PAGB

The Consumer Healthcare Association

PAGB Packaging Code for Medicines

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PAGB Packaging Code for Medicines

Introduction

Background

The labelling components of medicines are controlled by product information contained in the Summary of Product Characteristics (SmPC), and specific legislative requirements set out in national legislation and in European directives (for Northern Ireland). According to *Regulation 267 of the Human Medicines Regulations (HMR) 2012* as amended, the mock-ups of labelling components (e.g. labels and cartons) are submitted to the Medicines and Healthcare Products Regulatory Agency (MHRA):

- as part of the dossier in any application for a new product
- when there is a change to the information in the SmPC which impacts the labelling components or
- when a stand-alone change(s) to the labelling components is proposed.

PAGB, the consumer healthcare association, represents the manufacturers of branded OTC medicines, self care medical devices and food supplements in the UK. PAGB has developed this Code of Practice (the Code), with input from member companies and the MHRA, to encourage best practice in medicines labelling.

OTC medicines are designed for the public to choose and use without medical intervention for a range of illnesses. High quality patient information is part of the wider risk minimisation measures which are considered as part of the reclassification of medicines from prescription supply to pharmacy supply, and then to general sales. Good patient information is essential to ensure that people can choose and use medicines safely; the most important place for this information is with the product itself.

This Code has been developed to expand on the existing guidance and provide practical advice to manufacturers designing and amending the packaging of OTC medicines. It draws information mainly from the ***Best Practice Guidance on the Labelling and Packaging of Medicines*** developed in the UK and issued by the MHRA. This Code also refers to the Report of the Committee on Safety of Medicines Working Group on Patient Information, ***Always Read the Leaflet - Getting the best information with every medicine***, and the ***EMA Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use***.

This Code sets out legislative requirements and additional guidance that are needed to support pack design applications.

Please note that while labelling regulations establish the information which must be on a product label and the order in which it is to be set out, every medicinal product has its own information requirements, which are linked to its registered indication(s), active ingredient(s) and formulation. The SmPC is the blueprint for packaging information and each piece of information on the label must be supported by information in the SmPC.

Scope

The Packaging Code covers both the statutory and non-statutory information which may be permitted on packaging and labelling. It is intended to be read alongside the legislative requirements set out in Part 13 of HMR 2012 as amended, which sets out what information must be included on a medicine label and requires that this information must be clear and legible. The Code also provides further clarification on the provision of the critical information, which is part of the MHRA's Best Practice Guidance on the Labelling and Packaging of Medicines, from an OTC perspective. In addition, it gives guidance on:

- typography and layout
- the use of non-promotional symbols
- the addition of non-statutory information.

Please note that further clarification on the definition of critical information can be found under ***'PART ONE – Statutory information'***.

The Code has no legal standing, but it has been developed with input from the MHRA and reflects their interpretation of the legislation and current policy. The Code will be reviewed and updated to reflect changes in guidance and advice from the MHRA.

How does PAGB's pre-approval scheme work?

All PAGB member companies are required to adhere to this Code and can optionally submit packs for checking before submission to the MHRA. Non-members can ask for their packaging to be subject to pre-approval by PAGB in advance of submitting an application to the Product Information Quality Unit (PIQU) at the MHRA (please refer to the ***MHRA website***) and in this instance are similarly expected to comply with this Code when proposing changes to the labelling and packaging information.

PAGB's pre-approval scheme for OTC medicines covers changes to pack design and layout, also known and referred to as **P3Ex changes** (Figure 1). P3Ex changes can include:

- changes to any or all of the layout of the information
- changes to the content of the information and
- changes to graphics on the pack.

PAGB's pre-approval scheme also covers design changes to the brand logo that appears at the top of the Patient Information Leaflet (PIL). Please note that other changes to the PIL should continue to be submitted to the PIQU for assessment, or as a self-certification submission (both via the Information Processing Unit) at MHRA as usual.

Please also note that where packaging changes that can be self-notified are also being made alongside P3 changes, they can be grouped under a P3Ex submission.

Timelines: where these changes have been approved by PAGB, before submission to the MHRA, the application will be eligible for expedited assessment which will be carried out within 30 days of the application being deemed valid following receipt.

Follow up: all companies using PAGB's pre-approval scheme are required to notify PAGB of the outcome of their application to the MHRA.

PAGB's approval scheme does not apply to information changes which require a variation to the marketing authorisation.

