Position Statement 2013

Making Medicines
Naming, Labelling and Packaging Safer
The International Patient Safety Network

- The International Medication Safety Network (IMSN) is an international network of safe medication practice centres established with the aim of improving patient safety.
- This is achieved by operating medication error reporting programmes and producing guidance to minimise preventable harms from medicine use in practice.
- IMSN promotes safer medication practice to improve patient safety internationally.
Background

• Much of the death and serious harm caused by mistakes and accidents in health care is preventable.
• Safe design of healthcare products and systems, a key strategy for reducing preventable harm, is underutilised.
• In many countries the regulation of medicines naming, labelling and packaging is not providing adequate safeguards for patients.
• For example, there is little recognition of the importance of human factor principles in selection and design of drug names, labels and packages for minimising error potential and enhancing medication safety.
Commercial Considerations

- Current approaches to labelling and packaging privilege commercial considerations, such as “trade dress” or “umbrella” brands, and focus inadequately on the context in which the medicine will be used.

- These approaches:
  - are not patient-centred
  - assume perfect performance by healthcare professionals and by patients to avoid inevitable errors
  - risk patient safety
Position Statement

• The International Medication Safety Network recommends the following steps as part of a comprehensive, worldwide solution to the problem of unsafe medicines naming, labelling and packaging

1. Regulations for medicines naming, labelling and packaging in all countries should be strengthened to:
   a) Require better design and testing of medicines naming, labelling and packaging before release for use
   b) incorporate human factors theory
   c) promote safer use in practice
2. The pharmaceutical industry should ensure that their products are safely named, labelled and packaged to minimise errors in use.

3. Healthcare providers should assess medicines names, labels and packages for safety risks, as well as associated devices and software, before they are introduced into use and make purchasing decisions which minimise or otherwise manage these risks.
Specific Guidance

• Guidance for safe design of medicines labels and packaging should be developed and improved.

• The proprietary (trade/brand) and non-proprietary (generic/active ingredient) names of new medicines should be subject to human factors assessment and user testing by manufacturers.
Specific Guidance Continued

• The design of new medicines labelling and packaging, including associated devices and software, should be subject to human factors assessment and user testing by manufacturers

• Healthcare providers should review risk assessment data from industry and record their own risk assessment of new medicines naming, labelling and packaging before the products are purchased and introduced into use
Certain information is essential for using a medicine safely and should be presented clearly and prominently on the outer packaging label. Essential items are:

- proprietary (trade) name of medicine
- international non-proprietary (generic) names of active pharmaceutical
- substances
- dose strength/concentration
- route(s) of administration
- dosing instructions (for over-the-counter medicines)
- specific warnings including pictograms/symbols.

This essential information should always be presented on the main package face(s) and should be grouped together on the same face, where practicable. These items should not be separated by additional information, logos or graphics.
Essential Information

- Emphasise the generic medicine name.
- Emphasise the difference between look-alike/sound-alike medicine names.
- Differentiate between strengths of the same medicine.
- Do not add trailing zeros to numbers.
- Orientate text in the same direction.
- Body text in a minimum of 12 point.
- Use upper and lower case.
- Use sans serif typefaces.
- Use bold or semi-bold type.
- Do not use condensed typefaces.
- Do not squish lines of text closer together or adjust the space between letters.
- Create a strong contrast between type and background colour.
- For multi-dose injectable products, such as insulin, express strength as strength per unit volume only, e.g. units/ml or mg/ml.

Use blank space to emphasise critical information.
Do not place text over images or logos.
Include the use of braille labelling as required by medicines regulations for injectable medicines dispensed to patients.
Put critical information in the same field of vision on at least three non-opposing faces.
Position generic name and medicine strength above/next to dispensing label space.
Allocate 70 x 35mm white space for dispensing label.
Space for a dispensing label (4)
Medicine name and form (5,6)
Expression of strength (7)
Route of administration (8)

Proprietary Name
**Generic Name**
5ml ampoules  5mg/ml

For IV use  25mg/5ml

Extended Logo
Dosing instructions (9)
Special warnings (10)

**Generic Name 4.5g**
Contains penicillin

Each 50ml contains: Generic Name 4g and Generic Name 500mg.

For injection or infusion as sodium salts. Read directions for use carefully.

Store out of the sight & reach of children. Store below 25C. Store in the original container. Reconstituted solutions, prepared in sterile conditions may be stored for 24 hours in a refrigerator (2C to 8C).

PL Number: 4508/46008 T
Manufacturer address, Apple Street, Bridge town, Copper city, DE1 F23

FOR INTRAVENOUS USE ONLY
FATAL IF GIVEN INTRATHECALLY
KEEP IN A REFRIGERATOR
(2° - 8° C)
Format and Design (11)
Use of colour (12)
Machine readable codes (13)
Unit Dose
Bulk packs and Child proof tops
Dosing devices
Naming

- The medicine name should not be liable to confusion with a non-proprietary or proprietary name or an existing product when handwritten, typed, printed or spoken.
- The medicine name should not convey misleading information with regard to composition, clinical action, dose, frequency or administration of the product.
- The name preferably should consist of one word and avoid qualifications by letters or number. Exceptions may include, for example, insulin mixtures where the name may be followed by numbers representing the fast and slow acting part of the mixture.
- Avoid umbrella names – for a medicine range with different ‘actives’
- Innovative labelling can be used to highlight the difference between medicines with look-alike and sound-alike names. Enhanced differentiation should reduce the risk of confusion and mis-selection of medicines with confusable names by the use of Tall Man lettering and coloured lettering on labels and packaging.
Naming

ChlorproPAMIDE
10 mg
28 Capsules

ChlorproMAZINE
10 mg
28 Capsules

Proprietary Name 1
Cefotaxime
500 mg
(as sodium salt)

Proprietary Name 2
Ceftriaxone
500 mg
(as sodium salt)

Powder for solution for injection/infusion.

Each vial contains cefotaxime sodium equivalent to 500 mg of cefotaxime.

For intramuscular and intravenous use.

Powder for solution for injection/infusion.

Each vial contains ceftriaxone sodium equivalent to 500 mg of ceftriaxone.

For intramuscular and intravenous use.
INN’s

Attention should be paid to INNs that cause confusion. The likelihood of error should be reduced by:
• creating lists and computerised alerts emphasising the differences among INNs prone to confusion
• simultaneously using drug brand names as a double-check.

The World Health Organization (WHO) should revise INNs following associated errors with serious consequences. Effective and active management of INN-related risks should include:
• a systematic evaluation of each INN using appropriate risk assessment methods
• participation in a critical analysis of proposed INNs during WHO public consultations
• incorporating INNs and common stems into healthcare professional undergraduate curricula.
Computer screen display