

# **BEST PRACTICE GUIDANCE ON THE LABELLING AND PACKAGING OF MEDICINES**

## **EXPLANATORY MEMORANDUM**

As part of a move towards an increase in self-regulation of medicines labelling and packaging, this document has been developed to aid those responsible for the origination of labelling and packaging artwork. It sets out the legal framework for labelling and packaging as described in UK and EU legislation. In addition it describes best practice in the area of labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. It also reflects the expectations of healthcare professionals, patients and regulators with respect to reduction in medication errors, and safe selection and use of medicines by all users

This document is guidance and does not constitute a legal interpretation of the requirements on medicines labelling and packaging as set down within the medicines directives.

# BEST PRACTICE GUIDANCE ON THE LABELLING AND PACKAGING OF MEDICINES

## 1. INTRODUCTION

The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented. The primary purpose of medicines labelling and packaging is the clear unambiguous identification of the medicine and the conditions for its safe use. Common factors affecting all users of medicines may be summarised under three headings:

- **INFORMATION:** Certain items of information are vital for the safe use of the medicine.
- **FORMAT:** The information must be presented in a legible manner that is easily understood by all those involved in the supply and use of the medicine.
- **STYLE:** There is potential for confusion between both similarity in drug names and similarity in medicines packaging.

Medication errors occur due to many factors. “Building a Safer NHS for Patients”<sup>1</sup> published in April 2001, which implemented “Organisation With A Memory”<sup>2</sup>, identified such factors as training, communication, storage, and supervision. Problems with labelling have also been associated with a high percentage of errors<sup>3</sup>. Within the current regulatory framework there is the potential for improving the layout of medicines labelling to aid clarity. This can assist health professionals and patients/carers to select the correct medicine and use it safely, thereby helping to minimise medication errors.

## 2. PURPOSE

The purpose of this guidance is to expand a set of principles which have been agreed by the Committee on Safety of Medicines and 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 Medicines and Healthcare products Regulatory Agency as any deviations from this guidance may need to be justified where these impact on patient safety.

### 3. SCOPE

This is best practice guidance to be read alongside the legislative requirements, which are set out in Title V of Council Directive 2001/83/EC (as amended)<sup>4</sup>. The guidance has been drafted to support the legal framework set out in both European<sup>4</sup> and national legislation<sup>5</sup>. It should be taken into account by marketing authorisation holders when preparing the labelling provided with mutual recognition, decentralised and national licence applications and variation submissions or when submitting notifications or applications under article 61(3) of the Directive.

The guidance applies equally to prescription only medicines and those available over the counter. In assessing applications or undertaking audits of notifications or in 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, where relevant, whether or not a lesser information set is applicable by virtue of Article 55 of Council Directive 2001/83/EEC.

**4.1. Labelling must contain *all* elements required by article 54 of Council Directive 2001/83/EEC. 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**

Clarification on these items is provided below.

**4.2. These critical items of information should be located together on the pack 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 medicines available on prescription it is likely that these pieces of information will appear together on the front face of the labelling. In the over-the-counter sector due to the difference in pack design it is usual for this to appear together on the back of the pack.

The information hierarchy is important. Critical information as described here should be located 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, the space on the pack and any other graphic elements included in the design.

#### 4.2.1 Name of the medicine.

The name that is registered in the summary of product characteristics (SPC) must be used on all packaging components. The name is defined as comprising the name, strength and pharmaceutical form of the medicine. A number of different scenarios exist and for which different advice is provided.

MHRA has already provided detailed policy advice on naming which can be found at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Namingofmedicines/index.htm>

This information is not replicated here.

For a bespoke product name [example Bloggo Cold and Flu Relief 300mg Tablets], this must be reflected on all packaging components where the name is required to appear.

Where a generic medicine has a company name included as part of the name registered in section 1 of the SPC the full colour mock-ups should not include reference to the company name for reasons related to safe selection of the product. [Example Simvastatin Bloggo 20mg Capsules registered in Section1 of the SPC should be Simvastatin 20mg Capsules on the full colour mock-ups of the labelling and packaging intended for marketing.]

The name registered in the SPC may not be abbreviated for inclusion on the labelling and should be selected with this in mind.

