EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

Checking process of mock-ups and specimens of outer/immediate labelling and package leaflets of human medicinal products in the centralised procedure

1. Introduction

Since February 2007 the European Medicines Agency (EMA) has been operating an extensive checking process of the marketing-authorisation holder's (MAH) printed packaging materials for outer and immediate labelling of centrally authorised medicinal products as well as of the printed package leaflet ('mock-ups and specimens').

The EMA has now reviewed the experience with the checking process and considers that further amendments/simplification can be introduced. This document presents the proposed revision[1] of the current checking process for human medicinal products, and provides further details on its practical implementation.

2. General principles

2.1. Labelling and package leaflet requirements

All medicines are required by European law to be accompanied by outer and immediate labelling texts and a package leaflet setting out comprehensive information which is accessible to and understandable by those who receive it, so that they can use their medicine safely and appropriately.

Title V of Directive 2001/83/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 EMA website http://www.ema.europa.eu, which reflect the items which must appear on the labelling and package leaflet of medicinal products according to the Directive.

[1] The checking process of mock-ups and specimens of outer/immediate labelling and package leaflets of human medicinal products in the centralised procedure has been updated to reflect the new address of the European Medicines Agency (section 2.4).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The safe and correct use of all medicines depends (amongst others) 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 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 medicine is legible and clearly mentioned on prime spaces on the packaging and in the leaflet, so that confusion and medication errors are minimised.

The 'Guideline on the readability of the label and package leaflet of medicinal products for human use', as published by the European Commission in the Notice to Applicants, Volume 2C (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm), sets out helpful advice on the presentation of the content of the labelling and package leaflet (required in accordance with Title V of Directive 2001/83/EC) and on the design and layout concepts which will aid the production of high quality information. It is intended to assist applicants and MAHs when drawing up the labelling and package leaflet and preparing the mock-ups and/or specimens of the sales presentations. The guideline also includes information on how the requirements for Braille for the labelling and for 'consultations with target patient groups' for the package leaflet can be met, as well as how to make the package leaflet available in formats suitable for the blind and partially sighted patients.

As set-out in Article 57 of Directive 2001/83/EC, a Member State may ask for additional information to appear on the outer packaging (in a 'blue box') concerning identification and authenticity of the product, the legal category for supply and price/reimbursement. Details on the national requirements for the 'blue box' of centrally authorised medicinal products are given in the 'Guideline on the packaging information of medicinal products for human use authorised by the Community' as published by the European Commission in the Notice to Applicants, Volume 2C (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm).

Article 54 (e) of Directive 2001/83/EC requires that the outer packaging must also include a space for the prescribed dose to be indicated (e.g. to affix the dispensing label or for hand-written pharmacist instructions).

As stated in Article 61(1) of Directive 2001/83/EC one or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the authorities competent for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

The legal provisions within Article 62 of Directive 2001/83/EC permit the use of images, pictograms and other graphics to aid comprehension of the information, but these exclude any element of a promotional nature.

2.2. Mock-ups and specimens

Mock-ups and specimens of the outer and immediate packaging together with the package leaflet must be submitted by the applicant/MAH to the EMA for review, before commercialisation of the medicinal product.

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.

A ‘specimen’ is a sample of the actual printed outer and immediate packaging materials and package leaflet (i.e. the sales presentation).

2.3. Principles applied to the checking of mock-ups and specimens

The mock-ups and specimens checking process is based on the following general principles:

- The EMA, through the translations checking policy, ensures 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 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 EMA does not perform a detailed linguistic check of mock-ups and specimens, but rather a general check from the viewpoint of readability in order to contribute to the safe use of medicines.
- The EMA does not keep a full set of specimens of the whole product range covering all Member States, but keeps on file only example of mock-ups and specimens of printed packaging materials of all centrally authorised products, as reference samples of the whole product range marketed in the EU.
- The EMA can, at any time, request specific specimens from the MAH for review (e.g. further to a safety-related or product defect issue).

