Medicines & Healthcare products Regulatory Agency

MHRA - Additional guidance for submitting changes to labels and patient information leaflets as a self-certification.

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Published: June 2026

Additional guidance for submitting changes to labels and patient information leaflets as a self-certification.

1. Background

Regulation 267 of the Human Medicines Regulations (2012) sets out the requirement for the submission of mock-ups of packaging and leaflets to the licensing authority, as part of an initial licence application and subsequently to register any changes that are not connected with a change to the Summary of Product Characteristic (SmPC). The default route for registering changes to the label and / or leaflet is via a self-certification, unless the proposed updates fall into the categories P1-P4, where a full assessment is required.

2. What changes fall into the P1-P4 categories?

P1: First approval of mock-ups following grant of a Marketing Authorisation (MA) where only text versions were submitted and approved as part of the MA application. This is required prior to marketing the medicine.

P2: Changes to patient information leaflets which include significant changes to content and / or design and layout and must therefore be supported by additional user testing data or bridging data demonstrating that potential patients can find and understand the information presented, or data in connection with any extra statutory information which the applicant wishes to include. Full details on when a new user test or bridging report are needed are included in the MHRA Best Practice Guidance on Leaflets.

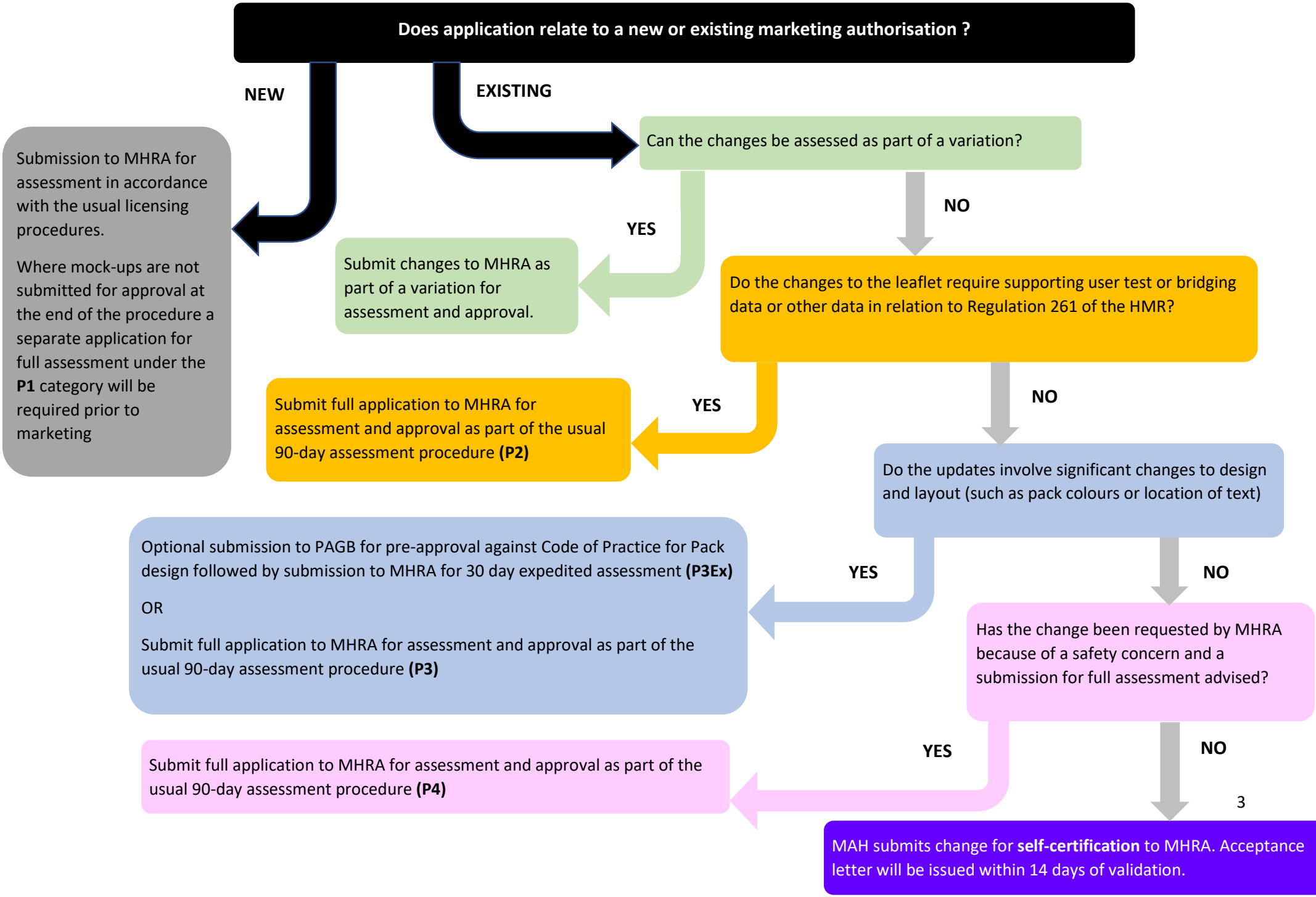
P3: Significant changes to pack design and layout will always be the subject of a full application. This will encompass changes to any or all of layout of the information, changes to the content of the information and changes to graphics on the pack.