#### BRAILLE

The legislation requires the name of the medicine to be shown on the packaging in Braille. The name selected should be chosen carefully to ensure that what is set out for sighted patients is also communicated in Braille to blind and partially sighted patients.

Separately guidance on Braille placement is also available from both the MHRA and the European Commission which can be found at:

<http://www.mhra.gov.uk/home/groups/pla/documents/websiteresources/con2031618.pdf>

This information is not replicated here.

**The full name of the medicine should appear on at least three non-opposing faces of the pack to aid accurate identification of the drug.** This is particularly applicable to carton presentations for medicines available on prescription but can be relevant on all medicines. Where this is, employed the end-face of the pack, the side face and the front face should include the full name of the product. However, an abbreviated pharmaceutical form may be used on the label in the interests of clarity for the patient but must accord with abbreviations accepted by the member states and the Commission. [The full pharmaceutical form, employing standard terms, must appear in section 3 of the SPC.]

Where the medicine contains up to three active ingredients, the common names of these active ingredients should immediately follow the name of the medicine on the pack, unless these are part of the name. There should be no intervening text of any kind. The recommended International Non-proprietary Name should be used, or the usual common name where no rINN exists.

**Where the common name(s) appears after the brand 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. If a “Co-” name is used for the medicine, this should be registered in the SPC and appear on the labelling as part of the name.

#### GENERIC CEPHALOSPORINS

The MHRA and the National Patient Safety Agency have reviewed the errors which have occurred with drugs in this class and have agreed a labelling design mechanism which will help pharmacy staff 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**TRIA**Xone  
cef**UROX**ime

#### 4.2.2 Strength.

**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. Reference to the total quantity per total volume should be highlighted.** This is particularly important for injectable products and other medicines available in solution or suspension.

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 and NOT 2.50mg). The decimal point need not be centred, provided that if a full stop is used it is clearly visible.

For safety reasons it is important that micrograms is spelt 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  $\mu\text{g}$  should be used.

#### 4.2.3 Route of administration.

**This should be as registered in the SPC only.** Positive messages should be used; for example “give by ...” and only standard abbreviations will be acceptable.

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. This is particularly important when medicines are made available for self-selection. However, use of the standard terms will be considered acceptable for those medicines that will have a dispensing label applied.

#### 4.2.4 Posology.

**This will be necessary only when the product is intended for self-medication.**

In general, posology will not appear on medicines that are intended to be supplied on prescription. Posology remains a legal requirement for products marketed for over-the-counter sale. Medicines that are supplied on prescription would have the posology added at the time of dispensing.

#### 4.2.5 Warnings.

It is not the purpose of this section to include all the warnings registered in section 4 of the SPC in the critical field. Only those warnings, specifically required by the terms of the marketing authorisation to be stated on the labelling, will form part of the critical 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.

As a result of the consolidation of the Medicines Act, with the exception of medicines containing paracetamol, the new legislation no longer requires any warnings to be applied by means of a legal obligation. Previously, a small number of warnings were added to over-the-counter medicines labelling through regulation. A much larger number of warnings were added to other medicines through the marketing authorisation. Updating statutory warnings is complex and recent experience has shown that adding these via the MA is more rapid and proportionate.

Separately many of the statutory warnings have been shown through user testing to be complex and difficult for patient to understand and act upon. For this reason and to create an equitable situation across all sectors particular warning statements will be published here and the expectation is that relevant marketing authorisations will reflect these on the labelling of the product.

A full list of warnings which are required to appear on the labelling of particular medicines is set out in a separate document. 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.

#### EXCIPIENTS OF KNOWN EFFECT

Many medicines will contain excipients which have a pharmacological effect in their own right. In line with article 54(d) these have to be included on the label. EU guidance developed in line with article 65 of Council Directive 2001/83/EC covers this provision and is available from:

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003412.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf)

It is not replicated here.

#### 4.2.6 Indications

Medicines available on prescription only (POM) do not need to make reference to the approved indications. Over-the-counter medicines, however, which are either pharmacy only [P] or general sales list [GSL] category must include the registered indications as part of the critical information set so that patients are easily able to ascertain whether the product is suitable for them.