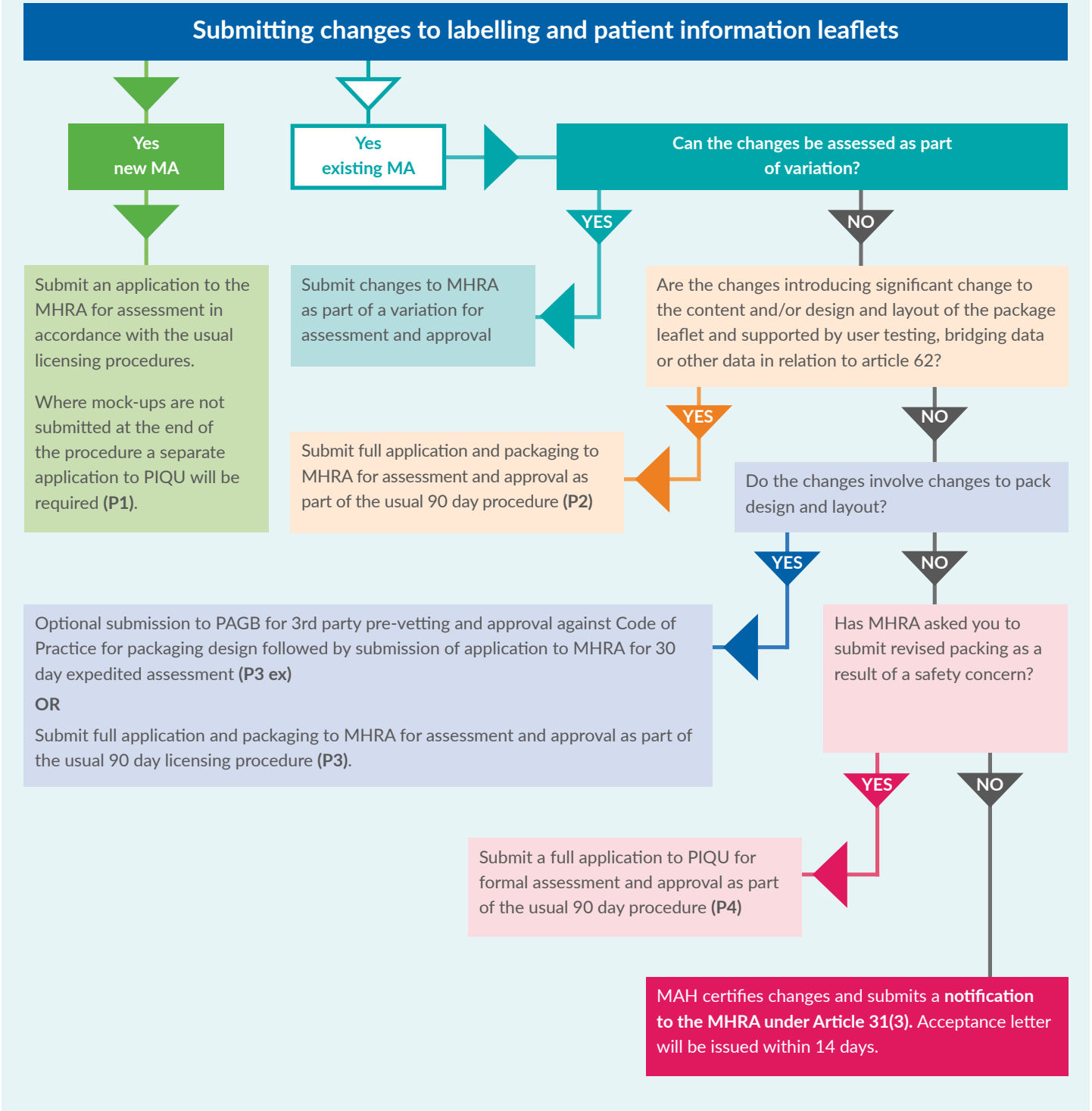

Figure 1: The different application routes related to pack design changes. Information taken from MHRA Guidance on Submitting Changes to Labelling and Patient Information Leaflets.

Principles of the Code of Practice

- The primary objective of the label is the clear and unambiguous identification of the medicine along with the critical information for safe and effective use. Any other information included on a label must not impact adversely on this principle. Any additional information must be subordinate in prominence and placement to the statutory information.

- All non-statutory information on a medicine pack must be compatible with the SmPC and must not include elements which are promotional in nature. Information appropriate on the labelling for one Marketing Authorisation Holder's (MAH) product may not be relevant on a competitor company label where the details within the SmPC are different.

- It is important that people using OTC medicines understand the condition that they treat and how the medicine should be used appropriately. The information should be given in language that people will understand and can act upon. Medical terminology should be avoided 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.

- While OTC medicines have a good safety profile, they are not suitable for everyone. For instance, pregnant women should be advised not to take medicines without professional advice. Other groups of the population, such as diabetics and parents, find it useful if the label includes information which is relevant to them and helps them choose the appropriate product. However, this information must be subordinate in prominence and placement to the statutory information to avoid being considered promotional.

- Within some therapeutic categories there are differences in the side effect 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 has "no known side effects", packaging information should not imply that the product is completely safe.

- People may have difficulty swallowing tablets and seek soluble, effervescent, capsule shaped tablets or suppositories.

- In established products, 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, provided it is clear that the product itself is not new e.g., new formulation.

- While the critical information must be the primary place for people to locate and understand the information needed to use the product safely, the rest of the pack is also important. For all medicines, similarity in product name and similarity in packaging is known to be one of the biggest contributing factors in medication error. 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 the assessment by MHRA.