For over the counter (OTC) medicines, where an optional submission has been made to PAGB for approval of extra-statutory information, these applications will be eligible for expedited review. Applications in this category will be assessed within 30 days of the application being considered valid by the MHRA.

P4: Changes which are notified to the Marketing Authorisation Holder (MAH) by the MHRA and for which a full application is solicited. Where such changes are made by means of a variation application the artwork will be considered as part of the variation assessment provided only changes consequential to the variation are introduced. In some cases, the variation applications will be handled within Product Information Quality Unit (PIQU). These may include but are not restricted to:

- Approval of artwork for a new own-label supplier
- Approval of artwork following a product name change
- Introduction of significant new safety information following consideration by an expert advisory committee
- Amendment of artwork following a complaint in relation to patient safety

3. Submission decision tree



4. How to submit – documentation required

Applications should be made using the eCTD. The correct form to accompany a self-certification submission can be found here (MS Word Document, 324 KB). Please note that this should be converted to a pdf document once completed and prior to submission, as all documents that are part of modules 1-5 of the eCTD should be provided in pdf format. Alternatively, the portal form in PDF format may be used.

Consolidated labelling mock-ups must be provided as the labelling file submitted will replace that currently approved. A consolidated labelling file includes all elements of outer and immediate labelling, regardless of whether they are being updated (see examples below). The consolidated labelling and / or leaflet mock-up files should be provided within module 1.

Example 1: Submission to correct a spelling error on the carton for the 30-tablet pack size. The error is not present on the 60 or 90-tablets cartons.

Labelling required: consolidated file containing

- Updated 30-tablet carton
- Currently approved 60-tablet carton
- Currently approved 90-tablet carton
- Currently approved blister foil

Example 2: Addition of an alternative leaflet profile for a second manufacturer

Leaflet required: consolidated file containing

- Currently approved leaflet profile for manufacturer 1
- New leaflet profile for manufacturer 2

Example 3: Addition of excipient information, in line with current guidance, to labelling and leaflet for product presented in 30 tablet blister pack and 60-tablet container (with carton). The presentations have a common leaflet.

Labelling required: consolidated file containing

- Updated 30-tablet carton
- Updated 60-tablet carton
- Updated 60 tablet immediate container label
- Currently approved blister foil

Leaflet required: file containing

- Updated leaflet (common to both presentations)

5. Examples of changes that can be registered via self-certification.

The following tables include changes that are considered acceptable for self-certification. It is not an exhaustive list and other simple changes that consider similar conditions and exclusions may be submitted for approval via this route.

Changes to currently approved labelling

	Proposed change	Conditions	Exclusions
1	Change in dimensions of outer carton, immediate label or blister foil or change to printing margin lines / cutter guides on package labelling	Layout of labelling text is not significantly changed. Font size remains the same or increased.	Font size decreased (P3 submission required)
2	Information text transferred to opposite end or side flap of carton	Text content and presentation (font size, style and colour) remains the same.	
3	Reorientation of a pictogram	Prominence and legibility of statutory text on labelling is not affected.	
4	Change in location, format or abbreviations for variable data (batch number and expiry date) on outer and immediate labelling	Legibility of variable data is not affected. Format and abbreviations comply with current guidance set out in the latest QRD product information template and QRD Appendix IV to the QRD templates for human medicinal products.	
5	Change in font style of labelling text on any labelling element	Character height meets minimum requirement set out in European Commission Guideline on the Readability of the labelling and Package Leaflet of Medicinal Products for Human Use.	Decrease in overall font size or line spacing (P3 submission required)
6	Change in colour of labelling text on any labelling element	Legibility of text is not affected and there is a strong contrast between text colour and background (including reverse printing of text).	Pastel colours should not be used for text on foils or on light / white backgrounds
7	Minor changes to the labelling colour due to technical reasons	Colour change does not impact on legibility of statutory information or effective pack differentiation within a portfolio.	