The proposed outer and immediate labelling and package leaflet will be reviewed for compliance with the requirements outlined in Directive 2001/83/EC. Detailed reviews of the content of the labelling and leaflet proposals and their translations will take place during the scientific assessment and linguistic review of the application.

Presentation of the information in terms of print size, colour and layout is an important factor in overall ‘readability’ of labelling and leaflet, and this will in particular be checked on the submitted mock-ups and specimens. Such a general, so-called ‘readability’ check[2] of mock-ups and specimens focuses on overall layout 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.

As the EMA is requiring only specimen examples of the whole range of authorised product presentations to be submitted (see section 3 for details), it is understood that these specimen examples will be representative of all other presentations, except for the elements directly related to the difference in presentation concerned (e.g. different number of tablets, different EU number).

The check is performed by dedicated EMA staff in close liaison with the product team leader and the QRD secretariat. In case of comments on the specimens, the EMA will discuss the best and feasible corrective action with the applicant/MAH, taking into account the nature and amount of issues identified.

If, however, major safety issues are identified, EMA may request revised specimens to be provided for review before marketing or may even request a recall of already marketed products.

[2] This is not the “patient group consultation” of the package leaflet which is to be performed by applicants/MAHs according to Article 59(3) of Directive 2001/83/EC.

2.4. Submission of mock-ups and specimens

For any questions on the checking process or to discuss upcoming mock-ups and/or specimen submissions, please contact the EMA **by e-mail** at muspecimens@ema.europa.eu.

Mock-ups:

Where required, mock-ups must be included in module 1.3.2 of the application dossier or should be sent directly to muspecimens@ema.europa.eu, as applicable.

In case of comments on the mock-ups, responses and/or updated mock-ups should be submitted, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the production or launch of the medicinal product.

When submitting responses to the EMA, applicants may use the mock-ups and specimens responses form (see annex 1).

Specimens:

All specimens, including renewals, must be submitted **by post** using the specimen submission form (see annex 2).

Refer to How to find us for the shipping address.

Applicants/MAHs must declare in the specimen submission form that:

- The specimen is in compliance with the relevant approved product information texts.
- The 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.
- Text in 'Braille' is embossed correctly on the pack, if applicable (in line with section 16 of the outer labelling text and in line with relevant national requirements of the Member State(s) concerned).

In case of comments on the specimens, responses and/or updated mock-ups should be submitted, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the production or launch of the medicinal product.

When submitting responses to the EMA, applicants may use the mock-ups and specimens responses form (see annex 1).

3. The mock-up and specimen checking process

The following requirements and checking process will apply, as summarised in annex 3:

3.1. New marketing authorisation applications and extensions applications

Mock-ups:

Based on Article 8.3 (j) of Directive 2001/83/EC, applicants must provide at submission an English and multi-lingual ('worst-case') colour mock-up of outer and immediate packaging for each pharmaceutical form in each container type (e.g. blister, bottle, vial, pen) in the smallest pack-size for new marketing authorisation applications. Mock-ups must also be provided for each strength or for each different total content per total volume, when the strength is expressed as concentration per unit volume (x mg/ml).

For extension applications, this will only concern the new strength, pharmaceutical form and/or route of administration applied for.

Mock-ups of package leaflets are not required at submission, but may be provided voluntarily in the application or at a later stage during the procedure.

At the initial submission applicants should, as far as possible, submit mock-ups which are considered final drafts.

In the validation letter, the EMA may include provisional comments on the mock-ups, which the applicant should take into account when further developing its packaging proposals.

The mock-ups will subsequently be reviewed in detail by the EMA in parallel to the scientific assessment, and any mock-up comments will be sent together with the PIQ comments on the EN product information by day 120[3].

In case of comments or in case the applicant changes the overall design, revised mock-ups should be submitted as part of the answers to the list of questions at day 121. Comments on the (revised) mock-ups will be sent together with the QRD comments (day 155).

