Medicines & Healthcare products Regulatory Agency

MHRA Best Practice Guidance on Labelling & Packaging of Medicines.

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Best practice guidance on the labelling and packaging of medicines

1. Introduction

The safe use of all licensed medicines depends on both patients and healthcare professionals reading the labelling and packaging carefully and accurately and being able to understand and act on the information presented. The primary purpose of medicines labelling and packaging is the clear unambiguous identification of the medicines and to present information necessary for its safe use. Common factors affecting all users of medicines include the following:

- **Information**: certain items of information are vital for the safe use of a medicine.

- **Format**: information must be presented in a legible manner, using accessible language that is understood by all those involved in the supply and use of the medicine.

- **Style**: there is a potential for confusion between medicines with lookalike-soundalike (LASA) names and those with similar packaging.

Medication errors occur due to many factors which have been identified in Building a Safer NHS for Patients. Problems with medicines labelling have also been associated with medication errors. The current regulatory framework is clear what information must appear on medicines labelling, however additional guidance has the potential to help improve the layout and design of medicines labelling to aid clarity. This in turn can assist healthcare professionals, patients and carers to select the correct medicine and use it safely, thereby helping to minimise medication errors.

Using this guidance

All applications submitted (either via the application process or via the notification scheme) to the MHRA that include a labelling component should take account of the criteria in this document. This applies in all areas of MHRA work (new MAs, PLPIs, renewals, variations and notifications and applications to the Product Information Quality Unit).

The Agency may consider the comparison of the proposed packaging against others in a range already approved in order to consider whether safety in use may become an issue.

Innovation in pack design will be a significant factor in the correct identification and selection of medicines. Where a Marketing Authorisation Holder (MAH) deviates from this guidance a full justification for this should be provided with the application.

Once new packaging components have been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) these must be introduced into packed stock being certified for release to the market by the Qualified Person within six months, unless MAHs have been advised of the need for earlier introduction of the new components for safety reasons. The Qualified Person should not certify a medicinal product for release to the market if the packaging components, at the time of certification, have not been updated within six months of approval.

2. Purpose

The purpose of this guidance is to support a move to more self-regulation by the pharmaceutical industry of changes to labelling and packaging of medicines. When the guidance is applied, it will help to ensure that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimised. In preparing this guidance, it is acknowledged that different users of medicines require and use information differently.

Those involved in the design of labelling and packaging components should ensure that the following sections are taken into account prior to submission to the MHRA as any deviations from this guidance may need to be justified where these impact on patient safety.

3. Scope

The legislative requirements for the labelling of licensed medicines is set out in Part 13 of the Human Medicines Regulations 2012 (HMR). The individual items of information that must be presented on the outer and immediate packaging are set out in Schedules 24 and 25 of the same regulations.

This guidance has been drafted to support the legal framework set out in national legislation. It should be taken into account by MAHs when preparing the labelling provided with Marketing Authorisation applications and variation submissions or when submitting notifications or applications under Regulation 267 of the HMRs.

The guidance applies equally to prescription only medicines (POM) and those available over-the-counter (OTC). In assessing applications or the handling of

complaints about medicines labelling, the Agency will consider patient safety, in the light of experience and any adverse incidents reported.

4. General considerations

The following items will apply to all labelling components for all medicines regardless of legal category or whether the component is subject to the full or reduced labelling requirements set out in Schedule 24 of the HMRs.

4.1 Font size

The particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm. This minimum font size applies to labels subject to full labelling requirements and those where reduced labelling information may be applied, such as small containers and blister foils.

4.2 Critical information

Labelling must contain all elements required by Regulation 257 and Schedule 24 of the HMRs. Nevertheless, certain items of information are deemed critical for the safe use of the medicine. These items are:

- name of the medicine
- expression of strength (where relevant)
- route of administration
- posology
- warnings
- indications (over-the-counter medicines only)

Clarification on these items is provided below.

4.3 Presentation of critical information

For outer packaging components and immediate labelling that are subject to full labelling requirements set out in Schedule 24 (Part 1) of the HMRs, critical items of information should be located together and appear in the same field of view where practicable. These items should not be broken up by additional information, logos or background texts or graphics.