8	Change in foil design	Font size and number of repeats of the product name must be the same as currently approved foil or increased.	Addition of days of the week i.e., introducing a calendar pack (P3 submission required)
9	Addition of the product name in Braille or change in location of Braille on labelling	Product name in Braille meets requirements of current guidance - European Commission Guideline on the Readability of the labelling and Package Leaflet of Medicinal Products for Human Use.	
10	Addition or removal of excipients from outer and / or immediate labelling	Excipient declaration complies with the Annex to European Commission Excipient Guideline.	
11	Update of statutory information in line with current legislation or QRD template	Changes align with requirements of Human Medicines Regulations (2012) or the latest QRD product information template – e.g., warnings for paracetamol-containing medicines, 'Keep out of the sight and reach of children.	
12	Addition or removal of information relevant to other countries (joint packs)	Information is limited to Marketing Authorisation (MA) number and details of MA holder (if different) for the relevant country and does not impact on size or prominence of national UK text.	Only joint immediate / inner labelling is still accepted. Joint outer packaging / cartons are no longer appropriate.
13	Addition, change or removal of distributor details	Distributor must be registered on the product licence.	
14	Change to MAH details	Change must be consistent with MAH details registered in SmPC.	
15	Addition or removal of company logo	Logo has been previously reviewed and approved via full assessment on another product label. Location and prominence of logo must be identical to that previously approved.	
16	Change to company logo	Location and prominence of new logo is identical to that previously approved for the old logo OR the logo has previously been reviewed and approved via full assessment on another product label. Location and prominence of logo must be identical to that previously approved.	New logo is larger, more prominent (P3 submission required)

17	Removal of ‘New’ flash after 12 months		Addition of ‘New’ flash must be made via a P3 submission.
18	Addition of recycling symbols	Recycling symbols must meet relevant guidance and not impact on the size and prominence of statutory labelling information.	
19	Correction of typographical error(s)		

20	Changes to barcode	Change to barcode details (e.g., number on barcode). Change in location of barcode provided that this does not result in significant changes to location or legibility of statutory text.	
21	Change to anti-tampering device	No significant change in layout or decrease in font size of text on any carton face.	
22	Safety update where the wording has been provided by MHRA	Wording has been provided by MHRA	MHRA has requested that update is submitted for full assessment under P4 category
23	Addition or removal of trademark symbol		
24	Introduction of extra-statutory information to the labelling of other pack sizes within a range of pack sizes	Information has previously been reviewed and approved via full assessment on another pack size within the range. Location and prominence of information must be identical to that previously approved.	
25	Introduction of warnings on to the labelling of other pack sizes within a range and other variants on a marketing authorisation	Warnings have previously been reviewed and approved via full assessment on another pack size. Location and prominence of information must be identical to that previously approved.	
26	Re-phrasing of the storage details provided that the overall meaning remains unchanged (store below 25°C / do not store above 25°C)	Storage precaution wording should reflect that set out in of the QRD Appendix III to the QRD templates for human medicinal products	
27	Changes to storage conditions on the	Change in wording has previously been reviewed and	

	labelling of other pack sizes within a range	approved via full assessment on another pack size.	
28	Changes to pharmacopeial name of ingredients on the labelling or removal of pharmacopeial status of ingredients on the labelling		

29	Removal of trademark symbol or change to the trademark statement on a carton e.g. if a statement is changed from 'Product X is a registered trademark of Company Y' to 'Product X is a registered trademark'		

