Version 1.0 Dated: 16 July 2020

Changes to packaging for human medicinal products for information only

Changes to packaging, including changes not affecting the SmPC and PL shall be informed and thereby approved according to Art. 9-2 Norwegian medicinal product regulation and Art.61(3) Directive 2001/83/EF, the Norwegian Medicines Agency (NoMA).

However, some changes concerning the packaging shall be submitted as a 61(3) notification for information only. The notification will be noted and no approval will be issued. Changes to be submitted for information are listed in table 1.

The submitted changes shall be considered as a confirmation from the marketing authorisation holder (MAH) that the conditions are fulfilled. NoMA shall make random sample check for discrepancies.

All other changes than those listed in this document (see table 1) shall be submitted through a variation for assessment and approval before implementation.

What shall be included in the submission?

- An email submitted to pi@noma.no with the heading "Notification 61(3) for information only"
- The MAH must verify that no other changes are made with correspondence to latest approved mock-ups and applicable category and conditions from table 1 shall be referred (**).
- Attachment: Mock-ups as pdf files as copies of the flat artwork design for the inner and outer packaging of the medicinal product, in full colour. It is required with mock-ups for the smallest package size of each strength, pharmaceutical form and type of package (bottle, box, carton). Larger pack sizes are considered approved on the presumption that the layout and the design are identical to the submitted smallest pack size.

Example of email

Heading: Notification 61(3) for information only The variation applies to [removal of Danish text]* and fulfil the conditions in accordance to [Category 1 a,b,c]** in the Norwegian Medicines Agency reference document «Changes in packaging in accordance with Art. 9-2 of the Norwegian medicinal product regulation can be submitted to Norwegian Medicines Agency for information only». No other changes in the mock-ups have been made to the latest approved mock-up dated <dd.mm.yyyy>.

*insert text that describes the change.
** refer to applicable category and conditions fulfilled in accordance with table 1.

Date of approval

The approval date will be considered as the date of submission. The changes may be implemented at the time of submission, provided that the notification submission is justified.

Table 1: Changes that can be submitted to NoMA for information only

Category	Conditions
1. **Removing of text intended for a market outside Norway**	a. Only information specific to a market outside Norway can be removed b. All other information in terms of location of the text, font and font size are identical with the last approved packaging c. Design, layout and colouring of the packaging are identical to the last approved packaging.
2. **Addition of braille**	a. The whole name of the medicinal product shall be stated in braille. If the medicinal product is available in more than one strength, the strength shall also be included in braille b. All other information, location of the text, font and font size are identical with the last approved packaging c. Design, layout and colouring of the packaging are identical to the last approved packaging.
3. **Typo corrections**	a. The adjusted text/word is easy to identify and all other information in terms of location of the text, font and font size are identical with the last approved packaging b. Design, layout and colouring of the packaging are identical to the last approved packaging.
4. **Change of package dimensions**	a. All other information, location of the text, font and font size are identical with the last approved packaging b. Design, layout and colouring of the packaging are identical to the last approved packaging.
5. **Addition of excipients with known effect in accordance with the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'**	a. The composition is otherwise unchanged b. Information, location of the text, font size and font are identical with the last approved packaging c. Design, layout and colouring of the packaging are identical to the last approved packaging d. The added text is in the same font and font size as the text already approved.
6. **Removing of excipients that are no longer considered to have any known effect in**	a. The composition is otherwise unchanged.

accordance with the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'	b. Information, location of the text, font and font size are identical with the last approved packaging c. Design, layout and colouring of the packaging are identical to the last approved packaging.
7. **Change in article number**	a. The new article number is located in the same location as the previously approved article number and the font, font size and colouring remains the same b. All other information, location of the text, font and font size are identical with the last approved packaging c. Design, layout and colouring of the packaging are identical to the last approved packaging.
8. **Update of existing barcode and data matrix code**	a. All other information, location of the text, font and font size are identical with the last approved packaging b. Design, layout and colouring of the packaging are identical to the last approved packaging.
9. **For parallel imported medicinal products: Change or addition of manufacturer**	a. The name of the new manufacturer is located on the packaging at the same location as the previously manufacturer or directly below the current manufacturer and font, font size and colouring are identical b. All other information, location of the text, font and font size are identical with the last approved packaging c. Design, layout and colouring of the packaging are identical to the last approved packaging.