**4.3. The critical information should appear in as large a font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information.** The critical information (see 4.1 above) should 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 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. Nevertheless related information should be co-located on the pack.

**4.4. Innovative pack design that may incorporate the judicious use of colour is to be encouraged to ensure accurate identification of the 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.

**4.5. In line with article 54(e) of Council Directive 2001/83/EC the labelling of packs intended for supply against a prescription should include space for the placement of the dispensing label. It is recommended that this should be a blank white space in which there is no text of any kind, to aid legibility of the dispensing label.** Where it is not possible to employ a blank space, use of a colour that will not interfere with the readability of the dispensing label should be considered for any text over which the dispensing label will be applied. In the UK the space required is 35mm x 70mm usually. This consideration need not apply to products intended for over-the-counter sale directly to the patient.

**4.6. 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” should not be used.

**4.7. Undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice.** Although user testing is not part of the legal provisions many companies choose to test packs when considering introducing a corporate redesign. 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 health care 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. Where the labelling requirements of article 54 of Council Directive 2001/83/EEC cannot be legibly applied to a container, the requirements of article 55(3) should be applied. The criteria for small container status would normally be considered to apply to containers with a nominal volume of 10mls or less.** However, other factors may need to be considered such as the amount of information which needs to appear on the label and the font size necessary to achieve legibility of the information.

**5.2.** The critical items outlined above (4.1) are not additional requirements here.



**5.3.** The use of innovative pack design will be applicable to small containers also and is regarded to be of particular importance where space is at a premium.

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

- PL number
- The MA holder's 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 MA holder's name will not be mandatory.

## **6. BLISTER PACKS**

**6.1.** Where a blister or strip pack is enclosed in a container which meets the requirements of article 54 of Council Directive 2001/83/EEC, the requirements of article 55(2) apply to the blister or strip packs.

**6.2.** 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.

**6.3.** In addition, blister foils should be printed to ensure maximum legibility of the statutory information using a sufficiently large font.

**6.4.** 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.

### **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. To help aid patient compliance, a number of medicines must be presented in calendar packs with the days of the week on the foil. Examples of these are oral contraceptives, medicines for hormone replacement therapy and medicines for the treatment of Alzheimers (e.g. rivastigmine, donepezil, galantamine and memantine. For some of these medicines the time of day at which the dose should be taken is also needed.

## 7. INCLUSION OF NON-STATUTORY INFORMATION IN LINE WITH ARTICLE 62 OF COUNCIL DIRECTIVE 2001/83/EC

Article 62 of Council Directive 2001/83/EC permits the inclusion on the label and in the patient information leaflet (PIL) of symbols and pictograms which are intended to clarify information presented under articles 54 and 59(1) in addition to being compatible with the Summary of Product Characteristics (SPC), useful for the patient and importantly, not promotional.

Many patients who take prescription medicines which are used chronically will benefit from additional information about the way in which the medicine works and the disease it is intended to treat. Detailed information on what can be included in the Patient Information Leaflet under article 62 is set out in separate guidance.

<http://www.mhra.gov.uk/home/groups/pla/documents/websiteresources/con046601.pdf>

This is not replicated here.

### 7.1 Quick Response (QR) codes

The following section sets out advice on the inclusion of Quick Response (QR) codes on labelling and packaging.

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 article 62). In addition such a code must link to information which is compliant with the provisions of article 62. It must therefore be:

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

An applicant intending to include a QR code on the labelling or in the patient information leaflet for a particular product must make an application to the Patient 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. 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.

## 7.2 E-mail addresses

An email address may be included as a means of contacting the marketing authorisation holder and in circumstances where a patient information leaflet is not separately available this may appear on the labelling along with other information consistent with article 59(1) of Council Directive 2001/83/EC.

## 7.3 CODE OF PRACTICE ON PACK DESIGN

### Labelling of over-the-counter medicines

Non-statutory information is frequently used in the labelling for medicines available over-the-counter. In this sector the Proprietary Association of Great Britain administer a Code of Practice on Pack Design which sets out MHRA policy in this area and examples of best practice.

<http://www.pagb.co.uk/codes/pack.html>

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

For medicines supplied over-the-counter for self-selection the use of this provision can be useful. While 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 staff to determine for example the suitability of a proposed name.

