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Executive summary

Pack design and labelling ensure that the critical information necessary for the safe use of a medicine is legible, easily accessible and that users of medicines can easily assimilate this information so that any risk of confusion and error is minimised.

For non-prescription medicines the clear identification and selection of the appropriate medicine is very important, especially in cases where there is no pharmacist intervention, therefore, pack design and labelling are considered key elements to ensure the safe use of this type of medicines.

The information which should be included on the labelling and package leaflet is provided in Title V of Directive 2001/83/EC. In addition, the details on the display and readability of such information on the printed materials are included in the Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1, 12 January 2009) (hereinafter "Readability guideline"). However, due to the different supply arrangements for non-prescription medicines across Europe, some of the principles of the presentation of the content of the labelling and package leaflet differ among Member States, in particular on the ones regarding the acceptability of symbols/pictograms and any additional information compatible with the Summary of Product Characteristics (SmPC).

A consultation with Member States on national practices regarding pack design and labelling for non-prescription medicines has taken place and this document summarises the basic recommendations/principles[1] to guide applicants and marketing authorisation holders when preparing the mock-ups and specimens of the sales presentations[2] of non-prescription medicines within the centralised procedure. It is acknowledged that national practices on pack design for non-prescription medicines differ across Member States, therefore, the recommendations included in this document should be considered in this context.

1. Introduction (background)

A good combination of clear/comprehensive information and pack design ensures that the information considered critical for the safe and effective use of a medicine is easily accessible by the consumer or healthcare professional selecting the product, and helps differentiate medicines within the same range (e.g. umbrella brands) to minimise the risk of confusion.

The main purpose of this document is to provide guidance across the European Union on the presentation of the packaging information required by Directive 2001/83/EC for non-prescription medicines authorised via the centralised procedure. This is to ensure that the information defined in the Title V of Directive 2001/83/EC and the inclusion of logos/pictograms or any additional information compatible with the SmPC, as per Article 62 of Directive 2001/83/EC, appearing on the labelling and package leaflet of non-prescription medicines, are suitably presented and can be understood by those who receive/select it, so that they can use their medicine safely and effectively.

In addition, there are different elements which contribute to the optimisation of the pack design such as the use of a clear layout, font type, the use of colour or graphic design and recommendations on such elements are addressed in the Readability guideline. Following the consultation with Member States on existing national guidance for non-prescription medicines, it became apparent that further

[1] The recommendations and examples presented in this document summarise national practices and experience and, therefore, are not considered exhaustive.
[2] A 'mock-up' is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the label text is clear. A 'specimen' is a sample of the actual printed outer and immediate packaging materials and package leaflet (i.e. the sales presentation).

emphasis and guidance on some of these recommendations was thought to be important for inclusion in this document.

2. Scope

The intended scope for this guidance is to apply these principles only to non-prescription medicines authorised via the centralised procedure. In addition, due to the differences in the way non-prescription medicines are supplied throughout the EU, i.e. pharmacy, general sales points etc, the final approach/set of common principles to be agreed upon should be sufficiently generic to cover all possible scenarios, i.e. dispensing with or without the intervention of a pharmacist.

3. Legal basis

This guidance document has to be read in conjunction with the articles listing the requirements relating to the contents of the labelling and package leaflet in Title V of the Directive 2001/83/EC.

- Articles 54, Article 55 and Article 59 of Directive 2001/83/EC lay down the information that must appear on the outer and immediate packaging information (labelling) and the package leaflet of medicinal products.
- Article 62 of Directive 2001/83/EC specifies that the outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the SmPC which is useful for the patient, to the exclusion of any element of a promotional nature.

The following EU guidelines provide further information on the presentation of the content of the labelling and package leaflet as well as on design and layout concepts:

- 'Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1, 12 January 2009)' (Readability guideline).
- 'Guideline on the packaging information of medicinal products for human use authorised by the community (Revision 13, February 2008).'

4. Pack design

Labelling must contain all elements required by Article 54 of Directive 2001/83/EC, however, there are certain items deemed **critical** for the safe use of the medicine like the name of the medicine (invented name + strength + pharmaceutical form), active substance and route of administration. The location and prominence of the critical information will contribute to the appropriate selection of the medicine, and will aid the differentiation between different medicines and within presentations of the same range (e.g. umbrella brands).

For non-prescription medicines there is also **other important information** (e.g. therapeutic indication, dosage, warnings, instructions for use etc), which contributes to the appropriate selection and safe use of the medicine. Where possible this information should be brought together in the same field of view and using a sufficiently large type size on the packaging in order to aid users.

