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The Checking Process of Mock-Ups and Specimens of outer/immediate labelling and package leaflets in the Centralised Procedure for Veterinary Medicinal Products

1. General principles

1.1 Labelling and package leaflet requirements

- All veterinary medicinal products are required to be accompanied by outer and immediate labelling texts and a package leaflet (unless all the necessary information can be conveyed on the immediate and outer labelling). In accordance with Article 14(3) of the **Regulation (EU) 2019/6 on veterinary medicinal products (the Veterinary Medicines Regulation (EU) 2019/6))**, the package leaflet shall be written and designed to be readable, clear and understandable, in terms that are comprehensible to the general public. Member States may decide that it shall be made available on paper or electronically, or both.

Articles 10, 11, 12 and 14 of the **Veterinary Medicines Regulation (EU) 2019/6** define the particulars to be included on the outer/immediate/small immediate labelling and in the package leaflet. Veterinary product information templates are provided in all EEA languages on the Agency website reflecting the particulars which must appear on the labelling and package leaflet of veterinary medicinal products.

The safe and correct use of all veterinary medicinal products depends on users reading the labelling and packaging accurately and being able to understand and act on the information presented. The primary purpose of labelling and packaging should therefore be the clear unambiguous identification of the veterinary medicinal product and the conditions for its safe use. Applicants/MAHs must make best use of the space available to ensure that the critical/important information for the safe use of the veterinary medicinal product is legible and clearly mentioned on the labelling and in the packaging leaflet, so that confusion and medication errors are minimised.

1.2 Principles applied to the checking of mock-ups and specimens

A proposed labelling text for the immediate and outer packaging shall be provided in accordance with Articles 10, 11 and 12 of the Veterinary Medicines Regulation (EU) 2019/6)**,** together with a package leaflet where one is required pursuant to Article 14. In addition the applicant is recommended to provide one or more specimens or mock-ups of the final presentation(s) of the veterinary medicinal product in at least one of the official languages of the European Union; the mock-up may be provided in black and white and electronically where prior agreement from the competent authority has been obtained.

A 'mock-up' is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the

three dimensional presentation of the label text is clear. It is generally referred to as a "computer generated version". Mock-ups may be submitted electronically, either in the Part 1 of the dossier as part of a specific submission, or to vet.applications@ema.europa.eu in all other cases.

A "specimen" is a sample of the actual printed outer and immediate packaging materials without any contents ("empty immediate packaging") and the "real" package leaflet.

The mock-up and specimen checking process is based on the following general principles:

- The Agency, through the translations checking process, will ensure that high-quality product information in all EU languages, as prepared by the Marketing Authorisation Holder (MAH) and checked by the Member States prior to the granting of the Marketing Authorisation (MA) is included in Commission Decisions on centrally authorised veterinary medicinal products;
- MAHs are responsible for the correct implementation of the agreed product information texts in their printed packaging materials, in line with the Commission Decision and relevant EU legislation;
- The Agency will not perform a systematic check of mock-ups, but will recommend applicants/MAHs to provide mock-ups taking into account a risk based approach;
- In some cases, the rapporteurs or the Agency may ask for a sample to be submitted as an aid in better understanding e.g. the shape of a novel type of container or applicator, or in order to get a clearer understanding of space limitations in regard to labelling issues.
- The proposed outer and immediate labelling and package leaflet should be in compliance with the requirements outlined in Articles 10, 11, 12 and 14 of Regulation (EU) 2019/6, and the agreed product information. Detailed reviews of the content of the labelling and leaflet proposals and their translations, i.e. Annexes III.A and III.B, will have taken place during the scientific assessment and linguistic review of the application.
- Presentation of the information in terms of text size, colour and lay-out is an important factor in overall 'readability' of labelling and package leaflet, and this should be taken into account when preparing mock-ups or specimens. Such a general, so-called 'readability' check of mock-ups or specimens should focus on overall lay-out and design of the packaging and leaflet, font-sizes, positioning of text, use of colours, pictograms, differentiation between strengths, presentation of critical labelling information etc.
- When submitted (see section 2), mock-ups must be included in Part 1 of the application dossier.
- When required by the Agency or the Rapporteurs, mock-ups or specimens should be submitted using the "Mock-Ups/Specimens Submission Form" (see Annex 2).
- When submitting mock-ups or specimens to the Agency, applicants/MAHs will declare that:
    - the mock-up/specimen is in compliance with the relevant approved product information texts
    - the mock-up/specimen is printed in the official language(s) of the Member State(s) where it will be marketed
    - that the final packaging will exactly mirror the approved mock-ups.
- Any comments on the mock-ups/specimens will be communicated to the applicant/MAH, taking into account the nature and amount of issues identified. If major issues are identified, the

Agency may request revised mock-ups/specimens to be provided for review or may even request a recall of already marketed products.

2. The mock-up and specimen checking process

The following recommendations and checking process will apply, as summarised in Annex 1:

2.1 New Applications and specific variations requiring assessment[1] at submission of the initial marketing authorisation application

For validation purpose the Agency requests that all applications for a marketing authorisation should include the labelling texts in English. Applicants are recommended to submit one English mock-up and one multi-lingual mock-up ('worst case') of the outer and small immediate packaging for each pharmaceutical form in the smallest pack size.

The texts for the Summary of Product Characteristics (SPC), labelling and package leaflet should be presented according to the veterinary product information templates developed by the Agency (see the latest version of "Quality Review of Documents veterinary product-information annotated template (English) - clean").