### 7.3.1. 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.

**Relieves, soothes** - may be used for all products which work by improving symptoms. They indicate an improvement in symptoms.

Statements in relation to excipients in the formulation will not be acceptable as these are generally considered to be inert.

**'Stop' as in stop coughing or stop scratching** - should be used with caution. Stop may imply a product guarantee and can only be used when supported by the SPC.

**Statements preceded by 'can', 'to', 'may', 'helps', 'could', 'for'** – 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.

### 7.3.2. 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** - may be used where the Summary of Product Characteristics 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.

**Gets to work in X minutes** - is acceptable if the Summary of Product Characteristic includes information regarding the onset of therapeutic action.

**24 Hour Action** - 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 SPC to show that the clinical benefits of the product last for 24 hours.

**Relieves pain for up to 12 hours** - is acceptable if supported by the SPC. 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** - where a medicine is formulated as a modified 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.

### 7.3.3. 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 are made on a pack, evidence must be provided to support the statement.

**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.

**Suitable for people with diabetes** - where this statement is used the guidelines issued by Diabetes UK must be adhered to which is available from [\[insert link\]](#). It is not acceptable to use it to describe products that are sucrose free but contain other sugars such as lactose. Some sweeteners also have a calorific value. The statement can be included within the critical health information panel.

**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 SPC. Dosage information must be included in section 4.2 of the SPC and a supporting statement must also appear in section 4.6 of the SPC. Front of pack statements in relation to use in pregnancy cannot be included.

**Symbols** - 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.

### 7.3.4. Statements relating to side effects and safety

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 Summary of Product Characteristics has '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 SPC would preclude use of this statement.

**Statements linking safety with natural ingredients** - may not be made unless supported by the SPC as described above.

### 7.3.5. 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.

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.

**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.

**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.

**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 promotional in style and not allowed as the statement is in relation to an excipient within the formulation.

**Natural** - this statement may only be used where all of the ingredients are natural. If only some of the ingredients are natural then the term is not permitted.

**Acts naturally, works naturally, natural relief for X, 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. A bulk forming laxative could claim to “act naturally” even if the product is not made from natural active ingredients. Conversely, stimulant laxatives such as senna and bisacodyl are not considered to mimic a physiological mechanism and reference to a natural mode of action cannot be made on the packaging for these medicines (see also 7.3.4).

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

**Excipient Statements** – 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.

Statements relating to flavour such as “pleasant” are deemed promotional and prohibited by article 62 of Council Directive 2001/83/EC.

### 7.3.6. Symbols or pictograms designed to clarify certain information

Symbols or pictograms are permitted under article 62 of Council Directive 2001/83/EC where these are designed to clarify information within the SPC. Any symbols or pictograms used must be accessible to consumers and testing may be required to show that this is the case.

**Pictures of children** - pictures of children on a pack 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 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 be the same as the dosage form inside and reflect the actual size. 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.

## **8. CONCLUSION**

All applications submitted (either via the application process or via the notification scheme) to the Medicines and Healthcare products Regulatory Agency that include a labelling component will be considered against the criteria in this document. This will apply in all areas of MHRA work (new MAs, PLPIs, renewals, variations and notifications and applications to the product information 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 will 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 deviates from this guidance a full justification for this should be provided with the application.

Once new packaging components have been approved by the MHRA these must be introduced into packed stock being certified for release to the market by the Qualified Person in accordance with Directive 2001/83/EC (as amended) within three to 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 three to six months following approval.

**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
**November 2015**

## **REFERENCES**

1. "Building a Safer NHS for Patients – Implementing Organisation with a Memory". Department of Health April 2001.
2. "Organisation with a Memory – Report of an expert group on learning from adverse events in the NHS." Department of Health May 2000.
3. "Preventing Adverse Events in Behavioural Health Care: A Systems Approach to Sentinel Events." Oakbrook Terrace IL: Joint Commission on Accreditation of Healthcare Organisations quoted in Building a Safer NHS for Patients.
4. Directive 2001/83/EEC of the European Parliament and Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended)
5. The Human Medicines Regulations 2012.