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Guidance

Medicines: packaging, labelling and patient information leaflets

How to package medicines for sale and what information you must provide to consumers and healthcare professionals.

From:
Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)

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Overview

MHRA approves all packaging and labelling information for medicines sold in the UK including the information that must be provided. Medicines must include a patient information leaflet (PIL) if the label does not contain all the necessary information.

> See best practice guidance on the labelling and packaging of medicines (https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines).

You should read the relevant UK legislation before making an assessment submission.

Guidelines on the readability of the label and package leaflet of medicinal products for human use (https://health.ec.europa.eu/system/files/2016-11/2009_01_12_readability_guideline_final_en_0.pdf) is available on the European Commission website and will remain relevant after transition.

Labelling for medicines

Labels must be clear. Healthcare professionals and patients must easily be able to identify the medicine by the label.

You should use the letters CD in an inverted triangle if your product is a controlled drug. This isn't compulsory but we encourage you to include this mark on your product's labelling.

All information on packaging for licensed medicines must be printed directly on to the packaging. Over-labelling must not be used.

Sample packs must have 'Free medical sample – not for resale' or similar wording on the outer packaging. Over-labelling must not be used.

To register a common pack for use in the UK and another country, the licence details for the product must be almost identical. This does not apply to marketing authorisation (MA) numbers and addresses. If you need to update the packaging to include an MA number it should be submitted as a notification

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Patient information leaflets (PILs)

Unless all the information is on the pack, all medicines must include a PIL, regardless of how patients get them. PILs must:

- be easy to understand
- not contain personal information that can identify an individual, including names of staff members or digital signatures

Each product authorised under a marketing authorisation must have its own leaflet as explained in our best practice guidance on patient information leaflets (https://www.gov.uk/government/publications/best-practice-guidance-on-patient-information-leaflets). Also see MHRA guidance document always read the leaflet - getting the best information with every medicine (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet___getting_the_best_information_with_every_medicine.pdf) (PDF, 588 KB, 173 pages).

Our assessment of PILs includes a review of the font, colours, text size and layout of the information to assure the accessibility and readability of the statutory information.

Warnings on labels and leaflets for medicines

Labels must include warnings for safe use of the medicine. All products that contain paracetamol must include statutory warnings (https://www.gov.uk/government/publications/statutory-warnings-for-all-medicines-containing-paracetamol). Additional warning statements (https://www.gov.uk/government/publications/warning-statements-for-labels-and-leaflets-of-certain-medicines) must be included on the packaging of specified medicines.

You should include these warnings when making an application to register labelling and/or leaflets with us. Deviations from the proposed wording must be fully justified in your submission.

Braille on labelling and in PILs

All medicines must have the name of the medicine displayed in Braille on the labelling.

You must make you PILs available for blind and partially-sighted patients (https://www.gov.uk/government/publications/patient-information-leaflets-for-blind-and-partially-sighted-patients).

Braille can appear on more than one side of a product's carton. You must not use

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You can submit changes to Braille on the labelling through a notification.

Guidance

From 2016 the official Braille code in the UK is the Unified English Braille code (UEB) (https://www.pharmabraille.com/braille-codes/)

Guidance concerning the braille requirements for labelling and the package leaflet (http://academy.gmp-compliance.org/guidemgr/files/BRAILLE_TEXT20050411.PDF)

The British Standards Institute has guidance on the application of braille to the labelling of medicines (http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030180500).

Child-resistant packaging for medicines

Child-resistant packaging is used to make it difficult for young children to open medicines but easy for adults to use.

Packaging must be child-resistant if the medicine contains:

- aspirin
- paracetamol
- more than 24mg of elemental iron

You don’t need to provide child-resistant packaging if your product is:

- effervescent
- in single dose units

An MA or variation must demonstrate that child-resistant packaging meets international standards for reclosable or non-reclosable containers:

- reclosable packaging consists of container-closure systems that, when the closure is removed, permit access to more than 1 dosage unit and can be reassembled to form a child-resistant pack; reclosable containers must comply with international standard BS EN ISO 8317 (http://shop.bsigroup.com/SearchResults/?q=BS%20EN%20ISO%208317)
- non-reclosable containers are container-closure systems that once opened can’t be reassembled to form a child-resistant package such as blister packs; such non-reclosable packs must must comply with international standard BS EN 14375 (http://shop.bsigroup.com/SearchResults/?q=BS%20EN%2014375)

The British Standards Institute has published a consumer’s guide to the standards for child-resistant packaging (http://www.bsigroup.co.uk/LocalFiles/en-GB/consumer

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If aspects of the packaging system change, it may be necessary to vary the MA and include additional evidence that the new packaging system has been shown to comply with relevant international standards.

Factors that can affect the child resistant properties of a container-closure system include:

- change in foil material
- change in blister material
- change in adhesive
- different orientation of blister pockets
- different wadding materials in closures
- inclusion of a liquid medicine in a container-closure system previously used for solid dosage forms

Submit information for full assessment

Product information which needs a submission for full assessment and approval must include change codes on the application form.

P1

First approval of mock-ups following a granting of a MA where only text-only versions were submitted and approved as part of the MA application.

