1 October 2018
EMA/14522/2007-Rev.1

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

1. Introduction

Previously, the Agency operated an extensive checking process of the Marketing Authorisation Holder's (MAH) printed materials for outer and immediate labelling of centrally authorised medicinal products as well as of the printed package leaflet in all EU languages ('mock-ups and specimens'). The process largely consisted of a detailed linguistic check of the printed materials of all authorised product presentations for all Member States, against the adopted product information annexes to the Community Marketing Authorisation (MA).

Over the past years, the checking process has been streamlined and simplified in view of a revised translation checking process agreed with the Member States at the end of 2005, and introduced at the beginning of 2006, reinforcing the linguistic checking of the product information annexes before granting of the Commission Decision.

Following implementation of this new process over the last few years, further review has been done and consideration has been given to implementing further process simplification.

DATE FOR COMING INTO EFFECT	1 April 2014*

* The revised checking process will apply as of 1 April 2014 to all centrally authorised veterinary products and all ongoing procedures.

For any questions on the updated process on mock-ups, please contact Vet.applications@ema.europa.eu.

2. General principles

2.1 Labelling and package leaflet requirements

All veterinary medicines 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). The package leaflet shall be written in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the product is marketed.

Title V of Directive 2001/82/EC defines the particulars to be included on the outer/immediate labelling and in the package leaflet. Templates are provided in all EEA languages on the Agency website (http://www.ema.europa.eu - Home - Veterinary regulatory - Product information - Product

information templates) which reflect the items which must appear on the labelling and package leaflet of medicinal products according to the Directive.

The safe and correct use of all medicines 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 medicine 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 medicine is legible and clearly mentioned on the labelling and in the packaging leaflet, so that confusion and medication errors are minimised.

2.2 New principles applied to the checking of mock-ups and specimens

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 "paper copy" or "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 revised mock-up and specimen checking process is based on the following general principles:

- The Agency, through the revised translations checking process, will ensure that high-quality product information in all EU languages, as prepared by the MAH and checked by the Member States prior to the granting of the 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 no longer perform a systematic check of mock-ups, but will ask 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 Directive 2001/82/EC 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, ‘blue-box’ location, differentiation between strengths, presentation of critical labelling information etc.
- Where required (see section 3), mock-ups must be included in Part 1 of the application dossier.

- When required by the Agency, mock-ups or specimens should be submitted using the “Mock-Ups/Specimens Submission Form” (see Annex 2). For renewals, mock-ups/specimens are to be provided only where the labelling and package leaflet have been significantly amended.
- When requested to submit mock-ups or specimens to the Agency, applicants/MAHs must 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
    - the ‘blue-box’ is in line with the relevant national requirements, as outlined in the current Guideline on Packaging Information. The local representative, when mentioned in the blue-box, is identical to the one mentioned in the package leaflet
    - 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.

3. The revised mock-up and specimen checking process

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

3.1 New Applications and Extensions

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, together with 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 SPC, labelling and package leaflet should be presented according to the 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.

3.2 Renewals

At renewal, the Agency will perform a check of the mock-ups only where there are significant changes to the product information.

3.3 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 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.

3.4 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 requirements

New Applications and Extensions

When	What to submit	When checked
At submission of application	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)	N/A
In advance of marketing	No submission of mock-ups / specimen requested	

Renewals

When	What to submit	When checked
As part of the renewal application	No submission requested, unless significant changes to the labelling have been made. In this case submit 1 multi-lingual example ("worst case" of mock-ups/specimens of outer and immediate packaging materials and package leaflet) or, if not available, a single language mock-up or specimen.	If submitted, checked during validation period

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) [1] where they will be marketed.

☐ The Blue Box(es) is(are) in line with the relevant national requirements, as outlined in the current Guideline on Packaging Information.
The local representative when mentioned in the blue box, is identical to the one mentioned in the package leaflet and in the approved product information.

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