Addition of new labelling

	Proposed change	Conditions	Exclusions
30	Addition of an alternative carton, label, or foil profile (e.g., where there is more than one manufacturing site)	The pack design and presentation of text is not significantly different to the currently registered labelling profiles	
31	Addition of a carton, label, or foils for a new pack size	The pack size is registered on the product licence. The pack design and presentation of text is the same as that for currently approved labelling	The proposed pack size must be within the range currently approved and cannot be the smallest registered pack size. A smaller pack size than those currently registered requires a category P3 submission.
32	Addition of carton, label and / or foil using the generic name, where both an invented and generic name are approved in section 1 of the current SmPC	Apart from the product name, the pack design and presentation of text must be identical to that for the approved labelling using the invented name	
33	Registration of an additional foil with a different text layout to that currently registered	Font size and number of repeats of the product name must be the same as currently approved foil or	Addition of days of the week i.e., introducing a calendar pack

		increased.	category P3 submission required
34	Submission of labelling mock-ups for a previously discontinued product	All artwork components must have been previously approved by MHRA. Design / layout is not significantly changed. Font size remains the same or increased.	Significant changes to design / layout or use of smaller font size (category P3 submission required)
35	Submission of labelling mock-ups where a variation has been granted with labelling text	All artwork components must have been previously approved by MHRA. Design / layout is not significantly changed. Font size remains the same or increased. Changes in labelling text are consequential to the variation.	

Changes to currently approved leaflet:

	Proposed change	Conditions	Exclusions
36	Change in dimensions of leaflet or changes to printing key lines	Layout of leaflet text (text flow and wrapping) is not significantly changed. Column and page breaks if not identical must not impact readability. Font size remains the same or increases.	Font size decreased - category P2 submission with supporting data such a user testing or bridging statement are required
37	Change in colour of leaflet text	Proposed colour should be black or dark blue.	
38	Addition or removal of excipients warnings from leaflet	Excipient declaration (or removal) complies with Annex to European Commission Excipient Guideline The relevant excipient information is in section 4.4 of the currently approved SmPC.	
39	Update of statutory information in line with current legislation or QRD template	Changes align with requirements of Human Medicines Regulations (2012) or the latest QRD template e.g., warnings for paracetamol-containing medicines.	
40	Introduction of a technical leaflet as a separate, tear-off portion of the patient	Information must reflect that set out in the relevant sections of the SmPC.	

	information leaflet		
41	Addition, change or removal of information relevant to other countries (leaflet provided with joint pack)	Information is limited to administrative information relevant to the other country (i.e. reporting details for side effects, MA holder and manufacturer details, product names in other countries).	
42	Addition of distributor details	Distributor must be registered on the product licence.	
43	Changes to MAH and manufacturer (site of batch release) details (including trading styles) within the patient information leaflet e.g. submission of artwork for a site registered but not previously used i.e. secondary assembler or batch release site change to help reworks	MAH (including trading style) and manufacturer details must be consistent with those registered on the product licence.	
44	Addition or removal of company logo	Logo has been previously reviewed and approved via full assessment on another leaflet. Location, size, and prominence of logo must be the same.	
45	Change to company logo	Position, size, and prominence of new logo is the same as that previously approved for the old logo OR the logo has previously been reviewed and approved via full assessment on another product label. Location and prominence of logo must be identical to that previously approved.	New logo is larger, more prominent or contains information of a promotional nature (category P3 submission required).
46	Addition of recycling symbols / information	Where there is limited space available on the outer carton, recycling information may be added to the end of the leaflet. Recycling symbols must meet current guidance.	
47	Correction of typographical error(s)		
48	Safety update where the wording has been provided by MHRA	Wording has been provided by MHRA.	MHRA has requested that update is submitted for full assessment under P4 category.
49	Changes to pharmacopeial name or removal of pharmacopeial status of ingredients in the		

	patient information leaflet		
50	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)	Storage precaution wording should reflect that set out in of the QRD Appendix III to the QRD templates for human medicinal products	

Addition of new leaflet

	Proposed change	Conditions	Exclusions
51	Addition of an alternative leaflet profile (e.g., where there is more than one manufacturing site)	Text content must be identical to currently approved leaflet. The layout should be sufficiently similar that additional user testing or a bridging report is not required.	Leaflet font size is smaller than that currently registered (category P2 submission with supporting data such a user testing or bridging statement required).
52	Addition of leaflet using the generic name, where both an invented and generic name are approved in section 1 of the current SmPC	Apart from the product name, the content and layout of the leaflet must be identical to that for the approved leaflet using the invented name.	
53	Submission of leaflet mock-up where a variation has been granted with leaflet text	Leaflet mock-up must have been previously approved by MHRA. Design / layout is not significantly changed. Font size remains the same or increased. Changes in leaflet text are consequential to the variation.	