

GUIDANCE ON CHANGES TO LABELLING AND PATIENT INFORMATION LEAFLETS FOR SELF CERTIFICATION

1. Introduction

Council Directive 2001/83/EC as amended, requires that marketing authorisation holders (MAH) inform the competent authority of all changes to the labelling and patient information leaflets which are not connected with changes to the summary of product characteristics (SPC) [Article 61(3)]. Notwithstanding the need for the applicant to notify the competent authority of the amendment, responsibility for the information presented on the packaging and in the patient information leaflet rests solely with the MAH.

2. Purpose

This document sets out the circumstances under which changes to the labelling and patient information leaflet can be subject to self-certification by the MAH, requiring only a notification be made to the MHRA.

3. General guidance

Where an applicant submits a notification for any one of the changes set out below and can meet the prescribed conditions associated with each change, such changes will be deemed to be for self certification by the applicant. Notifications made under article 61(3) for these individual changes will not be subject to formal assessment and approval by MHRA but will be self-certified by the applicant. Notifications made to the MHRA under these provisions will be acknowledged within 14 days of receipt and on receipt of the acceptance correspondence can then be introduced immediately. The fee which applies to such notifications is defined within the relevant statutory instrument.

Applicants intending to self certify the changes submitted must state clearly on the notification form that it is submitted under article 61(3), which change number(s) is/are relevant and that the necessary conditions have been complied with. Full colour mock-ups of the proposed final version of the packaging components affected by the change must accompany the notification.

4. Audit of submissions

Acceptance of these notifications is based on declarations by the MAH that the prescribed conditions have been fulfilled and the necessary supporting documentation has been submitted. MHRA will be operating a quality audit system based on both random and targeted sampling of applications submitted as notifications in the categories set out below to monitor the validity of the submissions. Outcome reports from these audits will be published on our website.

5. Other changes

Changes to packaging not covered by this guidance or where the prescribed conditions have not been met must be submitted to the Patient Information Quality unit for formal assessment and approval. Normal timescales for assessment will apply and changes should not be introduced in the absence of a formal letter of approval in these cases.

CATEGORY OF CHANGES APPROPRIATE FOR SELF CERTIFICATION

LABELLING CHANGES

Conditions to be met in all cases:

- All information on the pack is identical in terms of placement and text style and size to the currently approved packaging.
- Pack design, layout of information and colours used are identical in all respects to the previously approved packaging.
- Added or changed information is in a font size and style which is identical to (or proportionally equivalent, relative to the labelling being self-certified) that used in packs already subject to formal approval.

1. Addition of all common names immediately following the brand name to comply with new legal obligations set out in article 54 (a)

Additional conditions to be met:

- Prominence and placement of common names have already been subject to formal approval within the product range on the smallest pack size registered.
- Pack dimensions (front and back face) are identical to or larger than others in range already subject to formal approval.

2. Addition of pack size within a range

Additional conditions to be met:

- Pack size already authorised within section 6 of the summary of product characteristics.
- A full colour mock up of the smallest marketed pack size within the range has already been submitted for assessment and subject to formal approval.

3. Addition of excipients of known effect to the labelling to comply with guidance from the European Commission

Additional conditions to be met: none

4. Removal of excipients from the labelling which are no longer considered to be of known effect to comply with guidance from the European Commission

Additional conditions to be met: none

5. Addition of text specific to other markets

Additional conditions to be met:

- Where it is intended to market a joint pack with another member state(s), the patient information leaflet must be identical in both/all member states.
- Only changes to the information relating to distributor and the marketing authorisation number may be included.

6. Removal of text specific to other markets

Additional conditions to be met:

- Only information specific to a market outside the UK can be removed.

7. Updating of statutory warnings in line with new legislation or guidance (amending for example 'Keep out of the reach of children' to 'Keep out of the reach and sight of children')

Additional conditions to be met: none.

8. Re-phrasing of the storage details provided that the overall meaning remains unchanged (store below 25°C/do not store above 25°C)

Additional conditions to be met:

- The amended statement is in accordance with the information in section 6 of the SPC and there is no change in meaning.

9. Changes to MAH or distributor details (including company logos and trading styles) on the labelling

Additional conditions to be met:

- Details of the change have already been approved as part of a bulk variation.
- A full colour mock-up of the labelling for the smallest pack on the lead marketing authorisation in the bulk variation has been submitted with the application, assessed and approved [note a text amendment with the bulk variation application is not acceptable].