For POMs it is likely that these pieces of information will appear together on the front face of the outer packaging. For OTC medicines, due to the difference in pack design, it is usual for this to appear across both the front and back of the

pack. Where a medicine is provided without an outer carton, the critical information should be presented in the same field of view on the immediate label.

Information hierarchy is important. Items of critical information should be presented more prominently than information of lesser importance. Prominence is influenced by text size and style but is also impacted by other factors such as the colour used, location on the pack and any other surrounding graphic elements included in the design.

4.3.1 Name of the medicine.

The name that is registered in section 1 of the Summary of Product Characteristics (SmPC) must be used on all packaging components. Further guidance on product names can be found in the MHRA guideline for the naming of medicinal products and braille requirements for name on label.The name registered in the SmPC may not be abbreviated for inclusion on the labelling and should be selected with this in mind. For labelling elements where there is a reduced printing area, such as small container labels, the short term for the pharmaceutical form may be used within the product name, where this is set out in section 3 of the SmPC.

Braille

Regulation 259 of the HMRs requires the name of the medicine to be shown on the packaging in Braille. Braille consists of arrangements of dots which make up the letters of the alphabet, numbers and punctuation marks. The basic Braille symbol is called the Braille cell. As there are differences in Braille in different countries, the type of Braille letter (size of Braille cell) has to be standardised. The use of Marburg Medium is highly recommended.

The name selected and registered in section 1 of the SmPC should be chosen carefully to ensure that what is set out for sighted patients can be communicated in Braille to blind and partially sighted patients via the outer packaging. Where a medicine is only available in a single strength or unique pharmaceutical form, these may be omitted from the product name presented in Braille.

The product name in Braille is required on the outer packaging of all medicines that will be directly handled by patients or their carer. It is not required on the packaging for medicines only intended for administration by healthcare professionals.

The product name in Braille does not have to be located on an empty space on the outer packaging but the underlying printed text must remain easily legible.

Location of product name on the outer packaging

Where possible, the full product name should appear on three non-opposing faces of the outer carton, maximising visibility of this information when stored and aiding accurate identification of the product. This recommendation is relevant to both POMs and OTC medicines.

Location and prominence of the common name(s)

Where the medicine contains up to three active ingredients, Paragraph 4 of Schedule 24 of the HMRs requires that the common names of these active ingredients should immediately follow the name of the medicine on the pack, where the active ingredients are not integral to the name of the medicine registered in the SmPC. There should be no intervening text or graphic of any kind.

The recommended International Non-proprietary Name (rINN) should be used, or the usual common name where no rINN exists. The common name(s) should not be associated with any quantitative information. Where the common name(s) appears after the brand (invented) name, these should be given due prominence. Generally, this will be determined by the relative size of the text but other factors may be relevant such as colour of text, the font used and any other graphic elements on the pack. The size and prominence of the common name(s) must always be greater than any non-statutory text on the pack.

Where a “Co-” name is used for the medicine, this should be registered in section 1 of the SmPC and appear on the labelling as part of the name. The “Co-“name should be followed by the relevant common (names) as shown in the example below:

Name in section 1 of SmPC: Co-Codamol 8/500mg Tablets

Name presented on labelling: Co-Codamol 8/500mg Tablets

Codeine & Paracetamol

Generic cephalosporins and Tallman lettering

The MHRA have agreed a labelling design mechanism to help pharmacy staff and other healthcare professionals more easily identify the correct medicine. To reduce the likelihood of errors occurring in the dispensing environment, use of

Tallman lettering or other means of picking out key portions of the drug name, is required on the labelling of all medicines in this class.

Tallman lettering involves the use of capital letters (or the use of different coloured text) to highlight some unique aspect of the drug name. The particular string of letters to be highlighted in the cephalosporin range is set out below.

The labelling for any medicine in this drug class will be expected to comply with these provisions.

- cefa**CLOR**
- cef**ADRO**xil
- cef**ALEX**in
- cef**AZOL**in
- ce**FIX**ime
- cefo**TAX**ime
- cef**PODOX**ime
- cef**RAD**ine
- cef**TAZID**ime
- cef**TRIAX**one
- cefuroxime

Tallman lettering may be used to highlight portions of the drug name for other medicines. However, to reduce the risk of overuse of this design tool and consequential lack of impact, MAHs are asked to provide supporting evidence that there have been medication errors associated with the products they are intending to label using Tallman lettering.