PART ONE – Statutory information

The information specified in Part 1 Schedule 24 of HMR 2012 as amended must appear legibly on the labelling of all medicines. Also, instructions for use are required for all OTC medicines and this will need careful consideration, particularly when there are multiple indications and dosage regimens.

Please note that the PAGB Packaging Code for Medicines does not cover all the statutory information detailed in MHRA's Best Practice Guidance on the Labelling and Packaging of Medicines. The full requirements for statutory information can be found in the MHRA's guidance.

1.1 Critical information

MHRA's Best Practice Guidance on the Labelling and Packaging of Medicines refers to the "critical information" which is necessary at the point of use for safe and effective use of medicines.

While labelling must contain all elements required by legislation, the critical information is:

- name of the medicine
- expression of strength of active ingredients (where relevant)
- route of administration
- posology
- warnings
- authorised indications.

For OTC medicines, it is usual for this information to appear together on **the back of the pack**. Where space constraints make it difficult to fit all the statutory information onto one face of the label, priority should be given to this information. Where it is not possible to fit all critical information on the back panel, some of this information may also appear on a side panel provided the information is set out in a logical order e.g., what the medicine is for, how to use and warnings.

The minimum information that must appear on **the front of pack** includes:

- name of medicine
- strength (where applicable) and pharmaceutical form
- active ingredients (where relevant)
- contents by weight, by volume or by number of doses
- indication(s)
- warning statements (where applicable e.g. paracetamol, opioids).

1.2 Use of medicinal product name (name of the medicine)

The name of the medicinal product is registered in section 1 of the SmPC. In most cases, apart from some older products, the name of the medicine is comprised of the brand name (also known as invented or trade name), the strength, and the pharmaceutical form of the medicine. This should be followed by the common name of the ingredient(s) within the formulation where the product contains up to three active substances, unless these are part of the product name. There should be no intervening text or graphics. The recommended International Non-proprietary Name (rINN) should be used, or the usual common name where no rINN exists.

The components of the medicinal product name (brand name, strength, and pharmaceutical form) and the common name(s) of the ingredient(s) do not need to be in the same font size. However, all the components must be prominent and readable. Undue prominence should not be given to the brand name.

The name of the medicinal product should appear on at least three non-opposing faces of the carton to aid identification whichever way it is stored on a shelf (end-face of the pack, the side face and the front face should include the full name of the product).

The name of the medicinal product (as registered in section 1 of the SmPC), including the common name(s) of the active(s), must appear once in the critical information. If it is used often, then it could use up space that would reduce the area available for other essential information, or force the use of a smaller font size than would otherwise be unnecessary.

Where the name of the medicinal product (as registered in section 1 of the SmPC), is included more than once on the same panel, a shortened version of the name can be utilised after its initial use to help to provide more space for other items of information required. A shortened version of the pharmaceutical form could also be used after its initial use to help to provide more space for other items of information required. For a product with a long named pharmaceutical form, MHRA considers that it is acceptable to use the approved European Directorate for the Quality of Medicines (EDQM) shortened terms on all packaging as long as this shortened term is included in Section 3 of the SmPC. This applies to both the text of the printed label and the Braille requirements (please refer to the ***MHRA's Guideline for the Naming of Medicinal Products and Braille Requirements for Name on Label*** for further information).

Where appropriate, it should be indicated whether the product is intended for babies, children or adults aged 16 years and above.

1.3 Active ingredient(s) (generic name) and strength

Consumers using OTC medicines do not always pay attention to the active ingredients or realise that products utilising the same umbrella brand name may have different active ingredients. The MHRA Best Practice Guidance on Labelling and Packaging of Medicines advises that the pack must include the name of the medicinal product (brand name, followed by its strength and pharmaceutical form) and the generic name(s) of the active ingredients where the product contains up to three active substances.

MHRA requires that the generic name(s) (rINN names) appear on the front of the pack immediately after the name of the medicinal product. For the active substance, the rINN should be used, or the usual common name where no rINN exists. There must be no intervening text or graphics between the registered name and the common name(s) of the active ingredients.

Where there are up to three active ingredients in a medicine, all of these have to appear **immediately** after the name of the medicinal product on the front of pack.

The font size of the active ingredient(s) should be in the same relative proportion to the name of the medicinal product.

It may be necessary in some cases to express the strength as quantity per unit volume and as the total quantity per total volume. Reference to the total quantity per total volume should be highlighted. In addition, different strengths of the same drug should be expressed in the same manner: for example, 250mg, 500mg, 750mg, 1000mg and not 1g. Trailing zeros should not appear (2.5mg, not 2.50mg). For safety reasons it is important that strength in micrograms is spelt out in full and not abbreviated. However, in certain instances where this poses a practical problem which cannot be solved by using a smaller type size then the abbreviation mcg rather than µg should be used.

It is not necessary to repeat the names of the active ingredients on the pack sides or flaps, but where the names of the active ingredients are included, the font sizes should be in the same relative proportion to the name of the medicinal product as they are on the front of the pack.