10. Changes to pharmacopoeial name of ingredients on the Labelling

Additional conditions to be met:

- Details of the change have already been approved as part of a bulk variation.
- A full colour mock-up of the labelling for the smallest pack on the lead marketing authorisation in the bulk variation has been submitted with the application, assessed and approved [note a text amendment with the bulk variation application is not acceptable].

11. Removal of pharmacopoeial status of ingredients on the labelling

Additional conditions to be met: none.

12. Removal of “new” flash 12 months after introduction of a novel presentation

Additional conditions to be met:

- Only information in relation to “new” can be removed.

13. Correction of typographical errors in labelling information

Additional conditions to be met:

- Changed text is clearly identified.

14. Changes to pack dimensions

Additional conditions to be met:
none.

15. Introduction of warnings on to the labelling of other pack sizes within a range and other variants on a marketing authorisation

Additional conditions to be met:

- Details of the change have already been approved as part of a variation to the appropriate section of the SPC.
- A full colour mock-up of the labelling for the smallest pack size on the MA has been submitted with the variation, has been subject to formal assessment and been approved.
- The change is applied to packs registered on one marketing authorisation only or where different strengths of the same product are registered on more than one marketing authorisation.

16. Changes to storage conditions on the labelling of other pack sizes within a range

Additional conditions to be met:

- Details of the change have already been approved as part of a variation to section 6 of the SPC.
- A full colour mock-up of the labelling for the smallest pack size on the MA has been submitted with the variation, has been subject to formal assessment and been approved.
- The change is applied to packs registered on one marketing authorisation only.

17. Introduction of extra-statutory information to the labelling of other pack sizes within a range of pack sizes

Additional conditions to be met:

- The extra-statutory information has already been subject to formal approval on the smallest pack size on the particular marketing authorisation.
- Graphics (if present on the pack) are remote from the statutory information and have already been subject to formal approval within the product range.
- The change is applied to packs registered on one marketing authorisation only.

PATIENT INFORMATION LEAFLET CHANGES

Conditions to be met in all cases:

- All other information in the leaflet is otherwise identical in terms of placement and text style and size to currently approved leaflet.
- Leaflet design, layout of information and colours used are identical in all respects to the current approved pack.
- Changed or added information is placed in the leaflet in a font of the same style and size as the other approved statutory information.

18. Addition of excipient warnings within the patient information leaflet to comply with guidance from the European Commission

Additional conditions to be met:

- Wording used in the leaflet must replicate the text in the guideline.
- Section 4.4 of the summary of product characteristics for the relevant marketing authorisation must previously have been updated to reflect this information by variation in the usual manner.

19. Changes to Marketing Authorisation Holder and manufacturer details (including company logos and trading styles) within the patient information leaflet

Additional conditions to be met:

- Details of the change have already been approved as part of a bulk variation.
- A full colour mock-up of the patient information leaflet for the lead marketing authorisation in the bulk variation has been submitted with the application, assessed and approved [note a text amendment with the bulk variation application is not acceptable].

20. Changes to pharmacopoeial name of ingredients in the patient information leaflet

Additional conditions to be met:

- Details of the change have already been approved as part of a bulk variation.
- A full colour mock-up of the leaflet for the lead marketing authorisation in the bulk variation has been submitted with the application, assessed and approved [note a text amendment with the bulk variation application is not acceptable].

21. Removal of pharmacopoeial status of ingredients in the patient information leaflet

Additional conditions to be met: none.

22. Re-phrasing of the storage details in the leaflet provided that the overall meaning remains unchanged (store below 25°C/do not store above 25°C)

Additional conditions to be met:

- The amended statement is in accordance with the information in section 6 of the SPC and there is no change in meaning.

23. Correction of typographical errors in the patient information leaflet

Additional conditions to be met:

- Changed text is clearly identified.

24. Changes to dimensions of patient information leaflet

Additional conditions to be met:

- Size of text is identical to or larger than that on the approved leaflet.

25. Introduction of a technical leaflet as a tear-off portion of the PIL

Additional conditions to be met:

- Size of text is identical to or larger than that on the approved leaflet.
- The tear-off portion forming the technical leaflet for the healthcare professional is the approved summary of product characteristics.

**Medicines and Healthcare products Regulatory Agency
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