4.1. Display of the critical information

4.1.1. Name of the medicine

The name of the medicine (invented name, strength and pharmaceutical form), followed by the active substance, should appear in the order specified in section 1 of the SmPC. If possible, the invented name and strength may appear on the same line; however, this information together with the pharmaceutical form and active substance may also be presented in different lines of text as long as it appears as a cohesive unit and it is not to be separated by any text or graphics.

The name of the medicine should appear prominently and using a sufficiently large font type on prime spaces, particularly on the front panel. If possible, it should appear on at least three non-opposing sides of an outer carton (including one end panel), whenever space allows for the display. This will aid identification, whichever way the medicine is stored on the shelf.

Different colours in the name of the medicine are discouraged since they may negatively impact on the correct identification of the medicine name. However, the use of different colours to distinguish between strengths is strongly recommended, as per the Readability guideline.

The strength is preferably stated only once on each side of the package and within the name of the medicine. If further repeated, due to the marketing authorisation holder's preference and/or the house style, it should not be confused with the pack size.

4.1.2. Active substance

The active substance(s) should appear on the front of the pack in the same field of vision as the name of the medicine. As previously mentioned, the name of the medicine and the active substance may be presented in different lines of text as long as they appear as a cohesive unit. This is especially important where a range of medicines within the same umbrella brand include different active substance(s).

It is not necessary to repeat the names of the active substance(s) on the sides or flaps, but where the names are included, the type sizes should be in the same relative proportion to the name of the medicine as they are on the front pack.

Prominence should be given to active substance(s) through the choice of type size, font type or emboldening.

4.1.3. Route of administration

Applicants are encouraged to display the route of administration in the same field of vision as the rest of the critical information.

4.2. Display of other important information

In addition to the critical information identified in section 4.1, other important information necessary for the selection and use of the medicine should ideally be brought together on the pack in the same field of view and using a clear font type and sufficiently large type size. This other important information should comprise the following elements:

- Authorised indication.
- "Read the package leaflet before use"

Other elements (e.g. dosage, contraindication(s) and warnings) may also be included and whether this can be accommodated within the same panel will be assessed on a case by case basis taking into account potential safety considerations and space constrains (e.g. small packs and/or multilingual labelling).

4.3. General pack design and layout

Applicants and MAHs are encouraged to follow the recommendations included in the Readability guideline. However, there are certain elements of the pack design and layout that are considered particularly important for the design and layout of non-prescription medicines:

- **Graphic elements** - Graphic elements (e.g. figures, lines) may be presented, where space permits, on the outer packaging and on immediate packaging, provided they do not impede legibility of the statutory information and are not promotional.
- **Body text** - The largest type size possible should be used on all components. Where appropriate the company details should be moved on to a side panel to afford a greater amount of space for the rest of the product information. Where small type sizes have to be used, dark print on a light background may be easier to read and should be considered.
- **Multilingual packs** - On multilingual packaging, the information should be grouped per language, when feasible. When space does not allow the display of all information in different languages on the same panel, each panel may be used per language. The implementation of a clear demarcation between each of the languages is recommended.
- **Use of capitals/italics and bold-semi-bold** - Entire sentences in capital letters or italic type are hard to read. Capitals or italic type should not be used if an alternative method of emphasis, such as bold type, is available. Upper and lower case lettering should be used for sentences.
- **Use of colours** - The use of colour on packaging is a useful way to differentiate between packs but careful consideration needs to be given to ensure that it does not adversely impact on the legibility of information or cause confusion as to the nature of the product and should not encourage any misuse, particularly by children.
- Similarity in packaging which contributes to medication error can be reduced by the judicious use of colour on the pack. However, the number of colours used on the pack will need careful consideration as too many colours may cause confusion. Where colour is used on the outer pack it is recommended that it is carried onto primary packaging to aid identification of the medicine.
- **Contrast** - Colours should be chosen to ensure a good contrast between the text and the background to assure maximum legibility and accessibility of the information. The use of highly glossy, metallic reflective packaging may affect the legibility of the information. The choice of packaging material should ensure that information is clear and legible.

5. Labelling

The information to be included in the outer packaging of medicines or, where there is no outer packaging, on the immediate packaging is defined in Article 54 of Directive 2001/83/EC.

Article 62 of Directive 2001/83/EC specifies that the outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the SmPC which is useful for the patient, to the exclusion of any element of a promotional nature.