In case of a QRD sub-group meeting at day 165, EMA could take the opportunity to also discuss the draft mock-ups to complement the product information review.

At day 181, EMA will make sure that any outstanding comments made at Day 155 are solved prior to the opinion.

Submission of further mock-ups for review is not required after adoption of the Opinion. However, EMA would be willing to perform an additional review of updated mock-ups in the post-opinion phase, if requested by applicants prior to specimen printing.

[3] See 'The linguistic review process of product information in the centralised procedure – human' http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf

Specimens:

One set of relevant example specimen examples of outer and immediate packaging and package leaflet should be provided to the EMA (mock-ups and specimens) for review **at the latest 15 working days** before launch for each strength or for each different total content per total volume [when the strength is expressed as concentration per unit volume (x mg/ml)], pharmaceutical form and container type ('product presentation'):

- before their first marketing in the EU;
- before marketing as a multi-lingual pack in the EU;
- when any other multi-lingual pack is introduced which has a greater number of languages than the multi-lingual pack(s) previously reviewed.

For example: MAH plans to launch the newly approved product in Germany as the first MS –> German specimens are to be provided to the EMA. The MAH subsequently launches the product in the UK and Ireland –> no specimens to be provided. The MAH next launches the product in Italy and Spain, using a combined ES/IT language pack –> specimens to be provided to the EMA. Any further specimens will only have to be provided if the packs contain more than 2 languages.

Specimens can be sent to the EMA before the final Commission Decision is granted. Applicants should allow sufficient time for the review process of specimens, including any subsequent changes which may exceptionally have to be introduced to the specimens before launch.

Specimens for one pack-size are sufficient; in case of multiple pack-sizes being launched at the same time, EMA would prefer receiving specimens of the smallest pack-size. In case (first) marketing takes place in more than one Member State, it is not necessary to send several single-language and/or multi-lingual specimens in relation to different Member States; specimens for one of such Member States are sufficient (e.g. 1 set of specimens with 1 language, 1 set of specimens with 2 languages, 1 set of specimens with 5 languages….).

As such, the EMA will receive and review at least one set of specimens for each different product presentation before their first introduction on the EU market, as well as any relevant 'worst-case' multi-lingual specimens.

The EMA will perform a general check (see section 2.3) within 15 working days, and will check if any previous comments on mock-ups/specimens have been duly implemented. The applicant will be informed about the outcome of the check.

In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the launch of the medicinal product. EMA will discuss the best and feasible corrective action with the MAH, taking into account the nature and amount of issues identified. EMA will endeavour to provide such feedback as soon as possible and taking into consideration the launch plan of the medicinal product, as applicable.

3.2. Renewals

Mock-ups:

No mock-ups are required at the time of renewal of the marketing authorisation.

Specimens:

At renewal, EMA will perform a new check of the specimens across all marketed product presentations. Relevant specimen examples should be provided to the EMA (see section 2.4 for the submission details), for each strength, pharmaceutical form and container type in the smallest marketed pack-size. Ideally multi-lingual specimens should be provided but, if not available, a single-language specimen may be submitted. As such the EMA will receive and check at least one example specimen of the whole range of marketed product presentations after 5 years, in one submission.

The EMA will perform a general check (see section 2.3) in parallel to the renewal assessment procedure within 25 working days, and will check if any previous comments on specimens have been duly implemented. The applicant will be informed about the outcome of the check.

In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu) at the latest 15 working days prior to the finalisation of the renewal procedure. EMA will discuss the best and feasible corrective action with the MAH, taking into account the nature and amount of issues identified. EMA will endeavour to provide such feedback within 15 working days.

Note:

If the MAH plans to change the overall design and readability of the labelling and/or package leaflet around the time of renewal, submission of specimens of the “old” product design will not be necessary. In such a case, the same principles as in section 3.4 will apply. This approach should however be discussed with the product team leader in advance of the renewal submission (e.g. at the renewal pre-submission meeting).

