerned;
 - q) any warning specified in the marketing authorisation (target species or user or environment) considered to be essential for that product (e.g. penicillin hypersensitivity warning / mineral oil self injection);
 - r) disposal advice;
 - s) full indications;

- t) dosage instructions;
- u) contra-indications;
- v) further information required in the marketing authorisation;

Please note that the information highlighted in **bold** is a national requirement.

23. There is no need for any outer packaging or package leaflet if you are able to fit all of the required information on the immediate packaging. The use of flag or concertina labels on the immediate packaging is acceptable and is one way to provide sufficient space for the required statements and warnings.
24. If you are unable to fit all the information required in paragraph 22 on your immediate container then you must at least have the following information:
- a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;
 - b) the name and proportion of each active substance, (and of any excipient if knowledge of the excipient is needed for safety reasons);
 - c) the route of administration (if not immediately apparent);
 - d) the batch number;
 - e) the expiry date;
 - f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”;
 - g) the words “Keep the container in the outer carton”;
25. In addition to this information, the immediate packaging must also have as much information as reasonably practical from paragraph 22 while still being able to be easily read.

PACKAGE LEAFLETS

26. If all the information cannot be provided on the immediate container then the packaging must contain all the information at paragraph 22. If this is not reasonably practical, a package leaflet must be enclosed in the package. The package leaflet must provide all the information listed at paragraph 22 and relate solely to the veterinary medicinal product with which it is included. The immediate packaging and outer packaging must refer to the use of the package leaflet and must carry as a minimum the information set out in paragraph 24 together with as much information as reasonably practical from paragraph 22.

AMPOULES

27. In the case of ampoules or other small unit dose forms (for example tablets in blister packs), where the container cannot have the required information in a size that can be easily read, the following information must be shown on the immediate container:
- the name of the veterinary medicinal product ;
 - the name and quantity of the active substance

- the route of administration (if not immediately apparent);
 - the batch number;
 - the expiry date;
 - the words “For animal treatment only”;
28. As above, the packaging must contain all the information in paragraph 22. If this is not practical then a package leaflet must be supplied.

SMALL CONTAINERS OTHER THAN AMPOULES

29. In the case of small immediate containers, such as vaccine vials or very small volume spot-on products, containing a single dose, other than ampoules or other small unit dose forms, on which it is impossible to give the particulars mentioned in paragraph 24, then the container must include at least the batch number and expiry date and as much of the other information stated as possible. All information in paragraph 22 must still appear on the outer packaging. This should only occur in exceptional circumstances.

ADDITIONAL VMD REQUIREMENTS FOR LABELLING

30. Packaging may not refer to websites; however, it is acceptable to include a telephone number or an e-mail address.
31. The withdrawal period must always be shown, even if it is zero days, for products intended for food producing species.
32. For all products, the distribution category must appear in a box e.g.

AVM-GSL

33. The following statement should appear: “If signs of disease persist or appear consult your Veterinary Surgeon”, or words to this effect, for products in the distribution category AVM-GSL. In addition, if the product is intended for topical use it must carry the warning “For external use only”.
34. The name and level of any preservative should always be declared for parenteral (injectable) products and ophthalmic products.
35. The use of clear diagrams and pictograms in addition to wording, to reinforce the correct use of the product, is encouraged.
36. The inclusion of the pharmacopoeial grades of active substances or excipients on packaging is no longer required and is being phased out. Therefore, if the only change to be made to a label concerns the deletion of statements such as BP and Ph. Eur, it may be made without the prior approval of the VMD.

MULTIDOSE CONTAINERS FOR PHARMACEUTICAL PRODUCTS

37. For multi-dose containers of quantities **greater than**, or **equal to** 50ml, the in-use shelf-life and a suitably labelled space for either the date of first use or discard date must always appear on the label of the immediate container.
38. For multi-dose containers of **less than** 50 ml, the expectation is that a suitably labelled space for the discard date will be included on the label of the immediate container. The in-use shelf life should normally be included on the label of the immediate container. Where an in-use shelf life is included, the suitably labelled space may be used to record a date of first use rather than a discard date.
39. If you consider that there is insufficient space to include these important statements, you must first consider whether or not you have fully optimised the layout, font size etc. of the label. If necessary, to ensure the legibility of important warnings, the scale of promotional statements or company logos should be reduced. If, despite efforts to improve the available space on the label, you are convinced that the inclusion of these statements will render more important warnings illegible, you should submit to the VMD a mock-up of the proposed label to illustrate this. If the VMD is satisfied that the inclusion of these statements is impractical, then you may include the statements on the outer package instead.

