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Drug Packaging and Labelling: Guidelines for Manufacturers (2001)

Canadian Society of Hospital Pharmacists
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Drug Packaging and Labelling: Guidelines for Manufacturers

INTRODUCTION

This is the 2001edition of the Canadian Society of Hospital Pharmacists (CSHP) Drug Packaging and Labelling: Guidelines for Manufacturers. These Guidelines have been prepared with the co-operation of the pharmaceutical industry. The Guidelines reflect the National Standard of Canada: CAN/CSA-Z 264.2-99 “Labelling of Drug Ampoules, Vials and Pre-filled Syringes”. Patient safety with respect to drug administration is a major concern for everyone involved in the delivery of health care. Accurate selection of the correct drug product is necessary for safe drug administration. Drug package and label design can enhance the legibility of a label and increase product recognition, thereby supporting the goal of safe drug administration.

These guidelines were approved under the title of Guidelines for Drug Packaging and Labelling for Manufacturers; the title was fine-tuned in 2009.

1. SCOPE

These Guidelines are intended to assist pharmaceutical manufacturers in developing labels and packaging that facilitate the proper selection and safe administration of a drug product.

2. GLOSSARY OF TERMS, ABBREVIATIONS, AND SYMBOLS

The definitions given below apply to the terms used in these Guidelines. They may have different meanings in other contexts.

Bar Code	A system of vertical bars that are positioned in a certain order to represent characters, numbers, or symbols.
Common Name	With reference to a drug, the name in English or French by which the drug is: a) commonly known; and b) designated in scientific or technical journals, other than the publications referred to in schedule B to the Food and Drugs Act.
Colour Coding	The use of a colour to identify a specific product or strength.
Critical Information	The drug product's common name(s) in English and French and the total amount of the drug ingredient(s) as mg per total mL, followed by the concentration of drug ingredient(s) as mg per mL.
DIN	Drug information number
Generic Name	See Common Name.
House colours, House looks, Trade dress	Unique or distinctive packaging or labelling attributes adopted by a manufacturer in order to enhance manufacturer recognition.
IU	International Units
mEq	Milliequivalent
mg	Milligram
mL	Millilitre
mmol	Millimole
NMI	Nonmedicinal ingredient
SI	International system of units
Unit dose	A package which contains the particular dose of drug ordered for a patient and is fully identified and ready for administration directly from the package.

3. USER REQUIREMENTS

3.1

Pharmaceutical suppliers and manufacturers should identify the users of their products and should understand the medication cycle in hospitals.

3.2

Requirements of the users of the product shall be the primary consideration in label design.

4. GENERAL REQUIREMENTS FOR LABEL DESIGN

4.1 Basic Principles

4.1.1

The objectives of the label design shall be product recognition rather than manufacturer recognition. The legibility of the inner label shall be the primary consideration in its design.

4.1.2

Common name and strength shall be the most prominent part of the label on the main panel.

4.1.3

Variations of the same trade name shall not be used to designate different chemical entities.

4.1.4

Where products are available in different formulations, the formulation should be clearly specified on the front panel with the name of the product.

4.1.5

The common name of the drug shall be printed immediately above or below the trade name.

4.1.6

Labels for products which are dispensed in their original packages should include sufficient space for the application of the pharmacist's dispensing label without obscuring essential information.

4.1.7

Special storage conditions should be highlighted on both the inner and outer carton labels.

4.1.8

Product codes which are unique to each product package size may improve product recognition. Such codes should be displayed on the main front panel.

4.2 Print Size and Style

4.2.1

Print size and style shall be carefully selected to emphasize critical information. Common, unornamented typefaces shall be used.

4.2.2

A mixed character set shall be used.

4.2.3

The character height of the typeface of the common name shall be equal to or greater than that used for the brand name.

4.2.4

For containers larger than 2 mL, the character height of letters and numerals shall be at least 1.76 mm. For containers of 2 mL or less, the character height of letters and numerals shall be at least 1.5 mm.

4.2.5

The width of letters shall be 0.6 of the height, except for the following:

a) the letter "I" which shall be one stroke in width;
b) the letters "J" and "L" which shall be 0.5 of the height;
c) the letter "M" which shall be 0.7 of the height; and
d) the letter "W" which shall be 0.8 of the height.

4.2.6

The width of numerals shall be 0.6 of the height, except for the following:

a) the numeral "4" which shall be one stroke width wider; and
b) the numeral "1" which shall be one stroke in width.

4.2.7

Where conditions indicate the use of wider characters, as on a curved surface, the basic height-to-width ratio may be increased to 1:1.

4.2.8

Characters representing critical information shall have a height-to-stroke ratio of 6:1 to 7:1.