3.3. Transfer of MAH

Mock-ups:

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. Ideally, applicants must provide at submission an English and multi-lingual (‘worst-case’) colour mock-up of outer and immediate packaging for each pharmaceutical form in each container type (e.g. blister and bottle, vial and pen) in the smallest pack-size. If not available, relevant example mock-ups of the marketed presentation may be submitted instead.

If the transfer only affects the MAH details on the packaging and package leaflet without any impact on the overall design, a declaration 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 module 1.3.2 of the application dossier.

EMA will review the mock-ups in parallel to the handling of the transfer procedure. If EMA has any comments on the mock-ups; these will be sent to the MAH within 15 working days from the start of the procedure.

In case of comments on the mock-ups, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the specimen printing. EMA will

discuss the best and feasible corrective action with the MAH, taking into account the nature and amount of issues identified. EMA will endeavour to provide such feedback as soon as possible and taking into consideration the production plan of the medicinal product, as applicable.

Specimens:

Only in case the transfer has an impact on the overall design, relevant revised example specimens should be provided to the EMA by the new MAH, in line with the requirements for new applications and extensions (see section 3.1).

If the transfer only affects the MAH details on the packaging and package leaflet without any impact on overall design, specimens are not required.

The EMA will perform a general check (see section 2.3) within 15 working days, and will check if any previous comments on specimens have been duly implemented. The applicant will be informed about the outcome of the check.

In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the launch of the medicinal product. EMA will discuss the best and feasible corrective action with the MAH, taking into account the nature and amount of issues identified. EMA will endeavour to provide such feedback as soon as possible and taking into consideration the launch plan of the medicinal product, as applicable.

3.4. Other post-authorisation procedures

Mock-ups:

In principle, no mock-ups are to be provided in case of post-authorisation procedures other than extensions and transfers applications affecting the overall layout.

However, where the overall design and readability of the outer and immediate packaging and/or package leaflet is affected as part of a post-authorisation procedure, the need for the provision of mock-ups should be discussed with the EMA (muspecimens@ema.europa.eu) on a case-by-case basis (e.g. mock-ups would be required when proposing a new corporate design of packs, a new container type, use of different colours, major changes in layout, a new pack size smaller than the current approved range, but not e.g. when only limited new text is added in a leaflet section).

In case the submission of mock-ups is required, the relevant example mock-ups would need to be included in the module 1.3.2 of the application dossier.

The EMA will perform a general check (see section 2.3) within 15 working days. The applicant will be informed about the outcome of the check.

In case of comments on the mock-ups, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the specimens printing. EMA will discuss the best and feasible corrective action with the MAH, taking into account the nature and amount of issues identified. EMA will endeavour to provide such feedback as soon as possible and taking into consideration the production plan of the medicinal product, as applicable.

Specimens:

In principle, no specimens are to be provided in case of post-authorisation procedures other than extensions, renewals and transfers.

However, where the overall design and readability of the outer and immediate packaging and/or package leaflet is affected (e.g. when proposing a new corporate design of packs, a new container type, use of different colours, major changes in layout, a new pack size smaller than the current approved range, but not e.g. when only limited new text is added in a leaflet section), the need for the provision of specimens should be discussed with the EMA on a case-by-case basis.

In case specimens are required, in principle only one relevant example (multi-lingual if possible) would need to be sent to the EMA at the latest 15 working days before marketing. However, depending on the nature and extent of the change(s) concerned, additional specimens may be required by the EMA.

The EMA will perform a general check (see section 2.3) within 15 working days, and will check if any previous comments on mock-ups and/or specimens have been duly implemented. The applicant will be informed about the outcome of the check.

In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu) prior to the launch of the medicinal product. EMA will discuss the best and feasible corrective action with the MAH, taking into account the nature and amount of issues identified. EMA will endeavour to provide such feedback as soon as possible and taking into consideration the launch plan of the medicinal product, as applicable.