1.4 Instructions for use (posology and route of administration)

Instructions for use are required on the labelling of all P and GSL products. The instructions for use should include the route of administration, as given in the SmPC. Non-standard routes of administration should be spelt out in full to avoid confusion. This is particularly important for medicines available for self-selection.

Instructions should be given in active language in all parts of the information so that people are given clear instructions that they can act upon.

For example:

- “Take one or two tablets”, rather than “one to two tablets to be taken”
- “Do not give to children under 12” rather than “not suitable for children under 12”

1.5 Warnings

MAHs are not required to incorporate all the warning statements included in their SmPC however there are some warning statements that must be included on pack such as:

- Warning specifically agreed for the marketing authorisation
- Specific ingredient warnings as detailed in the MHRA guidance document ***Additional Warning Statements for Inclusion on the Label and/or in the Leaflet of Certain Medicines***
- ***Paracetamol statutory warnings***
- Excipient warnings as detailed in the excipient guidelines (***Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'***)
- Storage warnings.

The warnings which are specifically required to be on the labelling by the terms of the marketing authorisation must be included as dictated by the authorisation.

Where warnings are agreed for a class of products or for specific ingredients, these will be included in the MHRA guidance document ***Additional Warning Statements for Inclusion in the Label and/or in the Leaflet of Certain Medicines***. This document also refers to the statutory warnings that are applicable to products containing paracetamol.

The Code does not include all of the warnings required on packaging. It is the MAH's responsibility to ensure that the medicinal product has the required warnings on its packaging and labelling.

Warning	Further information
Do not take more medicine than the label tells you to	For Pharmacy (P) medicines where the product would be prescription only if it contained a higher proportion of the active ingredient unless it is an antihistamine or for external use (e.g. ibuprofen, codeine, paracetamol). This should be placed adjacent to the directions for use or the recommended dosage. "Do not exceed the stated dose" is not considered best practice. Existing packaging that includes this wording must be updated at the next regulatory opportunity.
Talk to your doctor before using this medicine	For Pharmacy (P) medicines and where the product is for asthma, bronchial spasm or contains ephedrine (or its salts), e.g. theophylline, aminophylline. "Talk to your doctor before using this medicine" is the MHRA recommendation in its warning statements guideline. "Asthmatics should consult their doctor before using this product" is not considered best practice. Existing packaging that includes this wording must be updated at the next regulatory opportunity.
This medicine may make you feel sleepy. If this happens do not drive or use tools or machines. Do not drink alcohol	For Pharmacy (P) medicines which contain sedating antihistamines, unless they are for external use (e.g. chlor-pheniramine, diphenhydramine). "This medicine may make you feel sleepy. If this happens do not drive or use tools or machines. Do not drink alcohol" is the MHRA recommendation in its warning statements guideline. "May cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink" is not considered best practice. Existing packaging that includes this wording must be updated at the next regulatory opportunity.
Use this medicine only on your skin	For products for external use only and is an embrocation, liniment, lotion, cream, liquid antiseptic or other liquid preparation or gel. Where the medicine is a Pharmacy (P) medicine, this statement must appear on the label. "Use this medicine only on your skin" is the MHRA recommendation in its warning statements guideline. "For external use only" is not considered best practice. Existing packaging that includes this wording must be updated at the next regulatory opportunity.
P (Pharmacy medicines)	For medicines which are available as Pharmacy. The P must appear in a box in which there is no other text.
Keep out of the sight and reach of children	In line with Part 1 Schedule 24 of the HMR 2012 as amended, a warning that the product must be stored out of the sight and reach of children should appear on the label of all medicines. This warning should not be given undue prominence. This warning could be located with and presented in a similar font/size style to any other storage conditions.

Table 1: Examples of general warning statements

1.6 Authorised indications

OTC medicines, either P or GSL, must include all the registered indications as part of the critical information so that consumers are easily able to ascertain whether the product is suitable for them.

Where information relating to dose recommendations, contraindication(s) and warnings cannot be printed in full, a reference to the package leaflet should be made, e.g. “Read the package leaflet before use”.

1.7 Other statutory information

1.7.1 Braille

All medicine packs must include the name of the medicinal product in Braille to allow clear identification of the medicine by visually impaired people who read Braille. There is no requirement to include Braille in the critical information nor is it necessary to add Braille to an otherwise clear part of the pack, but it is essential that the Braille does not obscure information for sighted people. The information presented in Braille may appear on more than one face of the packaging, provided it is presented logically. The name of the medicinal product in Braille may be truncated if the product name is particularly long and space is limited.

Regulation 259 of HMR 2012 as amended, requires the name of the medicine to be shown on the packaging in Braille. Further information can be found in ***MHRA’s Guidelines for the Naming of Medicinal Products and Braille Requirements for Name on Label***.

Please note that where a medicine is available in more than one strength, the strength should also appear in Braille on the label. In some circumstances where different pharmaceutical forms of the same medicine are available with the same name, the pharmaceutical form must also be included in the Braille declaration.