4.3.2 Strength

Presentation of strength of the medicine within the product name should be identical to that set out in section 1 of the SmPC.

Different strengths of the same drug should be expressed in the same manner, e.g., 250 mg, 500 mg, 750 mg, 1000 mg and NOT 1 g. Trailing zeros should not appear i.e., 2.5 mg and NOT 2.50 mg. The decimal point need not be centred, provided that if a full stop is used it is clearly visible.

For safety reasons, however it is important that ‘micrograms’ is spelled out in full and not abbreviated. In cases where this cannot be accommodated on a small label (e.g. vial label), the abbreviation “mcg” rather than µg should be used.

For injectable medicines or those available in solution or suspension, it may be necessary in some cases to express the strength as quantity per unit volume and also as the total quantity per total volume. If presented on the packaging, total quantity per total volume should be highlighted and would usually be more prominent than the unit strength within the product name.

4.3.3 Route of administration

The route of administration stated on the labelling should reflect that set out in section 4.2 of the SmPC. The information must be conveyed by a positive statement, for example:

“For oral use”

“For intravenous injection only”

“Give/administer by subcutaneous injection”

The route of administration should be written in full on the outer packaging and if space permits on the immediate label. For POMs, the route of administration should be located on the front face of the outer carton. Where available printing space is limited on the immediate label, such as for vials and ampoules, the route of administration may be abbreviated provided that the standard abbreviation in the Tables of non-standard abbreviations (published by EMA) is used. Non-standard routes of administration should be spelt out in full to avoid confusion.

Some routes of administration will be unfamiliar to patients and may need careful explanation. For medicines made available for self-selection in particular, the language used should be carefully considered to ensure the meaning is likely to be understood.

For example:

“For application to the skin” is more likely to be understood than “For cutaneous use.”

However, use of the standard terms will be considered acceptable for those medicines that will have a dispensing label applied.

4.3.4 Posology

Prescription only medicines

For POMs, the recommended dosage will be conveyed via the dispensing label applied by the pharmacist. This will only be necessary for products intended for

self-medication. Medicines that are only ever administered by healthcare professionals do not require a dispensing label.

Over-the-counter medicines

For OTC medicines, instructions for use must be presented on the outer packaging, as set out in Paragraph 18 of Schedule 24 to the HMRs. This information would usually be accommodated on the back of pack. If the immediate label is subject to full labelling requirements, it must also present the instructions for use.

4.3.5 Warnings

The warnings considered 'in scope' as critical information are those specifically required by the terms of the Marketing Authorisation (MA) to be stated on the labelling. Many medicines will not need the addition of any warnings on the front of the pack. This section is intended to convey only those critical warnings necessary immediately prior to administering the product and required by Paragraph 11 of Schedule 24 to the HMRs.

A full list of warnings which are required to appear on the labelling of particular medicines is set out in a separate addtional warning statement guidance document. Where relevant, advice on the location of these warnings is also provided. These have been prepared in accordance with the user-testing principles applied to patient information and are consistent with those published by the British National Formulary.

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Excipients of known effect

Many medicines will contain excipients which have a pharmacological effect in their own right. In line with Paragraph 7 of Schedule 24 to the HMRs these have to be included on the label. Guidance covering this provision is available from the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use and remains relevant to UK medicines. It is not replicated here.

4.3.6 Indications

POMs do not need to present the approved indications on the labelling. OTC medicines, i.e. those which are either pharmacy only (P) or general sales list (GSL) legal status must include the registered indications on the labelling in line with Paragraph of Schedule 24 to the HMRs. For OTC medicines this information is considered part of the critical information set, so that patients can easily identify if a medicine is suitable for them.

4.4 Presentation and location of critical information

The critical information should appear in as large a font as possible to maximise legibility, on at least one face of the outer packaging or in the same field of view if the medicine is provided without an outer carton. It should not be broken up or separated by non-critical information. The critical information (see section 4.2) should usually appear in the order stated. Although use of a large font may be appropriate, other factors may also be important in making the information legible. Consideration should be given to the colour of text or background, line spacing and use of white space to enhance the legibility of the information provided. For some small packs it may not be possible to present all the critical information on one face. For these packs, related information should be co-located on the pack.