Notes:

- In the case of a safety issue arising from **defective product labelling** (e.g. errors in handling/dosing instructions in the PL) and affecting marketed batches of a product, this will be handled according to the procedure for Dealing with Reports of Defective Medicinal Products (SOP/INSP/2018), with involvement of the EMA staff dedicated to the review of mock-ups and specimens, product team leader and QRD secretariat.
- MAHs are reminded that all **proposed changes to the text of the labelling or the package leaflet (i.e. changes to Annex IIIA and IIIB), which are not connected with the SmPC, and which are not part of any other regulatory procedure**, should be notified to the EMA according to Art 61(3) of Directive 2001/83/EC.
- For any **non-textual changes to the labelling and package leaflet introduced outside any regulatory procedure**, where the overall design and readability of the outer and immediate packaging and/or package leaflet is significantly affected, the principles for the review of mock-ups and specimens, as outlined in the paragraphs above, will also apply. However, in this case the relevant mock-ups should be sent by e-mail to the EMA (muspecimens@ema.europa.eu), copying the product team leader, together with the relevant background information about the change.

Annex 1 – Mock-ups and specimens responses form

Mock-ups and specimens responses form

For applicants when submitting responses/revised mock-ups and/or specimens to the European Medicines Agency

Product name	:	
Active substance/common name	:	
Procedure number	:	
Status of the application[4]	:	
Date submission of responses	:	
Applicant's details[5]	:	

All comments implemented	:	

Tick the box if appropriate

If not, a justification should be provided stating why certain comments are not reflected in the revised version of the mock-ups/specimens. Please indicate, as presented in the table included in the next page, the labelling item (outer carton, vial label, blister foil etc.) to which the comment relates together with an alternative proposal.

[4] Only for new marketing authorisation and line extensions applications: day 121, day 181, pre-opinion etc.
[5] Including details of applicant's contact person i.e. name, tel. fax, e-mail etc.

- <Please specify labelling item>>

EMA comments	Alternative proposal

Annex 2 – Specimen submission form

Specimen submission form

Product (invented) name:

Marketing authorisation holder:

Pharmaceutical form	**Strength**	**Container type (e.g. vial, pen etc.)**	**Procedure**	**Procedure number**	**Type of specimen submitted**	**Member State(s)(e.g. DK/FI/SE)**	**OC**	**LAB**	**PL**[6]
			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 EMA (e.g. description of changes affecting the layout or readability compared to the last reviewed specimens):

The undersigned declares that:

☐ The specimens are in compliance with the relevant approved product information.

☐ The specimens contain (all) the relevant official language(s) of the Member State(s)[7] 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.

☐ Braille (if applicable): The Braille is embossed correctly on the pack, is in line with section 16 of the outer labelling text, and in line with relevant national requirements of the Member State(s) concerned (where applicable).

Contact details:

Signature:	Date:

[6] OC: Outer carton, LAB: Immediate labelling/blister; PL: Package leaflet.
[7] Except for Malta, where packs can be marketed in English and/or Maltese.

Annex 3 - Summary of mock-up and specimen submission requirements

(Please refer to guideline text for full details)

New marketing authorisation and extensions applications

When to submit	What to submit	When checked
Day 0 (submission of the application	**Mock-ups** Colour mock-ups of outer and immediate packaging for each pharmaceutical form, each strength [or for each different total content per total volume when the strength is expressed per concentration per unit volume (x mg/ml)] in each container type (e.g. blister, bottle, vial, pen …) 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).	During validation PIQ review
Day 121	**Mock-ups** Revised mock-ups (if applicable).	• QRD review • Day 165 QRD sub-group meeting (if applicable)
Day 181	**Mock-ups** Revised mock-ups (if applicable).	Pre-opinion
At the latest 15 working days before marketing	**Specimens** One set of specimens of printed outer and immediate packaging materials and package leaflet for each strength [or for each different total content per total volume when the strength is expressed per concentration per unit volume (x mg/ml)] and each pharmaceutical form in each container type need to be provided to the EMA: • when first marketed in the EU; • when first marketed as a multi-lingual pack in the EU; • when any other multi-lingual pack is marketed with a higher number of languages than the multi-lingual pack(s) previously reviewed.	Within 15 working days
Prior to launch of the medicinal product	**Specimens** In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to EMA (muspecimens@ema.europa.eu).	Timeline to be adjusted on the basis of the intended launch date