4.2.9

The minimum space between characters shall be 1 stroke width.

4.2.10

The minimum space between two words shall be 1 character, except "L" or "I".

4.2.11

The minimum space between lines of text shall be 0.5 of character height.

4.2.12

Intagliated information should be avoided.

Note: *Intagliated information is often difficult to read, i.e., when used for a lot number or expiration date.*

4.2.13

If raised characters are used, characters should be highlighted by inking.

4.3 Standard Format

4.3.1

Information shall be placed in standard locations on the label to improve the accuracy and speed of drug selection while dispensing. (See Appendix for CSHP recommended label formats.)

4.3.2

Drug name, strength and size, where applicable, shall be grouped together on a label.

4.4 Standard Nomenclature

4.4.1

Values and amounts appearing on the label shall be expressed in SI (metric) units.

4.4.2

Abbreviations for drug names shall not be used, other than recognized chemical symbols for the salts.

4.5 Labelling of Liquids

4.5.1

For multiple use containers, expression of strength on the label shall always be in terms of the 1 mL unit (i.e., 5 mg/mL).

4.5.2

For unit dose containers, the expression of strength shall be in milligrams per total container.

4.5.3

Dose directions on the label shall be expressed in milligrams with the appropriate quantity in millilitres included.

4.5.4

Labels for powders requiring reconstitution shall include reconstitution directions, displacement factors, and solution stability information.

4.6 Colour

"The use of colour coding as a means of identifying drug products or strengths is opposed, until or unless scientific evidence can be established that the practice improves safety in medication use."[1]

4.6.1

The critical information field shall be represented in black characters on a white background. This the most legible form of communication under daylight conditions.

4.6.2

If colours are required, the following guidelines are recommended:

a) The use of colours or trade dress does not intrude upon the critical information field or distract from the legibility of critical information.
b) Different colours, rather than different intensities of the same colour, should be used for different strengths of the same product.

4.7 Product Codes

4.7.1

The use of a manufacturer specific product code is encouraged for product identification and should be unique to each product. Product codes should be located on the front main panel, upper right corner immediately after the DIN.

4.7.2

The use of the UPC bar code system is encouraged.

4.7.3

Bar codes (e.g., code 39 or UPC code) should be incorporated on both inner and outer packages provided they do not interfere with the legibility of the label.

4.8 Label Permanence

4.8.1

Adhesives should be colourless for the shelf life of the product under the recommended storage conditions to avoid distortion of the colour of solutions.

4.8.2

The label material and the adhesive used shall ensure that labels are "tamper-evident", i.e. neither removable nor transferable intact, unless the label is intended to be removed.

4.8.3

Inks should resist isopropyl or ethyl alcohol wipes and shall be durable enough to withstand normal handling.

4.9 Safety Seals/Closures

4.9.1

Containers may be standardized as long as closures differ for products which are meant for different routes of administration.

4.9.2 Tamper Evident Closures

4.9.2.1
Tamper evident closures shall be used routinely and the following are recommended:

a) Bands or seals around caps (e.g., shrink wrapped cellophane, "sealons", etc.) must be of such quality that they cannot be readily removed and replaced;
b) Tamper-evident seals for containers of controlled and narcotic drugs should be outer visible seals rather than inner seals;
c) Inner seals (over bottle mouth) if used, must be firmly attached so they do not come off when the cap is removed.

4.10 Expiry Dates

4.10.1

All drug products shall have an expiration date indicated on the label. The expiration date should be represented as an alphanumeric expression comprising six characters as shown in the example below, where CCYY represents a calendar year in four digits, and MM the calendar month within the calendar year in two letters (JA, FE, MR, AL, MA, JN, JL, AU, SE, OC, NO, DE). The expiration date is understood to be the last day of the stated month, unless otherwise specified.

Format: EXP CCYYMM
Example: EXP 2000 MA

4.10.2

Where a product requires reconstitution, the label shall indicate the stability of the solution after reconstitution.

4.11 Storage Conditions

4.11.1

Storage conditions should be clearly identified on the inner and outer label using accepted USP terminology and conditions.

5. SPECIAL PACKAGING AND LABELLING REQUIREMENTS FOR ORAL PRESCRIPTION PRODUCTS

Note: *Refer also to General Requirements for Label Design.*

5.1

The strength of the product should have prominence over the number of units in the package.

5.2

Solid oral dosage forms should have readily identifiable, unique markings to facilitate product recognition.

5.3

Special instructions such as “Store in Refrigerator” or “Shake Well” should be highlighted and positioned so that they are readily seen.

Note: *It is not necessary that they be on the main panel, but they should be the first written line on the side panel.*

5.4

Multi-ingredient products should have the name and strength of each ingredient listed on separate lines.