4.5 Innovative pack design and colour

The judicious use of colour is encouraged to ensure accurate identification of a medicine. In considering the acceptability of a particular pack design, it will be necessary to consider the relative distinguishing features compared to other packs in a range. A range may mean all packs bearing a corporate livery or a group of packs carrying the same design theme. The primary aim of innovative design of packaging is to aid in the identification and selection of the medicine. To reduce the risk of pack similarity, or identification of packs solely by colour, the use of ‘colour-coding’ is not supported. Colours should be assigned randomly to highlight strength. When assigning colours to highlight active ingredient and strength, MAHs should consider lookalike-soundalike (LASA) product names, how products might be stored (e.g. alphabetically in pharmacy) and commonly co-prescribed medicines, to further reduce the risk of issues with pack similarity.

4.6 Dispensing label requirements

The outer packaging for POMs intended for self-medication should have a dedicated space to accommodate the pharmacy dispensing label, as set out in Paragraph 9 of Schedule 24 to the HMRs. In the UK the space required is usually 70 mm x 35 mm. The dispensing label area must not cover any statutory information on the carton or the product name in Braille.

4.7 Positive labelling statements

Only positive statements should appear on medicines labelling to avoid ambiguity of the message. For example, “For intravenous use only”. Negative statements such as “Not for intravenous use” must not be used.

4.8 User testing

Although user testing is not part of the legal provisions, undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice. These data (where they have been generated) should form part of the package of information supporting the changes applied for.

It is not necessary to user test all labelling components, but consideration should be given to carrying out a user test when significant changes are proposed to the layout and colour of the information presented, such as the introduction of innovative pack design. In addition to a formal user test, focus groups and panels may be useful means of evaluating the changes.

Care should be taken to ensure that the test undertaken is applicable to the "user" because healthcare professionals have different needs compared to patients in relation to the same pack. Testing must therefore be tailored to the needs of the particular user groups.

5 Small containers

5.1 Small container regulations

Where the full labelling requirements cannot be legibly applied to a container, Regulation 257 of the HMRs alongside Part 3 of Schedule 24 permits a lesser information set to be applied. A small container is not defined within the legislation but the reduced labelling requirements would normally be considered to apply to containers with a nominal volume of 10 ml or less, or tubes of 10 g or less. However, other factors may need to be considered such as the size and shape of the label, the amount of information which needs to appear on the label and the font size necessary to achieve legibility of the information.

5.2 Critical Items of information

The critical items set out in section 4.2 are not additional to the information set out for small container labelling. Posology, warnings and indications would not be required.

5.3 Font size

All information on a small container label must meet the minimum font size requirement of 7 point (see section 4.1).

5.4 Pack design

The use of innovative pack design is also applicable to small containers and is regarded to be of particular importance where space is at a premium and the presentation of critical information (name, strength and route of administration) will be smaller. The following points should be considered:

- The use of colour and design elements to highlight strength and active ingredient(s) on the outer carton should be extended to the immediate small container label where possible.
- Transparent labels are discouraged due to legibility issues.
- The label should be as large as possible but for ampoules and vials, a label-free area should be left for inspection of the contents.
- Ideally, the label should be applied along the length of an ampoule with the product name printed longitudinally. Patients and healthcare professionals should not have to rotate the container to read the name.

5.4 Additional information

For traceability purposes it is recommended that the following information should appear on the labelling of small containers, where space allows:

- PL number
- MAH name. This may be replaced by the company logo where the MAH name is an integral part of it, but the use of a logo should not be at the expense of other critical information and it should be of a small size relative to the rest of the text. Where space is at a premium, the inclusion of the MAH name will not be mandatory.

Other additional information that is considered useful to the user may also be presented, provided that this does not impact on the size and prominence of the critical information.

6 Blister packs

6.1. Blister pack regulations

Where a blister or strip pack is enclosed in a container which meets the full labelling requirements, Regulation 257 of the HMRs alongside Part 2 of Schedule 24 permits a lesser information set to be applied to the blister or strip packs.

6.2. Layout of information

Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack. It is important that the particulars remain available to the user up to the point at which the last dose is removed from the blister pack.

Often it will not be possible to apply all the information over each blister pocket. Consequently, where a random display of the information is proposed, it should frequently appear across the pack. In all cases, it will be acceptable to apply the batch number and expiry date to the end of the blister strip. If technically possible, this could be applied to both ends of each strip.