P2

Changes to PILs which include significant changes to content and/or design and layout and must show continued compliance with user testing or bridging data. Changes to the leaflet in line with article 62 (allowing a MA holder to include extra statutory information on the label and in the PIL) also fall into this category.

P3

Changes to pack design must always be submitted for full assessment. Changes include either layout of the information or changes to graphics on the pack, or both. If a third party has pre-approved the changes they will be assessed in 30 days.

P4

Changes where we inform you about the change, for which a full application is

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- approval of artwork for a new own-label supplier not previously known to us
- approval of artwork following a product name change where the changes proposed to the pack are considered to go beyond being relevant to the changes to the summary of product characteristics (SmPC) being applied for
- introduction of new safety information following consideration by an expert advisory committee
- amendment of artwork following a complaint relating to patient safety

Changes which do not fall into 1 of the 4 categories above will not be accepted for assessment and will need to be re-submitted as a notification.

Notification scheme registration

You must inform us of all changes to the labelling and PIL of a product if those changes are not part of changes to the SPC.

If the proposed changes don't need to be submitted for full assessment you must register the changes using the notification scheme.

The notification scheme is based on your declaration that the packaging meets legislative requirements and supporting documentation has been submitted.

Although you need to notify us of the amendment, you are responsible for the information on the packaging and in the PIL.

Fees

Fees for assessment of labels (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees#licence-renewals-reclassifications-and-assessment-of-labels-and-leaflets-fees)

Make a payment to MHRA (https://www.gov.uk/make-a-payment-to-mhra)

Make a submission or notification

Once you have received approval from us, you must introduce the changes within 3 to 6 months, unless you have been told to introduce the new information early because of safety reasons.

You can submit changes to labels, leaflets and packaging for the same product at the same time using a notification or for full assessment.

A separate application must be submitted for each product name. The submission must also include all affected MAs, particularly when a leaflet may be shared across

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A number of changes to labels and PILs can be made with each submission or notification using the same notification form or application form. You can also group changes that would have been a notification on their own with changes that need to be submitted for full assessment.

Format of data for submission

For a single MA, all label, leaflet and label-leaflet mock-ups must be submitted as a set of consolidated PDF documents. For a single product there could be 3 documents containing either all of the labels, all of the leaflets or all of the label-leaflets for all pack sizes and presentations of the product.

Where a single MA includes more than 1 product - branded or generic - the associated labels, leaflets and label-leaflet mock-ups for all pack sizes and presentations of each product must be submitted as separate sets of consolidated PDF documents.

To vary a label, leaflet or label-leaflet you must resubmit the entire PDF document which may contain labels, leaflets or label-leaflets that are not part of the variation. The new version of the data should be identified within the document.

The names of the PDF files should be in the format Label-Brand/Generic/Distributor name or Leaflet-Brand/Generic/Distributor name or Label-Leaflet-Brand/Generic/Distributor name. See out guidance on file naming requirements for labels, leaflets and label-leaflets (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/329900/File_naming_requirements_for_labels__leaflets_or_label-leaflets.pdf) (PDF, 67.1 KB, 2 pages).

The SmPC and PIL will be published on GOV.UK so it is essential that any personal information about company employees, printing companies or their employees or any other similar information, is removed from all label, leaflet and label-leaflet mock-ups PDF documents.

Submission forms

Submission of applications must use the application form (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/275799/Application_for_changes_to_labels_and_patient_information_leaflets.doc) (MS Word Document, 34 KB) in Word format or the portal form in PDF format. This form is not for changes accompanying a variation. See variations guidance (https://www.gov.uk/guidance/medicines-apply-for-a-variation-to-your-marketing-authorisation).

Guidance is available to help you submit a change

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Submission of notifications for self-certified changes to labels and/or leaflets must use either the notification application form (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/275800/Notification_of_changes_to_labels_and_patient_information_leaflets_for_self_certification_form.doc) (MS Word Document, 324 KB)in Word format or the portal form in PDF format.

If you are submitting electronically you will need to copy over the declaration statement and describe the changes applied for.

We acknowledge notifications within 14 days, after which any changes should be implemented immediately.

Complaints about labels, leaflets or packaging

We investigate complaints about the labelling and packaging of medicines made by patients, healthcare professionals or pharmaceutical companies.

We assess any complaint to decide if there is a safety issue or if there is no case to answer.

If a safety issue is identified the MA holder is required to respond – usually within 7 days.

We may identify other issues of regulatory compliance in addition to that raised in the complaint.

Investigations are usually completed in 30 days. It may take longer if the case requires detailed discussion or statutory action.

The complainant and the MA holder both receive a copy of the outcome report, which details the complaint and any action taken.

We do not reveal the identity of the complainant to the MA holder unless they are a competitor company.

UK regulation

The regulations for labelling and patient information leaflets are set out in The Human Medicines Regulation 2012 – Part 13 (http://www.legislation.gov.uk/uksi/2012/1916/part/13/made).

Contact

To discuss the content of you application, email patient.information@mhra.gov.uk.

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To request further information, email variationqueries@mhra.gov.uk.

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