EXPIRY DATE ON LABELS

40. In order to avoid confusion on whether the expiry date means that the product can be used until the end of the stated month, or used by the end of the preceding month, the expiry date of your product should be clearly expressed. For example, the labels or package leaflet could include the phrase “Do not use after the expiry date stated on the label”. Alternatively the following formats for the expiry date of the labels could be used:
 - Expiry date: DD/MM/YY;
 - EXP: DD/MM/YY;
 - EXP: end MM/YY;
 - Use by end MM/YY;
41. Where the shelf life of the product is less than 12 months then a DD/MM/YY format should be used for the expiry date.
42. Expiry dates, and batch numbers, may be printed, embossed or engraved onto labels. However, it is essential that, irrespective of the method of application, these are clear and easy to find.
43. It is illegal to sell a product after its stated expiry date.

SUBMISSION AND APPROVAL OF SPCs

44. Applicants are required to submit a draft SPC with an application whether it is for a new, renewal or variation procedure (where the proposed change affects the SPC). For new applications only, SPCs should be submitted electronically in MS Word format. The wording and layout of the draft SPCs will be checked during the assessment process and any proposed amendments will be annotated on the draft version.

APPLICATIONS FOR NEW MAS

45. The VMD will send a draft SPC to the applicant at the end of the assessment period (i.e. once all assessors have signed off an application). The clock will stop pending receipt of the revised electronic SPC and will re-start once the correct version has been received. The revised SPC will be checked and issued with the approval documentation.

RENEWAL AND VARIATION APPLICATIONS

46. **For minor and/or routine changes** – the VMD will update the eSPC on behalf of applicants once the application has been approved; we will print out a hard-copy, which will be stamped 'approved', signed and issued to the applicant along with the rest of the authorisation documentation. The website will then be updated to show the latest authorised version.
47. **For more substantial changes** – The approved SPC will be issued to the applicant along with the rest of the authorisation documentation. Applicants are then required to submit a revised electronic version of the SPC, incorporating all the proposed amendments, within 30 days of the grant of the application. Once received, the VMD will check the revised SPC against the approved version held on file. If any discrepancies are identified the VMD will highlight them on the SPC and return it to the applicant requesting an updated version. If correct, the VMD will print out a hard-copy, which will be stamped 'approved', signed and issued to the applicant. The website will then be updated to show the latest authorised version.

Please note if an SPC is not received within 30 days, the VMD will make the amendments to the document on behalf of applicants as per the procedure described in paragraph 47.

GENERAL INFORMATION

48. Before issuing an approved eSPC the VMD will amend the header to include the issue date (for new applications) or revision date (for variations or renewal applications), which will be the date of issue of the application, and application number, e.g. Issued/Revised 10/04/2008 – AN 01234/2008, this will show on each page and will help maintain version control of the document. We will also amend the 'Date of Last Revision' to reflect the header, for consistency.
49. The agreed SPC will then be retained as the latest version and published on the VMD website in accordance with the Regulations

50. The VMD would prefer revised SPCs to be submitted in electronic format, preferably Microsoft Word, by email, or on a disc, with the product name and application number clearly marked. The e-mail address to send your revised SPC to is: f.manin@vmd.defra.gsi.gov.uk.

SUBMISSION AND APPROVAL OF PRODUCT LITERATURE

51. Wherever possible mock-ups of the product literature should accompany applications. Mock-ups should reflect the proposed labelling and packaging exactly. The VMD's assessors need to see the mock-ups in order to fully assess the application. This is particularly relevant where sight of the labelling in colour is necessary for the assessment, e.g. where use of colour text could potentially mean that some or all it could be difficult to read or would not adequately draw the eye to the text. However, if the requirement to see mock-ups is not deemed necessary (i.e. for certain variation applications) then text will be accepted. The requirements for individual application types are set out below.