Where possible, perforated blister foils must present the name and strength of the product over each blister pocket. Where a perforated blister foil is considered to be unit dose, each pocket must be fully labelled i.e. including MAH name or logo, and batch number and expiry date details.

6.3. Font size

All information on a blister foil must meet the minimum font size requirement of 7 point (see section 4.1).

6.4 Use of colour on foils

Colour for the text and the font style should be chosen carefully as the legibility of the text on the foil is already impaired due to the nature of the material. Where possible, non-reflective material or coloured foils should be considered to enhance the readability of the information presented and the correct identification of the medicine. Use of pastel shades to present text on foils is not recommended.

6.5 Calendar packs

Calendar packs are only appropriate for tablets or capsules that are taken as a single dose once, or twice daily. The packs must be supplied in multiples of 7, and all blister pockets must be labelled with the days of the week.

7. Non-statutory information on labelling

7.1 Non-statutory information regulations

Regulation 261 of the HMRs permits the inclusion on the label and in the patient information leaflet (PIL) of symbols and pictograms which are intended to clarify information presented, in addition to being compatible with the SmPC, useful for

the patient and importantly, not promotional. Design elements, such as the innovative use of shapes, colours, symbols and pictograms can help differentiate products and are a useful tool especially for medicines available OTC as they can help aid self-selection.

There may be instances where additional information about the way in which the medicine works and the condition it is intended to treat will be beneficial. This could for example be the case for patients who take prescription medicines which are used chronically. Leaflet information under this provision is set out in separate Best practice guidance on patient information leaflets.

7.2 Quick Response (QR) codes

QR codes may be included on packaging provided they are subordinate in prominence and placement to the statutory information. In addition, such a code must link to information that is compliant with Regulation 261 of the HMRs, i.e.

- compatible with the SmPC
- useful for the patient
- non-promotional

When access to such information is provided via a QR code on the pack, the corresponding URL (uniform resource locator) must also be presented on the pack, so that those without mobile scanning capability can access the information

An applicant intending to include a QR code on the labelling or in the PIL for a particular product must make an application to the Product Information Quality Unit in the usual manner. Inclusion of a QR code on the label or in the PIL cannot be achieved by means of a notification since the application must include as part of the dossier a detailed account of the information to which this code links.

Information which would be deemed acceptable would be likely to include patient support materials such as additional disease-related information and life-style information. The QR code may also link to the authorised product information such as the SmPC and PIL.

Medicines for which such support materials are considered appropriate would usually be for long term medical conditions and/or medicines where additional support was required as part of the licensed indication. Many such medicines already make reference to additional support in the PIL, and it may be appropriate in these cases to include a QR code in addition to other signposting to such support materials.

QR codes should not be confused with 2D barcodes which are added to labelling at the time of packaging to enable batch number, expiry date, and other product specific details to be recorded on the labelling.

7.3 E-mail and website addresses

An email address may be included as a means of contacting the MAH. In circumstances where a PIL is not separately available, this may appear on the labelling.

Website addresses may not be included on the outer packaging of any medicine. However, in certain limited circumstances, a website address may be permitted to appear at the end of the PIL. Applications will be considered on a case-by-case basis by the MHRA but will generally be accepted for products where additional support is referenced in the SmPC as being essential for the safe and effective use of the medicine.

Applicants intending to include website addresses in the PIL should ensure that the website is fully compliant with national legislation and MHRA guidance. The URL should be accessible by the MHRA assessment team at the time of application so that the information can be assessed against these provisions.

7.4 Code of Practice on Pack Design

Non-statutory information is frequently used in the labelling for medicines available OTC. In this sector, the Proprietary Association of Great Britain (PAGB) administer a Packaging Code for Medicines which sets out MHRA policy in this area and examples of best practice.

Non-statutory information must be subordinate in placement and prominence to the statutory information. Generally, this would mean that any such statements are smaller than the declaration of the common name(s) of the active ingredients on the front of the pack.

For medicines supplied OTC for self-selection the use of this provision can be useful. For POMs, whilst the critical health information panel must be the primary place for people to locate and understand the information they need to use the product safely, the rest of the pack is also important.

