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4 **QRD recommendations on pack design and labelling for**
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6 **products**
7 **Draft**

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28 **Executive summary**

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

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

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

43 A consultation with Member States on national practices regarding pack design and labelling for non-
44 prescription medicines has taken place and this document summarises the basic
45 recommendations/principles¹ to guide applicants and marketing authorisation holders when preparing
46 the mock-ups and specimens of the sales presentations² of non-prescription medicines within the
47 centralised procedure. It is acknowledged that national practices on pack design for non-prescription
48 medicines differ across Member States, therefore, the recommendations included in this document
49 should be considered in this context.

50 **1. Introduction (background)**

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

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

62 In addition, there are different elements which contribute to the optimisation of the pack design such
63 as the use of a clear layout, font type, the use of colour or graphic design and recommendations on
64 such elements are addressed in the Readability guideline. Following the consultation with Member
65 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).

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

68 **2. Scope**

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

74 **3. Legal basis**

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

- 77 • Articles 54, Article 55 and Article 59 of Directive 2001/83/EC lay down the information that must
78 appear on the outer and immediate packaging information (labelling) and the package leaflet of
79 medicinal products.
- 80 • Article 62 of Directive 2001/83/EC specifies that the outer packaging and the package leaflet may
81 include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and
82 59(1) and other information compatible with the SmPC which is useful for the patient, to the
83 exclusion of any element of a promotional nature.

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

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

90 **4. Pack design**

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

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

101 **4.1. Display of the critical information**

102 **4.1.1. Name of the medicine**

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

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

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

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

118 **4.1.2. Active substance**

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

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

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

129 **4.1.3. Route of administration**

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

132 **4.2. Display of other important information**

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

- 137 • Authorised indication.
- 138 • "Read the package leaflet before use"

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

143 **4.3. General pack design and layout**

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

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

173 **5. Labelling**

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

176 Article 62 of Directive 2001/83/EC specifies that the outer packaging and the package leaflet may
177 include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and
178 59(1) and other information compatible with the SmPC which is useful for the patient, to the exclusion
179 of any element of a promotional nature.

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

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

201 ***5.1. Use of symbols or pictograms designated to clarify certain information***

202 **5.1.1. Pharmaceutical form**

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

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

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

212 **5.1.2. Special administration aids**

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

215 **5.1.3. Indication of the target group**

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

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

220 **5.1.4. Pictures of toys**

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

223 **5.1.5. Pictures of parts of the body (site of administration/treatment or 224 indication)**

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

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

232 **5.1.6. Pictures of leaves and fruits**

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

236 ***5.2. Other information compatible with the SmPC which is useful to the 237 patient, to the exclusion of any element of a promotional nature.***

238 **5.2.1. Excipients/Formulation statements**

239 • **Change in the formulation** – A statement may be used on the packaging in order to alert
240 pharmacists and consumers of a change in an existing medicine (e.g. addition of a new excipient
241 with known effect, lactose) and only when considered to be relevant for the safe use of the
242 medicine. In these cases, the change may be displayed prominently e.g., 'Lactose added' or
243 'Important: Lactose added'. The launch of a new flavour, for example, would not qualify for the
244 inclusion of such a statement.

245 • **Flavour(s)** – Highlighting the taste of a medicine may be helpful to the patients in choosing the
246 appropriate medicine. It is particularly useful for medicines such as throat lozenges and gum,
247 which stay in the mouth for a time. Any added characteristics to the flavour (e.g. cooling mint)
248 would be considered promotional in style.

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

253 **5.2.2. Name for special groups**

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

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

260 **5.2.3. Special warnings**

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

263 **5.2.4. Speed and duration of action statements**

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

267 **5.2.5. Statements relating to side effects and safety**

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