The use of symbols or pictograms and any additional information may appear on the outer packaging and package leaflet of medicines alongside the statutory product information, following the criteria below:

- Must comply with the SmPC and must not include any promotional information. The inclusion of any additional information to clarify certain information should be scientifically assessed and should be supported by data included in the SmPC.
- Should be used to explain the appropriate and safe use of the medicine, as long as it is not promotional, especially if there may be a risk of incorrect use.
- Should not replace mandatory information required on the packaging and may only be used to clarify certain information.
- Should be subordinate in placement and prominence to the statutory packaging elements and shall not affect the readability of the mandatory information.
- The pictograms should be unambiguous and the meaning should not be misleading or confusing. It is not acceptable to use the packaging designs to suggest characteristics that the medicine does not contain, such as a broader therapeutic indication.
- The medicine should always be clearly distinguishable from non-medicinal products. The pack should not cause confusion as to the nature or the product and should not encourage any misuse, particularly by children.
- Should be useful to identify the individual medicines and to differentiate from other medicines, especially in the case of umbrella brands, however, it should not be the only element used to differentiate and should never be used in place of a distinctive invented name.

5.1. Use of symbols or pictograms designated to clarify certain information

5.1.1. Pharmaceutical form

A pictogram, picture or illustration of the pharmaceutical form may be included on the packaging. Such additional element(s) may be included for purposes of identification of, for example, the shape or to point out whether the tablets are soluble, effervescent or chewable etc.

It must also accurately represent the actual form and must correspond to the appearance (e.g. with respect to shape) and should be in accordance with the medicine in the package and to the description in the SmPC. This means that if, e.g. a score-line line is present, then this must also appear in the illustration.

The number of solid pharmaceutical forms (e.g. tablets, capsules, suppositories) shown must be considered so as not to mislead about the dose.

5.1.2. Special administration aids

Pictograms of special administration aids (e.g. spoons, oral syringes, scoops) may be allowed, if the inclusion is considered to be relevant for the appropriate and safe use of the medicine.

5.1.3. Indication of the target group

Images of children should not be included since they may lead to confusion as to the exact age group they are representing. However, information that the medicine is intended for children or even for a

specific age range may be helpful for the selection of the medicine (see section 5.2.2. Name for special groups).

5.1.4. Pictures of toys

Images of toys, balloons etc should not be placed on the packaging since these can cause confusion with other type of products like, for example, confectionary products.

5.1.5. Pictures of parts of the body (site of administration/treatment or indication)

A picture or pictogram of the part of the body to be treated by the medicine, or where the medicine will be administered (e.g. an ear for a medicine to treat ear pain, a nose for a nasal decongestant, or a foot for products to treat athletes' foot) may be permitted since these may help consumers understand what a medicine is for and where it works. It can also help to distinguish between medicines in a range.

In principle, this should only be allowed if the medicine can be administered **at only one site** or if the medicine is authorised for **only one indication**.

5.1.6. Pictures of leaves and fruits

A drawing of a fruit or other item of this type, reflecting the taste of the medicine should not be placed on the packaging. Specifying only the name of the flavour of the fruit (e.g. strawberry flavour) on the pack is considered to be sufficient to help with the correct identification of the medicine.

5.2. Other information compatible with the SmPC which is useful to the patient, to the exclusion of any element of a promotional nature.

5.2.1. Excipients/Formulation statements

- **Change in the formulation** – A statement may be used on the packaging in order to alert pharmacists and consumers of a change in an existing medicine (e.g. addition of a new excipient with known effect, lactose) and only when considered to be relevant for the safe use of the medicine. In these cases, the change may be displayed prominently e.g., 'Lactose added' or 'Important: Lactose added'. The launch of a new flavour, for example, would not qualify for the inclusion of such a statement.
- **Flavour(s)** – Highlighting the taste of a medicine may be helpful to the patients in choosing the appropriate medicine. It is particularly useful for medicines such as throat lozenges and gum, which stay in the mouth for a time. Any added characteristics to the flavour (e.g. cooling mint) would be considered promotional in style.

Statements related to excipients which are not part of the medicine formulation and, therefore, do not have any known action or effect, should not be allowed on the packaging. Exceptionally, the statement 'sugar-free' could be allowed, as it can be considered useful information for the patient and can help the identification of the product and/or differentiation within a range (e.g. umbrella brands).

5.2.2. Name for special groups

- **Age group** - If a medicine is exclusively indicated for use by a certain age group, this age group should be additionally listed on the packaging and may help parents of children to choose the appropriate medicine.

Other groups of the population such as pregnant women and diabetics should be advised not to take medicines without professional advice. Therefore, statements like ‘can be used in pregnancy’ or ‘suitable for diabetics’ should not be allowed on the packaging.

5.2.3. Special warnings

Any special warnings to be displayed on the outer packaging should be scientifically assessed and supported by the SmPC.

5.2.4. Speed and duration of action statements

Any statements related to the characteristics of action of the medicine would not be allowed unless it is deemed to be helpful for the safe use of the medicine (e.g. compliance). Any statement should be subject to assessment and be based on the SmPC.

5.2.5. Statements relating to side effects and safety

Statements related to a lack of side effects are not permitted on the packaging.