GENERAL REQUIREMENTS

Format

52. Mock-ups may be submitted in either electronic format (i.e. computer-generated) or hard copy. It should be noted that e copies do not always print out as clearly as hard copy mock ups, particularly for small labels and small font text. Applicants may choose to submit printed mock ups that are clearer to read. If e copies are not legible, applicants will be asked to submit printed hard copy mock ups. They must be submitted as actual size or, if not, the dimensions must be provided; e.g. large containers may have reduced size mock-ups provided an indication of the actual size is given. Very small ones should be provided as actual size but, in addition, a scaled up copy should also be supplied to make it easier for the VMD to mark any required changes. If applicants wish to deviate from this procedure, they must first discuss it with the relevant assessor, who will deal with each request on its merits. Electronic versions, with the product name and application number clearly marked, should be provided on a disc, or via email to f.manin@vmd.defra.gsi.gov.uk.

Incomplete Mock-Ups

53. Your application will be refused at validation if it has inadequate mock-ups (or text). If an application is validated but later found to have incomplete mock-ups, eg. missing package leaflet, labels, box or carton, the clock will be stopped at the end of the initial assessment period and the missing data requested. The clock will restart once the missing data has been received. The VMD encourages applicants to use the checklist at Annex A when submitting mock-ups.

Mock-ups for non-marketed products

54. Applicants are required to present the product as it is intended to be marketed; if they choose not to market the product then that is their choice. The VMD has to assess whether the application for the product satisfies the criteria set out in the legislation and this includes the assessment of mock-ups.
55. To ease the burden on applicants, the VMD is happy to accept text with applications. If the Marketing Authorisation Holder (MAH) then decides to market the product they must first obtain VMD's approval of the finalised mock-ups. The assessment of these mock-ups will be dealt with via a variation application, which will attract the normal fee. Similarly, if a MAH only markets some of the authorised pack sizes, then text may be submitted for the non-marketed pack sizes. Again, if the MAH then decides to market one of these pack sizes, it will be necessary to submit a variation application, which will attract the normal fee.

Pack sizes

56. Mock-ups for all pack sizes (e.g. 50ml, 100ml etc.) should be submitted with the application. However, reference should be made to paragraphs 52 and 53.

NEW MA APPLICATIONS, INCLUDING EXTENSIONS AND COPYCATS

57. At the time of application, where possible, mock-ups accompanied by text should be submitted with a new application. Where this is not possible, text should be submitted before the application can be validated. However, mock-ups must be submitted before the assessors can sign off an application. The assessors will deal with the submission of mock-ups during the assessment period and will inform the applicant of any required changes.
58. Please note that the requirements for the submission of mock-ups for Parallel Import (MAPI) applications are slightly different to the above. VMG Note No. 6: *Marketing Authorisations for Veterinary Medicinal Products – Parallel Imports* provides further information.
59. Amended versions will be sent to the applicant at the end of the assessment period (i.e. once all assessors have signed off an application). The clock will stop pending receipt of revised mock-ups and will re-start once the correct mock-ups have been received. Revised mock-ups will be checked and issued with the approval documentation. Again, the VMD encourages applicants to use the check list at Annex A when submitting the revised mock-ups.

RENEWAL APPLICATIONS

60. Current product literature should be supplied in order for the application to be validated. For products that are not marketed, text will suffice (see paragraphs 53 and 54). Please note there should be no proposed changes highlighted on the product literature submitted as part of a renewal application; all changes to product literature must be dealt with by way of a variation application; therefore

the product literature submitted as part of the renewal application should reflect the latest authorised versions.

61. During the assessment process the assessor(s) will identify any changes to the product literature and notify the applicant of these proposed changes in their 'question letter'. The applicant should submit revised versions, incorporating all proposed changes, part of their company response; if an applicant wishes to query a proposed amendment they should discuss this with the appropriate assessor(s) before submitting their company response. Approved versions will be issued to the applicant with the rest of the authorisation documentation once the application has been approved.

VARIATION APPLICATIONS

62. If the variation affects the product literature then the current packaging should be supplied, accompanied by draft versions of the relevant product literature showing the proposed changes. The term "draft" refers to the same mock-up but printed in black and white, i.e. the artwork, size, format and layout are the same; the only difference is the lack of colour. Failure to supply these items, if required, will result in an invalid application.
63. The criterion for granting or refusing an application for a variation is simply whether the proposals will adversely affect the safety, quality and efficacy of the authorised product. It is a matter of judgement, depending upon the nature of the variation, e.g. any change that would alter the labels' content or size, as to whether the VMD needs to see mock-ups during the assessment. If mock-ups are required then the assessors will request these during the assessment process.
64. Where changes to the mock-ups are required, the assessors will inform the applicant of this and also a date by which the revised product literature should be introduced to the market place. Unless requested, revised versions of the mock-ups do not need to be submitted to the VMD following the approval and issue of the variation application.
65. When the VMD approves labels and package leaflets these will be signed, dated and returned to you. In the case of variations and renewals, where a timescale for the introduction of any required changes has been agreed, this will be indicated on these documents.