1.7.2 Batch number and expiry date

The expiry date should be written in clear and unambiguous terms. The expiry date printed on medicinal products stating only month and year should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits or at least 3 characters and the year as 4 digits, e.g. February 2007, Feb 2007, 02-2007. Where possible, this should be printed on packaging for clarity, rather than embossed.

The batch number and expiry date do not need to be present in the critical information.

Allowable terms in UK:

- Batch Number: Batch No; BN No; Lot No; Lot
- Expiry Date: Exp Date; Exp

1.7.3 Name and address of the MAH

The name and address of the MAH should be included as specified in section 7 of the SmPC. The address of the MAH may be shortened on pack as long as it has been established that correspondence will reach the MAH using the details on the pack.

1.7.4 Blister packs

The information that must be provided on blister packaging is specified in Part 2 of Schedule 24 of the HMR 2012 as amended. This includes:

- The name of the medicinal product (as registered in section 1 of the SmPC)
- The strength and pharmaceutical form of the product
- Where the product contains up to three active substances, the common name of each active substance
- The name of the holder of the marketing authorisation
- The product's expiry date (month and year), in clear terms
- The manufacturer's batch number.

1.7.5 Small containers

The information provided on small containers must be provided as specified in Part 3 of Schedule 24 of the HMR 2012 as amended. The criteria for small container status would normally be considered to apply to containers with a nominal volume of 10ml or less. The following particulars at least should appear on small immediate packaging units:

- The name of the medicinal product (as registered in section 1 of the SmPC)
- The strength and pharmaceutical form of the product
- Where appropriate, whether the product is intended for babies, children, or adults
- Where the product contains up to three active substances, the common name of each active substance
- The method of administration of the product and if necessary, the route of administration
- The product's expiry date (month and year), in clear terms
- The manufacturer's batch number.

In addition to the above requirements, for traceability purposes, the MHRA recommends that the following additional information is included on the labelling of small containers:

- PL number
- The MAH name

The MAH name may be replaced by the company logo where the MAH name is an integral part of it. However 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.

The use of innovative pack design, for example peel back labels, will be applicable to small containers also and is regarded to be of particular importance where space is at a premium.

1.7.6 Registered Traditional Herbal Medicines

The information required for Traditional Herbal Medicines is specified in Part 7 and Schedule 29 of HMR 2012 as amended. Labelling for products with a traditional use registration will be required to include information and instructions about the safe use of the product, as with any licensed medicine. In addition, it will also need to be made clear to the consumer that the indications are based on information obtained from long-standing use and experience.

The following wording would be considered to be acceptable:

"Traditional herbal medicinal product used to relieve (condition) exclusively based upon long-standing use".[1]

There will also need to be advice that the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the medicinal product or if adverse effects not mentioned in the package leaflet occur.

The Traditional Herbal Registration (THR) Certification Mark is a trademark that indicates that the herbal medicine has been registered with the MHRA under the THR scheme and meets the required standards relating to its quality, safety, evidence of traditional use and other criteria as set out in HMR 2012 as amended. The Certification Mark is owned by the MHRA and can only be used by those companies granted a THR for their traditional herbal medicinal products. Permission to use the THR Certification Mark would normally be granted as part of the THR registration process.

Further details about the use of the Certification Mark can be found in MHRA's guidance:

The Traditional Herbal Registration (THR) Certification Mark: Guidance for Business.

1. Registered Traditional Herbal Medicines: Guidance on consumer advertising. Date accessed 12/03/2021 *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956851/Appendix_1.pdf*

PART TWO – Non-statutory information

2.1 Packaging information must be compatible with the Summary of Product Characteristics (SmPC)

Regulation 261 of HMR 2012 as amended, permits the inclusion on the label of information which is compatible with the SmPC and which is useful for the patient, provided that it is not promotional. The MHRA will assess all non-statutory information against these criteria and will consider the impact on the statutory information, which must take precedence.

- It is acceptable to include information that describes how the product works, or which highlights a particular attribute of the product, provided it is compatible with the SmPC, is useful for the patient, and does not include elements which are promotional in nature.
- The fact that the same phrase may appear in advertising or public relations material does not mean that it can be included on the packaging, and it will require careful consideration and justification in relation to Regulation 261.
- Information included on one MAH's labelling may not be appropriate for another company's label where the SmPC contains different information.
- Non-statutory information must be subordinate in placement and prominence to the statutory information. As a guide the common name of the active ingredient's declaration on the front of the pack will be used to determine the prominence and placement of other information on the pack. The inclusion of non-statutory information should not compromise the space available to display statutory information.

Section *'PART THREE – Promotional information'* includes guidance on wording which may be promotional and therefore prohibited.

2.2 Condition or indication statements

It is important that consumers using OTC medicines understand the condition that they treat.

The information should be given in language that people will understand and can act upon. Medical terminology should be avoided, unless there is evidence from user testing that it is understood.

Repetition of claims on several sides of the pack is allowable as long as space and readability for statutory information is not compromised. Consideration should be given to removing repeated claims to make space for statutory information.

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.