Innovative pack design across manufacturers' product ranges should ensure accurate identification of the individual products and differentiate between products in a range. Where similarities exist between product names, pack

design should allow differences to be easily discernible. This will form part of any safety assessment carried out by MHRA to determine for example the suitability of a proposed name.

7.4.1 Condition or indication statements

It is important that people using OTC medicines understand the condition that it treats. The information should be given in language that people will understand and can act upon. Medical terminology should not be used unless there is evidence from user testing that it is understood.

Where a product relieves symptoms, the language used must not imply that the product cures the condition. If a medical diagnosis is needed before self-medication is undertaken, this should also appear on the packaging.

Clarification on when certain indication statements may be used is provided below.

Relieves, soothes: May be used for all products which work by improving symptoms. These words indicate an improvement in symptoms.

Stop as in "stops coughing" or "stops scratching": These statements should be used with caution. "Stop" may imply a product guarantee and can only be used when supported by the SmPC.

Statements preceded by "can", "to", "may", "helps", "could", "for": These words avoid implying that the product will work for 100% of the population, 100% of the time. These statements may be used for all products.

Effective relief: May be used for all products as the issue of a Marketing Authorisation is evidence that the product is effective.

7.4.2. Speed or duration of action statements

Knowing when a product will work and how long it might work can be useful to ensure safe use of a medicine, and can aid compliance with dosage instructions. Such information can help people know if the product is working for them and enable them to make a decision about seeking professional advice for a diagnosis or a different, more appropriate product.

Fast acting (or similar wording): May be used where the SmPC allows it. Fast acting statements may only be made for conditions where a fast onset of action is relevant to the clinical condition being treated such as acute pain relief. These

statements may not be appropriate for chronic conditions or those not requiring immediate relief.

For most conditions, “fast” is regarded as producing a clinically significant effect (e.g. meaningful onset of relief) within 30 minutes. Information will need to be included in section 4 or 5 of the SmPC to support any statements of this nature.

Gets to work in X minutes: Is acceptable if the SmPC includes information regarding the onset of therapeutic action. Absorption data alone is not sufficient to support efficacy claims.

24 hour action/One a day: Dosage instructions to take the product once a day do not necessarily mean that a statement of 24-hour relief is acceptable. Clinical evidence must have been presented for inclusion in the SmPC to show that the clinical benefits of the product last for 24 hours.

Relieves pain for up to X hours: Is acceptable if supported by the SmPC. Clinical evidence must have been presented for inclusion in the SmPC to show that the clinical benefits of the product last for up to X hours. This is preferable to more general statements such as “lasts for hours” which will not be considered acceptable.

Double or Triple action: Can only be used where a product has ingredients which work in two or three different ways. It cannot be used for products with a number of ingredients with the same mode of action.

Long acting or long lasting: Where a medicine is formulated as a modified or sustained release preparation the name of the medicine will reflect this and the term “long acting” or similar will appear within the name of the product.

All night: This statement may be used where the product is indicated for night-time use and has a therapeutic action that lasts for a minimum of 8 hours as supported by the SmPC.

Comparative statements: Top parity or superiority statements must not be used in packaging because a comparison is being made with all the other products in the category. Examples include: “Nothing acts faster”, “nothing works better”, “there is no stronger pain relief.”

7.4.3. Statements relating to particular groups of the population

While OTC medicines have a good safety profile, they are not suitable for everyone. Pregnant women in particular should be advised not to take medicines without professional advice.

Other groups of the population such as diabetics and parents of children find it useful if the label includes information which is relevant to them, which helps them choose the appropriate product. Where such statements as below are made on a pack, evidence must be provided to support the statement.

Can be used in pregnancy: This statement may only be included within the critical health information where a product is specifically indicated for use in the pregnant population in section 4.1 of the SmPC. Dosage information must be included in section 4.2 of the SmPC and a supporting statement must also appear in section 4.6 of the SmPC. Front of pack statements in relation to use in pregnancy cannot be included.

7.4.4 Free from statements

The requirements for the information which must appear on medicines labelling is set out in Part 13 of the HMRs 2012. The primary purpose of the label is (a) to unambiguously identify the medicine and (b) to convey key warning statements in relation to safe and effective use of the product.

