

MEDICINES CONTROL AGENCY



BEST PRACTICE GUIDANCE ON THE LABELLING AND PACKAGING OF MEDICINES

EXPLANATORY MEMORANDUM

The Chief Medical Officer, in 2001, published “Building a Safer NHS for Patients” to provide mechanisms for improving the way in which adverse events are recorded and learnt from, within the clinical environment. Medicines management plays an important role in the way in which medicines are used and clear labelling of medicines is part of the safe use of all medicines.

As part of a wider impetus to reduce medication errors, the Committee on Safety of Medicines has reviewed the factors that are involved in labelling and packaging and as a result of their work, have agreed the principles that should be used when labelling for medicines is drawn up. This document expands these principles, which are set out in the emboldened text within the guidance. The main objective is to make improvements to medicines labelling within the current regulatory framework which will add clarity to the information provided, assist healthcare professionals and patients/carers to select the correct medicine and use it safely, thereby helping to minimise medication errors. This is only one strand of the work being undertaken across the Department of Health to meet the target set by the Chief Medical Officer of reducing medication errors by 40% by the year 2005.

The guidance was developed by a working group comprising members drawn from the CSM, pharmaceutical industry, health care professionals, National Patient Safety Agency, lay interests, Department of Health and the MCA. In addition, the developing guidance has been shared with other member states in Europe who have also provided contributions to the text.

This is a working document that will be implemented from 1 March 2003. This guidance will be subject to review and re-issued annually.

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 should be 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”(1) published in April 2001, which implemented “Organisation With A Memory”(2), identified such factors as training, communication, storage, and supervision. Problems with labelling have also been associated with a high percentage of errors (3). Within the current regulatory framework there is the potential for improving the layout of medicines labelling to aid clarity. This would 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. 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 Control Agency as any deviations from this guidance may need to be justified.

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/EEC (4). The guidance has no legal standing but it will be taken into account when the Medicines Control Agency assesses the labelling provided with mutual recognition and national licence applications. The guidance applies primarily to prescription only medicines but the principles should be applied as appropriate to all medicines, including those available over the counter.

In assessing applications, 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, 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.

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. For medicines that include either a company name or a trademark as part of the product name, this must be reflected on all packaging components where the name is required to appear. The name registered in the SPC may not be abbreviated for inclusion on the labelling and should be selected with this in mind.

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 applicable only to carton presentations in which case the end-face of the pack 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 a single active ingredient, the common name of this active ingredient should immediately follow the name of the medicine on the pack, unless it is 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 appears after the brand name, it 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 and the font used.

If a medicine contains more than one active ingredient consideration should be given to including all common names on the front of the pack where practicable.

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.

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.

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 retail 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. Examples of warnings that are considered appropriate for the critical field include:

<i>Fatal if given by other routes</i>	Vinca alkaloids
<i>Check dose and frequency - methotrexate is usually taken once a week</i>	Oral methotrexate
<i>Dilute before use</i>	Concentrated potassium chloride
<i>Contains paracetamol</i>	Paracetamol-containing medicines.

- 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.
- 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. Where practicable, packs 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. 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.** 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. It will not be 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.

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:**
- **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.

7. **CONCLUSION**

All applications submitted for assessment to the Medicines Control Agency that include a labelling component will be considered against the criteria in this document. This will apply in all areas of MCA work (new MAs, PLPIs, renewals, variations and applications to the product information unit). Assessment may involve 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 an applicant deviates from this guidance a full justification for this should be provided with the application. Once approved, amended components will be expected to be introduced ideally within three months and within six months at most.

MEDICINES CONTROL AGENCY
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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.