Statement	Further information
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 are encouraged as it avoids implying that the product will work for 100% of the population, 100% of the time and 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.

Table 2: Examples of condition statements, indication statements

Please note that statements in relation to excipients in the formulation will not be acceptable as these are generally considered to be inert. The exception to this is flavouring but there should be no inference that such flavours are "pleasant" as this is subjective and promotional. A factual statement is all that will be accepted.

2.3 Speed or duration of action statements

Knowing when a product will work and how long it might work for is valuable information in ensuring safe use of a medicine and can aid compliance with dosage instructions.

Such information can help people understand 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.

Statement	Further information
Fast acting (or synonyms)	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. 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. Please note that these statements may not be appropriate for chronic conditions or those not requiring immediate relief.
Gets to work in X minutes	Is acceptable if the SmPC includes information regarding the onset of therapeutic action. Please note that 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, or one ingredient showing two or three different therapeutic actions. It cannot be used for products with multiple ingredients with the same mode of action.
Long acting / long lasting	Where a medicine is formulated as a modified/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	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.

Table 3: Examples of speed or duration of action statements

2.4 Mode of action statements and natural statements

Please note that statements must not imply that a product is safe because it contains natural ingredients. Statements linking safety with natural ingredients may not be made unless supported by the SmPC as described above.

Statement	Further information
Natural	May only be used where all the ingredients are natural. If only some of the ingredients are of natural origin, then the term is not permitted.
Acts naturally, works naturally, natural relief for congestion, relieves symptoms naturally	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.

Table 4: Examples of mode of action statements, natural statements

2.5 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 people with diabetes and parents/carers of children, find it useful if the label includes information which is relevant to them, and which helps them to choose the appropriate product. Where such statements are made on pack, evidence must be provided to support the statements. Furthermore, such information must be subordinate in prominence and placement to the statutory information to avoid being considered promotional.

2.5.1 Can be used in pregnancy

This statement may only be included within the critical 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.

2.6 Free from statements

The PIL, and when applicable the labelling, are required to include comprehensive information on what is included in the formulation. A statement which does not have an impact on patient safety or is a medical requirement should not be used.

Statement	Further information
Sugar-free	May be used as part of the product name 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. A sugar-free statement may also be added to the packaging provided the product fulfils the above criteria and is subordinate in prominence and placement to the statutory information.
Suitable for vegans or vegetarians	Where it is possible to demonstrate from the pharmaceutical dossier that the product and the individual ingredients in the formulation have not been tested on animals or have not been derived from animal products this may be acceptable following a detailed assessment.
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.
Gluten-free	Where information is available from the SmPC and any supporting information in the pharmaceutical dossier that the product can be deemed gluten-free, a statement to this effect can be included within the critical information. No graphic or promotional symbols may be included.

Table 5: Examples of free from statements

2.7 Statements relating to side effects, safety and excipients

Within some therapeutic categories, there are differences in the side effect or interaction profiles and it helps people to choose the appropriate products if this is included 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 has “no known side effects,” packaging information should not imply that the product is completely safe.

The statement “non-drowsy” 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.

2.7.1 Excipient statements

Information in relation to the action of excipients within the formulation may not be included as non-statutory information, as excipients are generally considered to be inert.

Information about the non-pharmacological action of excipients may be acceptable for certain types of formulation.

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” would be acceptable. However, statements such as “pleasant” are subjective and deemed promotional and are therefore prohibited.

Excipients known to have a recognised action should be stated in the labelling in accordance with the Annex in the ***EMA Guidance***. For Great Britain, the retained guidance on excipients can be found ***here***. When a medicinal product contains any of the excipients listed in the Annex to the guideline on excipients in the labelling and package leaflet, the name of the excipient and/or the E number where relevant, (e.g. for colourants) must be stated on the pack together with a statement such as “see leaflet for further information”.

All excipients must be included on the carton/outer pack for topical and eye preparations.

2.8 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, 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, provided it is clear that the product itself is not new e.g. “new formulation”.

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.

Statement	Further information
Unique formulation	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	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.
New flavour	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.
Pharmacy only formulation	May be used if the product contains an ingredient (or concentration) 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.
Peppermint (or other) flavour	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 promotional in style and not allowed as the statement is in relation to an excipient within the formulation.
Herbal	May not be included unless the active ingredients are 100% herbal. It is not necessary for the excipients to be of plant origin.

Table 6: Examples of formulation statements

2.9 Symbols or pictograms designed to clarify certain information

While the critical information 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 clearly 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.

Symbols can be included to support the statutory information. The meaning of symbols should be clear and supported where necessary by user consultation. Logos and symbols relating to particular trade bodies or patient organisations are not acceptable, and images should not be offensive.