The patient information leaflet and package labelling must provide information about what ingredients are present in a medicine. In general, **statements indicating what a medicine does not contain are not permitted.** Any statements regarding the formulation of a medicine must be related to patient safety.

Sugar-Free: This statement may be used in relation to oral liquid medicines, lozenges pastilles, chewable tablets and gums which do not contain fructose, glucose or sucrose. Medicines containing hydrogenated glucose syrup, mannitol, maltitol, sorbitol or xylitol may also be referred to as sugar-free as there is evidence that these excipients do not cause dental caries. Where the product contains other sugars such as lactose this statement may not be included as the information may be misleading.

Gluten-Free: Where information is available from the SmPC that the product can be deemed gluten-free a statement to this effect can be included within the critical health information pane (for POMs). No graphic or promotional symbols may be included particularly on the front of pack.

Free from artificial colours and flavourings: The PIL, and when applicable the labelling, are required to include a comprehensive list of all ingredients in a formulation. Statements such as “free from” flavourings or artificial colours are not allowed as they are considered to be promotional claims.

Suitable for vegans or vegetarians: There is no legal requirement for a pharmaceutical manufacturer to state whether or not a particular medicine is suitable for vegans or vegetarians. A statement of this nature is not foreseen in the legislation, as it is not a statement which identifies the medicine nor conveys warnings on the safety of the medicine.

Where it is possible to demonstrate from the pharmaceutical dossier that the product and the individual ingredients have not been derived from animal products, a statement such as “Contains no ingredients of animal origin” may be permitted following detailed assessment. If allowed, this statement should be located with the statement of active content and declaration of ingredients on the outer packaging. It may not be used as a front of pack statement, as this is considered promotional.

To permit a statement indicating suitability for vegans or vegetarians, the pharmaceutical dossier would need to demonstrate that none of the ingredients of a medicine are derived from an animal source or have been tested on animals. Additionally, no animal derived materials may be used in the manufacture or testing of the medicine. Taking account of all of the above issues in relation to formulation and testing, it is exceedingly unlikely that any medicine could confidently be labelled as “suitable for vegans or vegetarians”.

7.4.5 Excipients in the formulation

Those ingredients in a medicine that are known to cause problems for some patients must be declared on the outer packaging. A comprehensive list of these ingredients can be found in the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use.
‘Excipients in the labelling and package leaflet of medicinal products for human use.’

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Factual statements about excipients in the formulation may be acceptable where these are not deemed to be promotional, e.g. “This product contains x mg of Vitamin C”. Statements informing consumers of flavour variants e.g. strawberry flavour, mint flavour are also acceptable. However, subjective wording such as ‘pleasant tasting’ is considered promotional and must not be used on labelling.

7.4.6 Statements relating to side effects and safety

Within some therapeutic categories, there are differences in the side effects or interaction profiles and it helps people to choose the appropriate products if this is highlighted on the pack.

No medicine is absolutely safe. To the consumer, “safe” means that there are no side effects or interactions. Even if the SmPC states “no known side effects” packaging information should not imply that the product is completely safe.

Non-drowsy: This statement may be used on products in a range where some contain ingredients which cause drowsiness, to help people identify or avoid products which may affect their driving. It may not be used to artificially distinguish between products where this is not an issue for the ingredients commonly available in a category.

Any reference to “drowsiness” or “sleepiness” in the side effects section of the SmPC would preclude use of this statement.

7.4.7 Formulation statements

While the most important ingredient in any medicine is the active ingredient, other aspects of the formulation are important. People who have difficulty swallowing tablets seek soluble, effervescent or capsule-shaped tablets or suppositories.

In established products, active ingredients or excipients change from time to time as new ingredients replace older, less safe or less efficacious ones. It is acceptable to highlight such changes to alert people who are already using the products to some new aspects of it. Updating packaging to remove a “new” statement after one year may be done via a self-certification submission.

It can also be helpful to draw attention to higher dose products and to those products which are available only in pharmacies where professional assistance can be obtained provided these do not suggest superiority of the product or contain elements which are considered to be promotional.

Clarification on when certain formulation statements may be used is provided below:

Unique formulation: This statement may be included where the product in question is the only licensed medicine with that particular qualitative formulation. Should another medicine be authorised with the same ingredients this statement will need to be removed.

New: This statement may be used where appropriate for a period of one year from launch of the new product. It can be used to identify a change in the formulation of an existing product or to identify a new product (i.e. not new pack size or packaging design) within a range. The relevance of the word "new" must be obvious from the context and there should usually be some qualifying statement to clarify this.

New flavour: This statement may be used for a period of one year from launch of the new flavour. It can be used to draw attention to a change in the formulation or the introduction of a new product with a different flavour.

Peppermint (or other) flavour: This statement can be used to highlight the taste of a product. It is particularly useful for products such as throat lozenges and gum, which stay in the mouth for a time. Statements such as “cooling mint” are not acceptable as they are promotional in style and imply a sensory effect of an excipient. Any reference to flavour variants should be factual and non-promotional.

Pharmacy Only formulation: This may be used if the product contains an ingredient which is restricted to pharmacy sale. It may not be used to describe a pack size that is restricted to pharmacy sale.

Maximum strength: May be used where a product is part of a range to designate the higher strength product or where a product contains the maximum level of an active ingredient which is permitted in an OTC product. It cannot be used when there is only one strength of an ingredient available.

Herbal: May not be included unless the active ingredients are 100% herbal. It is not necessary for the excipients to be of plant origin.

7.4.8 Mode of action statements and use of “natural”

Wording on the labelling must not imply a product is safe because it contains natural ingredients. Statements linking safety with natural ingredients may not be made unless supported by the SmPC.

Natural: This statement may only be used where all of the ingredients in the medicine are natural. If only some of the ingredients are natural then the term is not permitted.

Acts naturally, works naturally, natural relief for congestion, relieves symptoms naturally: Such statements are only acceptable for products which have a natural mode of action, i.e. an action which mimics a physiological

mechanism of the body. For example, the term "natural action" has been used for products for constipation which work by stimulating peristalsis to distinguish them from irritant or bulk-forming laxatives.

7.4.9 Symbols or pictograms designed to clarify certain information

Symbols or pictograms are permitted under Regulation 261 of the HMRs where these are designed to clarify information within the SmPC. Any symbols or pictograms used must be accessible to consumers and testing may be required to show that this is the case. Logos and symbols relating to particular trade bodies, professional bodies or patient organisations are not acceptable.

Pictures of children: Pictures of children on a pack can help highlight medicines which are suitable for children. Where pictures of children are used, they should appear to be in the age range that the medicine is intended for. It is not sufficient to establish the child's actual age is in the target group.

Pictures of parts of the body: Pictures of parts of the body can help patients understand what a product is for and how it works. It can also help distinguish between products in a range.

Pictures of dosage forms: Including pictures of the dosage form on packs helps consumers identify their shape, whether they are soluble, effervescent or chewable. Where a picture is used on a pack the illustration must reflect the dosage form inside and be representative of the actual size, shape, colour and markings. The number of dosage forms shown must also be considered so as not to mislead about the dose e.g. where the OTC dose of the active ingredient is limited, the number of tablets shown for example must not depict a quantity of ingredient which is a prescription only dose.

Pictures of leaves and fruit: Images of leaves or fruit are only acceptable where natural extracts are used in the formulation. The use of artificial flavours will preclude the use of these devices on labelling.

Pictures of honey or honeycombs: Images of honey or honeycomb are only acceptable where natural extracts are used in the formulation. The use of artificial flavours will preclude the use of these devices on labelling.

Recycling logos: Symbols that provide information on which components can or cannot be recycled are acceptable. The placement of the recycling logos and symbols should be considered to avoid compromising the required information related to the medicine.

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

June 2026

Term / abbreviation	Definition
LASA	Lookalike-soundalike (name)
MHRA	Medicines and Healthcare products Regulatory Agency
HMR	Human Medicines Regulations (2012)
PLPIs	Product Licence Parallel Imports
POM	Prescription Only medicine
OTC	Over-the-counter (medicine)
SmPC	Summary of Product Characteristics
rINN	Recommended International non-proprietary name
MAH	Marketing Authorisation Holder
MA	Marketing Authorisation
P	Pharmacy medicine (legal status)
GSL	General Sales List (legal status)
PIL	Patient Information Leaflet
QR code	Quick Response code
URL	Uniform Resource Locator - web address that specifies the location of a resource on the internet.
PAGB	Proprietary Association of Great Britain