6. SPECIAL PACKAGING AND LABELLING REQUIREMENTS FOR UNIT DOSE SOLIDS

Note: *Refer also to General Requirements for Label Design.*

6.1

Mandatory components of the label for each unit dose package include:

a) common name or trade name for multiple active ingredient products;
b) strength;
c) lot number;
d) name of the manufacturer; and
e) expiry date.

6.2

Optional components of the label include the trade name, route(s) of administration, and identification code number, i.e., DIN or GP number.

6.3

The unit dose package shall be easily opened and the medication easily removed from the package to be administered directly to the patient.

6.3.1

The “peel-off” style should be used, but the strip pack format is also acceptable.

6.3.2

“Push-through” packages should not be used because the label is destroyed when the tablet or capsule is removed.

6.4

The outer carton should be labelled on the sides and ends to allow for maximum storage flexibility.

7. SPECIAL PACKAGING AND LABEL REQUIREMENTS FOR SMALL VOLUME PARENTERALS OF 5mL OR LESS

Note: *Refer also to General Requirements for Label Design.*

7.1

The inner label shall read from left to right when the top of the container is held in the right hand, i.e., from bottom to top.

7.2

The orientation of the label shall be such that the brand and common names, the concentration, and the total content are legible with minimum rotation of the container.

7.3

When ampoules or vials are intended to be used as single dose containers, the most prominent strength designation shall be total milligrams per total volume, with mg/mL in close proximity.

Example: **400 mg/ 5 mL**
(80 mg/mL) (in smaller type)

7.4

For electrolyte products, the strength should be expressed as total millimoles per total volume with mmol/mL in close proximity.

7.5

All necessary information for determining concentration, total amount and total volume should be positioned in the same field of vision.

7.6

Reconstitution directions for final volume **should** be included on both inner and outer labels for products of volume of 5 mL or less and **shall** be included on both inner and outer labels for products of volume greater than 5 mL.

7.7

The outer container should incorporate 'windows' where possible to enable the user to tell at a glance how many ampoules or vials remain.

7.8

A single tray of five or 10 units is preferred.

7.9

Cardboard dividers which collapse after vials are removed should not be used.

7.10

In addition to labelling the main panel of the outer container, all faces of the box should be labelled with the common name and strength as well as the trade name.

7.11

Package design should be adaptable for use as a prescription item, a wardstock item, or as a unit dose item.

7.12

Plastic trays on which the company name, logo, or product name is embossed should not be used.

8. SPECIAL PACKAGING AND LABELLING REQUIREMENTS FOR PREFILLED SYRINGES

Note: *Refer also to General Requirements for Label Design.*

8.1

Syringes should have a single calibration scale.

8.2

Calibrations should indicate the actual volume of drug that is contained in syringe.

8.3

Graduation scales shall be represented in black on a white field.

9. SPECIAL PACKAGING AND LABELLING REQUIREMENTS FOR UNIT DOSE LIQUID NEBULES

Note: *Refer also to General Requirements for Label Design.*

9.1

Standardized nomenclature for the containers shall be used, i.e., unit dose for injection, unit dose for inhalation, unit dose for oral use, etc. rather than using “patented” names (e.g., “Polyamp”).

9.2

Mandatory components of the label include:

a) common name;
b) strength (total concentration/total volume);
c) expiry date;
d) lot number;
e) manufacturer’s name or logo; and
f) route of administration.

9.3

Optional components of the label (in decreasing order of priority) include:

a) strength (concentration per millilitre);
b) trade name; and
c) DIN.

9.4

Unit dose liquid nebules, whether packaged individually or in attached units, shall follow identical labelling formats although some flexibility should be allowed with the sealing or closure strip (e.g., attaching the lot number and expiry date to the back of the seal instead of on the nebule itself).

9.5

Exceptions may be required for “specialized” items, for example, sterile Operating Room packs such as minims. The labelling on the outer wrap is acceptable in place of the inner container because the two should never become separated.

9.6

If unit dose nebules are grouped in multiple sheets, individual doses should be easy to separate without the use of scissors.

10. PACKAGING MATERIALS

10.1

Packaging materials should be kept to the minimum required for safe shipping, storage, identification, and use of all products.

10.2

All packaging materials should be environmentally friendly.

11. SPECIAL LABEL CONSTRUCTIONS

Special label constructions such as accordion, fold-out, or multipanel labels can be used as long as the basic principles of the guidelines are not compromised.

12. LITERATURE CITED

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13. ADDITIONAL RESOURCES

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APPENDIX A: PROTOTYPE INNER LABEL – SMALL VOLUME PARENTERAL