Statement	Further information
Pictures of children	Can help highlight medicines which are suitable for children. Where children are used, they should appear to be in the age range that the medicine is intended for. It is not sufficient to establish that the child's actual age is in the target group.
Pictures of parts of the body	Can help consumers understand what a product is for and how it works. They can also help distinguish between products in a range.
Pictures of dosage form	Showing pictures of tablets or capsules on packs helps consumers identify their shape, and whether they are soluble, effervescent or chewable. Where a picture is used on a pack, the illustration must be the same as the dosage form inside and reflect its actual size. The number of dosage forms shown must be considered so as not to mislead about the dose. For example, where the OTC dose of the active ingredient is limited, the number of tablets shown must not depict a quantity of ingredient which is a prescription only dose.
Pictures of leaves and 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.
Recycling logos	Symbols that provide information on which components can or cannot be recycled are acceptable. These recycling logos and symbols are acceptable on pack as long as they do not take space required for statutory information.

Table 7: Examples of types of symbols or pictograms and further information

2.10 Quick response (QR) codes

QR codes may be included on packaging provided they are subordinate in prominence and placement to the statutory information (in line with all information included under Part 1 Schedule 24 of HMR 2012 as amended). In addition, such a code must link to information which is compliant with the provisions of Part 1 Schedule 24 of HMR 2012 as amended. It must therefore be:

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

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 PIQU 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.

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 the labelling at the time of packaging to enable batch number, expiry date and other product specific details to be recorded on the labelling.

2.11 Email 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.

PART THREE – Promotional information

3.1 What you cannot say

Promotional information cannot be included on medicines packs. The term "promotional information" does not have a firm definition and differences in interpretation between regulatory bodies and the industry have caused problems in the past.

The statements below are examples of promotional phrases which are not permitted on medicines packaging. This list is not exhaustive, and other statements may be deemed unacceptable too. A key indicator that a phrase may be promotional is that it is based on phrases which are subjective, rely on market research or sales evidence, and/or the phrase is not supported by the SmPC.

- Extra value – 15% extra for the same price
- Multi-buys – buy one get a related product at a discount
- Ideal
- Cares for you
- Handy pack or any other reference to portability rather than medicinal use
- Free prize draws, loyalty schemes, competitions
- Free forehead thermometer or free oral syringe
- Charity promotions
- Endorsement by healthcare professional bodies (however the inclusion of a company name such as "Company X the Chemist" on the products marketed by that company is acceptable)
- Improved formulation
- Especially formulated
- General "quality" statements
- Any claim of activity for an excipient – for example, "cooling mint sensation" for a mint flavour
- Especially effective
- Shown to be beneficial
- May shorten the duration
- Intensive relief
- New pack size
- Prescription strength
- Contains natural colours

3.1.1 Comparative statements may not be made on packaging

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".

3.1.2 Not habit-forming, non-addictive

While the criteria for non-prescription status includes the factor that the ingredient must have a low potential for dependence, these phrases should not be used without qualification where there is potential for psychological dependency.

3.1.3 Website addresses

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 PIQU 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 (for further information please also refer to section ***'Quick response (QR) codes'*** above).

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 PIQU assessment team at the time of application so that the information can be assessed against these provisions.

PART FOUR – Typography, layout and design

4.1 Text, legibility, layout and prominence

People find it easier to read dark coloured type (e.g. black or dark blue) on a light coloured background (e.g. white, pale pink, pale yellow). Therefore, where small text sizes have to be used, printing which is blue or black on a light background should be considered.

Strongly reflective packs also present difficulties for readers. Companies who wish to use coloured or reflective backgrounds must ensure that the type chosen is still readable. Testing the packs with users can give helpful information in this respect but this is not mandatory.

The generic name(s) should be given due prominence through the choice of point size, font, or emboldening. Non-statutory information should be subordinate in placement and prominence to the generic name(s) of the active ingredients. Prominence is determined by factors other than size of the text including and not limited to blank space, font style, colour of the text and background, and position.

The font size and colour chosen should ensure that the generic name(s) can be seen clearly. Prominence is achieved by means other than just size. Other factors are:

- colours used
- contrast
- other graphics on the pack which may lead the eye away from the statutory information
- product name on different faces of the pack
- font size should not be smaller than the smallest font of any strapline (e.g. claims)

Any non-statutory information included must be subordinate in placement and prominence to the statutory information.

4.1.1 Orientation of text

The text in the critical information should be orientated in the same direction to make it easier for people to read it. Portrait layout of text rather than landscape layout of text may make it easier to read the information.

4.1.2 Font size

The critical information should appear in as large a font as possible to maximise legibility. It should not be broken up or separated by non-critical information.

All information should be printed in characters no smaller than 7pt size (for outer and inner pack labelling) and leaving no less than 3mm between lines. Consideration should be given to the font style as 7pt text may not be readable in all styles. Readability of the packaging should be assessed as a whole. ***The European Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use*** further states that the labelling of package leaflets 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.

For immediate packaging, if the required text cannot fit at the 7pt size, consideration should be given to the minimum labelling requirements for small containers. For further information, ***please refer to section 'Small containers' in this Code***.

4.1.3 Blank space

Blank space should be usilitised to emphasise critical information. The space for providing this information is limited, therefore the critical information should not include information such as company logos, trademarks or graphics as this unnecessarily restricts the space available for essential information.