DECENTRALISED AND MUTUAL RECOGNITION APPLICATIONS

66. Applicants are required to submit revised mock-ups, accompanied by a completed checklist (see Annex A), following the end of the assessment period for Decentralised and Mutual Recognition procedures (new, variation (where applicable) or renewal). Revised mock-ups will be checked and issued with the approval documentation. Mutually recognised products, which are not marketed in the UK, are subject to the same criteria outline in Paragraphs 52 and 53.

67. Applicants should advise the VMD at the end of the procedure if joint labelling with Ireland is required. Joint labelling is where a veterinary product has undergone either the Mutual Recognition or Decentralised procedure, and the applicant requires one set of labels for the product to be marketed in Ireland and the UK. Applicants must advise the VMD as soon as the procedure has ended of their intention to have a joint label for their product.

MULTI LINGUAL PACKS

68. All labels and package leaflets must be in English. However, they may contain other languages provided that the information given is identical, the requirements of the UK MA are respected and the legibility of the UK warnings is not compromised.
69. A variation application is required for the use of multi-lingual labels for an existing product.

DEDICATED DISPENSING CONTAINERS

70. The authorised packaging of a product usually consists of either immediate packaging labelled with all of the required information and warnings, or outer packaging containing a labelled inner container and a package leaflet. Some distributors additionally provide empty, partly-labelled packs, such as envelopes, wallets or cartons for use with specific products. These are intended to be used by veterinary surgeons to supply the dispensed medicines. These product-specific (or manufacturer-specific) dispensing containers offer a convenience for the veterinary surgeon. For the company marketing the product, they help to promote the name of the product or the authorisation holder.
71. Where such dedicated dispensing containers are supplied to the veterinary surgeon separately from the authorised pack, they are not subject to the requirements applied to labels and other packaging texts for authorised products. Instead, the usual requirements for labelling of dispensed medicines will apply. However, if the dedicated dispensing containers are enclosed within the authorised packaging, then these are considered to form part of the authorised packaging and subject to scrutiny and approval by the VMD.
72. Veterinary medicines, which fall under the distributional category POM-VPS, may be supplied by Suitably Qualified Persons (SQPs). SQPs operating at registered merchants cannot supply only part of the contents of an immediate container, for example 200 ml of drench from a 500 ml pack. However, for certain medicines they may supply a number of immediate containers removed from a larger package as long as package leaflets are provided, for example two vials of vaccine from a pack of 24. In order to clearly identify these veterinary medicines

it is intended that the following statements will be introduced into the product literature and SPC:

Carton/Package Label

“Individual units of this product may be supplied but each must be accompanied by a package leaflet.”

SPC, section dealing with the packaging:

“Each carton/package contains a sufficient number of package leaflets so that individual units may be supplied by Suitably Qualified Persons.”

FURTHER INFORMATION

73. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618 or E-mail: VMGNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.gov.uk).

ANNEX A

**Check list for the Submission of
Mock-ups**

ANNEX A CHECK LIST FOR SUBMISSION OF MOCK-UPS TO VMD

Item to be Checked	For applicant's use	For VMD use
Name of Product		
Strength(s) of product		
List the pack types and sizes approved (as per SPC)		
List the pack types and sizes to be marketed ¹		
Confirm that mock-ups of primary pack labels are enclosed for each pack size to be marketed		
State if there is any intermediate packaging and, if so, confirm that a mock-up of it is included for each pack size to be marketed		
State if there is a carton and, if so, confirm that a mock-up of it is included for each pack size to be marketed		
State if there is a package leaflet and, if so, confirm that:		
a) a mock-up of it is included,		
b) it is referred to on the label of the primary pack and carton,		
c) indicate the means of presenting it with the product		
Confirm that mock-ups are actual size or, if not, indicate the scale		
Check the legibility of the mock-ups, e.g. font size, colours, etc		
Confirm that all changes requested during the assessment phase have		

¹ Text rather than mock-ups may be included for packs that are not marketed.

VETERINARY MEDICINES GUIDANCE NOTE

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ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES