



30th June 2011

European Medicines Agency
7 Westferry Circus,
Canary Wharf,
London E14 4HB

Consultation on the Recommendations on Pack Design and Labelling for Centrally Authorized Non-prescription Medicinal Products

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

We have discussed the proposed recommendations with the NHS Pharmaceutical Quality Assurance Committee (NHSPQAC) and we fully support the following comments put forward by the NHSPQAC:

1. General comments

We are fully supportive of the EMAs efforts to improve the packaging and labelling of OTC medicines. The extended guidance proposed is on the whole sensible and should help to protect the public by reducing medication errors from the mis-selection of an inappropriate OTC medicine by a member of the public or a healthcare professional. Where no specific comment is made it can be assumed that we are in full agreement with the proposed guidance as outlined. We make a number of specific proposals below which we believe will improve the proposed guidance and further improve public safety; however a number of areas are not covered in the guidance document that should be considered.

There is no comment made in the guidance with respect to how numbers and strengths are expressed on packaging and labelling. Errors occur if the abbreviation mcg or μg is used for micrograms as this can be misread as mg – milligrams. Trailing zeroes after a decimal point should not be used as 5.0 can be mistaken for 50. Decimal points should be easy to see, spaced halfway up the numbers not at the bottom as generated by current word processors. If tablets are enclosed in opaque blister strip packaging a picture of the tablet on the outer packaging can be helpful for patients who may pop out a number of different tablets from different packs of medicines and may be confused as to which tablet is which. The labelling of blister strip foils is equally important as the labelling of the box in which they are contained. The

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critical information (as identified below) should be repeated across the foil or printed on a central “island” in the middle of the strip so that this information is not lost as tablets are removed from the strip. This is particularly important, as patients will often remove strips from the carefully designed outer carton, thereby negating any safety features incorporated on the outer packaging material.

2. Specific comments on text

Section 109 – 110

Comment:

The direction that the critical information outlined in section 4.1.1 “If possible, appear on at least three non-opposing sides of an outer carton (including one end panel), whenever space allows for the display.” should be strengthened.

Proposed change: Change to “The critical information must appear on at least three non-opposing sides of an outer carton, unless otherwise justified.”

124 – 126

Comment:

The direction with respect to the display of the name of the active ingredient in section 4.1.2 “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.” requires revision. The name of the active ingredients is equally important as the brand name, particularly if Umbrella trade names are allowed. Due to space constraints medicines may not be stored with the main face of the pack facing outward. In this case the ingredient name would not be seen.

We feel that the use of Umbrella trade names should be banned due to the high potential for selection error however, we appreciate this is not a specific part of the consultation.

Proposed change: The names of active ingredients are part of the critical information identified in section 4.1.1 and must appear on at least three non-opposing sides of an outer carton, unless otherwise justified.

127 – 128

Comment:

The active ingredients are of equal importance as the other critical information (especially when umbrella trade names are used) and must be given equal prominence.

Proposed change: “Equal prominence should be given to active substance(s) through the choice of type size, font type or emboldening.”

130 – 131

Comment:

The route of administration is important information. The words “are encouraged to” in line 130 should be changed to “must”.

Proposed change: “Applicants must display the route of administration in the same field of vision as the rest of the critical information, unless otherwise justified.”

150 – 153

Comment:

The 2009 EU Guideline on readability recommends a minimum font size of 9 points. If applicants stick to the minimum requirements for font size (except for small containers) this will be too small for the majority of elderly patients (or even middle aged ones!) to comfortably read. It is probably more useful for these guidelines to specify a larger font size as a minimum (e.g. 16 points for critical information) and not reference the 2009 readability guidelines. The last sentence should be more directing as outlined below.

Proposed change: “Where small type sizes have to be used, dark print on a light background must be used.”

170 - 171

Comment:

We agree with the statement with respect to metallic and glossy packaging causing problems with readability. This also needs to be extended to consider machine readability as well, as examples of packaging using silver barcodes on a white background have been sanctioned in the past and are were found to be unreadable by barcode scanners on dispensary robots etc.

Proposed change: “The use of highly glossy, metallic reflective packaging may affect the legibility of the information and barcode readability.”

212

Comment:

Whilst not a comment with regard to pictograms and the use of special aids, special aids such as measuring devices can cause administration error. They should be labelled in units of volume only (not a mass) and the unit of measurement marked on the device (teaspoons, mls) must correspond to the units of measurement given in the dosage directions on the packaging and in the PIL.

Proposed change: None

250 – 252

Comment:

The statement “sugar free” can be helpful, though can be misleading if sugar is taken to mean sucrose by the manufacturer. Sugar free products have been noted in the past that do not contain sucrose but do contain glucose. The terms “alcohol free” and “preservative free” should also be considered and defined.

Proposed change: “Where alcohol or sugar is present in the formulation, this should be clearly declared on the label. Where alcohol is present, the label should clearly state the alcohol content in weight per volume. NB non-carcinogenic sugars that are suitable for diabetics are acceptable in sugar free formulations (e.g. liquid maltitol).”

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

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