4.1.4 Readable body text

The largest text size possible should be utilised on all components. Where appropriate, company details should be moved onto a side panel to afford a greater amount of space for the critical information.

4.1.5 Usage of upper and lower case

Entire sentences in capital letters or italic type are hard to read, and therefore this should be avoided. Mixed upper and lower case (sentence case) should always be used for sentences. Italic type should also be avoided as this further reduces readability. An alternative method of emphasis, such as bold type, can be utilised.

4.1.6 Use of boxes

Boxes should only be used where user testing shows they help highlight information. When information is put in boxes, the eye can scan round them not taking in the information. Although some of the required warnings need to be in boxes, generally, boxes should not be used for critical information, unless user testing shows they are helpful.

4.1.7 Text alignment

An irregular amount of space between words affects legibility, therefore text should be aligned to the left-hand margin to even out word spacing. Word spaces need to be clear but narrow.

4.2 Branding, design & graphics

Good pack design aids assimilation of the key information necessary for the safe selection and use of the medicine. It involves the use of colour, typography, graphic style, imagery, illustration and photography, and an understanding of how people choose and use products.

For the consumer, the pack has to spell out what the product is for, who it is for, and provide the information about all the attributes which are important to ensure it can be chosen and used safely and effectively.

As more new products are introduced under existing brand names, differentiation between products in a range is critical for safe and effective use. Good design will ensure that different products are adequately differentiated so that there is no confusion for consumers. The best design will build in elements to help differentiation from the outset.

Please note that no statement or image should be included on packs unless the relevant SmPC supports it. This is particularly important in designing product ranges where the different products may have been authorised over a period of years and have different SmPCs. It may be necessary to amend the SmPCs to ensure that there is consistency in the final pack designs.

The greater the risk which might arise from use of the wrong product, the greater the differentiation must be. Please ensure that you look at product ranges as a whole and review the products for risk as well as benefit. For instance, note the different indications, active ingredients, side effects and target groups and ensure that these are highlighted appropriately in elements of the pack design.

Risk may be interpreted differently if the products are P or GSL. Those in the GSL class will not have healthcare professional advice available at the point of sale and will need greater differentiation since it cannot be assumed that people will purchase only one class of product.

While computer generated images will be the main way to submit pack designs for approval, pack mock-ups may be requested in some cases to allow the impact of colours and fonts to be evaluated. This can be important in the case of reflective backgrounds or where the differentiation between important elements relies on shades of the same colour.

Research can help clarify whether design elements communicate clearly. While it is not essential to submit research supporting the pack design, research can assist in the approval and evaluation of packs under this Code of Practice, particularly where differences of approach or opinion arise in the process. Generic market research with focus groups, for example, is unlikely to be sufficiently robust. However, formal targeted consultation with selected consumers and patient groups may be acceptable. Companies are advised to submit the research protocol to the MHRA for review of the study methodology prior to commencing the work.

Therapeutic category guidance may evolve. Where evidence exists that a key element of information is important in helping consumers identify products within a range or across a category, guidance will be developed to promote good practice and consistency in designing this information into the pack. For analgesics, for example, it is important that consumers are made aware from the front of the pack exactly which active substance is present within the formulation and this needs to be given due prominence.

Summary of key points

DO's	DON'Ts
Check that the full name of the product as stated in section 1 of SmPC appears on the front of the labelling immediately followed by the active ingredients (where the product contains up to three active substances).	Do not place text in the critical information over images or logos. Fitting text around or over images or logos breaks the flow of information and makes it difficult for consumers to read.
Ensure the product name appears on at least three non-opposing facing sides of the carton.	The product name and generic names(s) should not be broken up by additional information, logos or background text or graphics.
Use colour differences where appropriate to differentiate products – but do not rely on colour as the sole method of distinguishing between active ingredients or between important safety attributes.	Don't forget that any non-statutory information must be less prominent than the statutory information.
Create a strong contrast between text and background colour and use dark text on a light background wherever possible.	Do not use background colours/materials with very high shine properties, as they can induce excessive glare and impair readability.
Avoid the use of iconography which detracts from clear understanding of the indications and use of the medicine. Look at the design as a whole and use images which help people to navigate and identify the products.	"Contains natural colours" is considered to be promotional and therefore not acceptable on pack.
Ensure that non-statutory information does not appear in a more prominent way than statutory.	Do not imply that the product cures the condition.
Do ensure that your SmPC is kept up to date and supports any claims you want to make on pack.	"New pack size" is deemed promotional and therefore not acceptable on pack.
Symbols and pictograms can be useful provided the meaning of the symbol is clear and the size of the graphic makes it easily legible.	"Prescription strength" is considered to be promotional and therefore not acceptable on pack.
The indication must be in line with section 4.1 of the SmPC.	Any claim of activity for an excipient – for example, "cooling mint sensation" for a mint flavour – is not acceptable as excipients are generally considered to be inert.

Who to contact

Please contact ***packdesign@pagb.co.uk*** if you have any queries relating to the packaging and labelling of medicinal products or require further information or assistance.

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