At submission and during assessment, only the English language version of the product information is submitted and reviewed. Applicants may present the SPC and package leaflet for different strengths of the same pharmaceutical form in one document. Different pack sizes of the same strength can be presented in one labelling document. Translations of the agreed SPC, labelling and package leaflet in all EEA languages are to be provided after adoption of the CVMP English opinion.

Before marketing the product and after receipt of CVMP opinion/Commission decision

There is no requirement to submit mock-ups systematically. Instead, the applicant is responsible to ensure that their packaging is correct from the outset. A mock-up checklist is available, summarising critical labelling elements and providing guidance for compiling compliant mock-ups.

The Agency will not routinely perform checks of mock-ups but will instead institute random post-authorisation checks (as per current guideline possibilities). This new approach is to ensure that all mock-ups may be checked, rather than only those specifically submitted for checking.

It is therefore the responsibility of the applicant to ensure that their mock-ups and subsequent packaging are in conformity with the adopted opinion and then Decision text. The veterinary medicinal product may therefore be marketed once the MAH is satisfied that their packaging is in line with all requirements. Applicant does not need to seek confirmation from the Agency that their mock-ups are acceptable.

Upon receipt of a specific request from the Agency to submit their mock-ups, any applicant should be in a position to provide such mock-ups of the requested packaging and will be asked to deal with any observed issues that could be highlighted during the specific review by the Agency.

2.2 Transfer of MAH

According to point 6 in the Annex to Regulation (EC) No 2141/96 on transfers of centrally authorised medicinal products, mock-ups are to be included in the transfer application. At submission, applicants should therefore provide an English and multi-lingual ('worst-case') colour mock-up of outer and

[1] variations requiring assessment classified as changes of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species in chapter I of the EMA/CMDv Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations

immediate packaging and package leaflet for each pharmaceutical form in each container type (e.g. blister and bottle, vial) in the smallest pack-size.

However, if the transfer only affects the MAH details on the labelling and package leaflet without any impact on overall design, one relevant example (multi-lingual if possible) of the revised outer and immediate packaging and package leaflet of one presentation is sufficient.

A declaration from the new MAH stating that only the details of the MAH have been modified, and that such changes will be introduced in all product presentations should be included in the 'Mock-up/Specimen Submission Form'. The Agency will perform a general check within 15 working days of receipt and will check if any previous comments on specimens have been duly implemented. The MAH will be informed about the outcome of the check.

2.3 Other post-authorisation procedures (including variations)

The Agency will not routinely perform checks of mock-ups but will instead institute random post-authorisation checks (as per current guideline possibilities). This new approach is to ensure that all mock-ups may be checked, rather than only those specifically submitted for checking.

Annex 1

Summary of mock-ups and specimen submission recommendations

New Applications and specific variations requiring assessment

When	What to submit	When checked
At submission of application	No submission of mock-ups / specimen requested If submitted: Colour mock-ups of outer and immediate packaging for each pharmaceutical form in each container type (e.g. blister, bottle, vial…) in the smallest pack-size · 1 EN mock-up · 1 multi-lingual mock-up ("worst-case") Mock-ups of package leaflet may be included (optional)	If submitted, checked within 15 days from receipt of the application
In advance of marketing	No submission of mock-ups / specimen requested	

Transfers

When to submit	What to submit	When checked
At submission of application	Colour **mock-ups** of **outer and immediate packaging and package leaflet** for each pharmaceutical form in each container type (e.g. blister, bottle, vial …) in the smallest pack-size · 1 EN mock-up · 1 multi-lingual mock-up ("worst-case") However, if the transfer only affects the MAH details on the packaging and package leaflet without any impact on overall design, one relevant example (multi-lingual if possible) of the revised outer and immediate packaging and package leaflet of any presentation would be sufficient.	Within 15 working days from receipt of the application

Other post-authorisation procedures (including variations)

When to submit	What to submit	When checked
At submission of application	No mock-ups requested, unless specifically requested by the Agency	If submitted, checked within 15 working days from receipt of the application

Annex 2

MOCK-UP/SPECIMEN SUBMISSION FORM

MOCK-UP/SPECIMEN SUBMISSION FORM

Product (invented) name: **Marketing Authorisation Holder:**

Pharmaceutical form	**Strength**	**Container type (e.g. vial)**	**Procedure + Procedure number**	**Type of mock-up/specimen submitted**	**Member State(s) (e.g. DK/FI/SE)**	**OP**	**IP**	**PL***
			Choose from list	Choose from list		☐	☐	☐
			Choose from list	Choose from list		☐	☐	☐
			Choose from list	Choose from list		☐	☐	☐
			Choose from list	Choose from list		☐	☐	☐
			Choose from list	Choose from list		☐	☐	☐
			Choose from list	Choose from list		☐	☐	☐

Notes to the Agency (e.g. Description of changes affecting the layout or readability):

The undersigned declares that:

☐ The mock-ups/specimens are in compliance with the relevant approved product information.

☐ The mock-ups/specimens contain (all) the relevant official language(s) of the Member State(s) [2] where they will be marketed.

☐ Transfer procedures only (if applicable): only MAH details have been modified. The same changes will be introduced in all product presentations.

Contact details:

Signature:	Date:

* OP: Outer package, IP: Immediate package; PL: Package leaflet

[2] Except for Malta, where packs can be marketed in English and/or Maltese.