Renewals

When to submit	What to submit	When checked
At the same time as the submission of the renewal application (i.e. at least 6 months before MA expiry)	**Specimens** One set of specimens of printed outer and immediate packaging materials and package leaflet for each strength and each pharmaceutical form in each container type in the smallest **marketed** pack-size: • 1 multi-lingual example specimen ("worst-case") for each of the above, or • if not available, a single-language specimen.	Within 25 working days
At the latest 15 working days prior to the finalisation of the renewal procedure	**Specimens** In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu).	Within 15 working days

Transfers

When to submit	What to submit	When checked
Submission of application	**Mock-ups** Colour mock-ups of outer and immediate packaging for each pharmaceutical form in each container type (e.g. blister, bottle, vial, pen …) in the smallest pack-size: • 1 EN mock-up • 1 multi-lingual mock-up ("worst-case") Should English and/or multi-lingual ('worst-case') are not marketed, relevant example mock-ups of the marketed presentation may be submitted instead. **If the transfer only affects the MAH details** on the packaging and package leaflet without any impact on the overall design, a declaration 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 module 1.3.2 of the application dossier. If EMA has any comments on the mock-ups; these will be sent to the MAH within 15 working days from the start of the procedure.	Within 15 working days from start of procedure
Prior to the specimens printing	**Mock-ups** MAHs should submit responses and/or updated mock-ups to the EMA (muspecimens@ema.europa.eu).	Timeline to be adjusted on the basis of the intended production date

When to submit	What to submit	When checked
At the latest 15 working days before marketing	**Specimens** **Only in case the transfer has an impact on the overall design**, relevant revised example specimens should be provided to the EMA by the new MAH. One set of specimens of printed outer and immediate packaging materials and package leaflet for each strength and each pharmaceutical form in each container type: • when first marketed in the EU, • when first marketed as a multi-lingual pack (if different from the first specimens sent to EMA), • when any other multi-lingual pack is marketed with a higher number of languages than the multi-lingual pack(s) previously reviewed. If the transfer **only affects the MAH details** on the packaging and package leaflet without any impact on overall design, submission of **specimens is not required**.	Within 15 working days
Prior to the launch of the medicinal product	**Specimens** In case of comments on the specimens, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu).	Timeline to be adjusted on the basis of the intended launch date

Other post-authorisation procedures

When to submit	What to submit	When checked
Submission of application	**Mock-ups** Only when the overall design and readability of the outer & immediate packaging and/or package leaflet is affected: • Submission of mock-ups should be discussed with the EMA (on a case-by-case basis).	Within 15 working days
Prior to the specimens printing	**Mock-ups** In case of comments on the mock-ups, the MAH should submit responses and/or updated mock-ups, as applicable, to the EMA (muspecimens@ema.europa.eu).	Timeline to be adjusted on the basis of the intended production date
At the latest 15 working days before marketing	**Specimens** Only when the overall design and readability of the outer & immediate packaging and/or package leaflet is affected: • Submission of specimens should be discussed with the EMA (on a case-by-case basis). • In principle only one relevant set of example specimens (multi-lingual if possible) would be required. However, depending on the nature and extent of the change(s) concerned, additional specimens may be required by the EMA	Within 15 working days
Prior to the launch of the medicinal product	**Specimens** MAHs should submit responses and/or updated mock-ups to the EMA (muspecimens@ema.europa.eu).	Timeline to be adjusted on the basis of the intended launch date