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 an 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

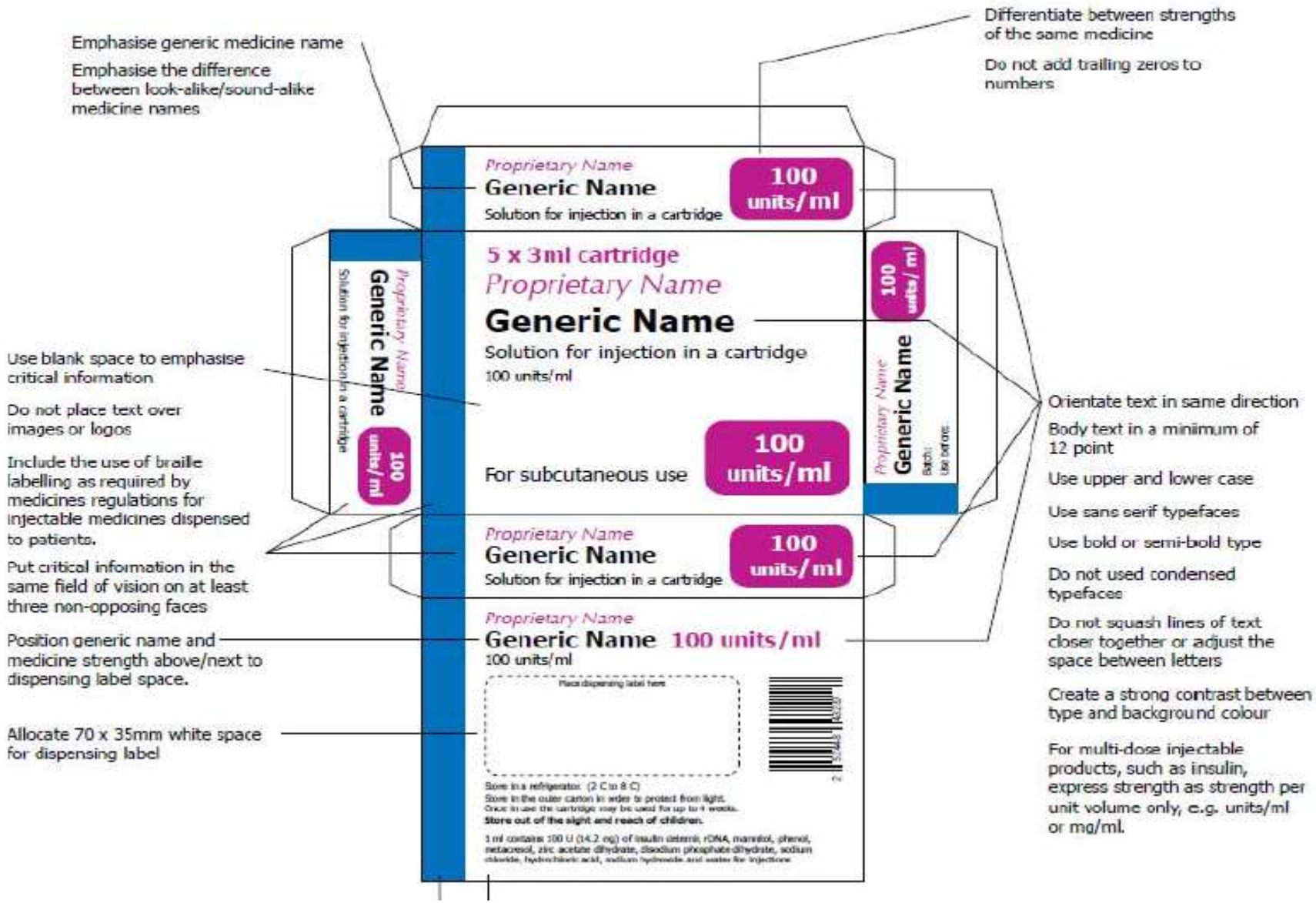
Essential information (1, 2)

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



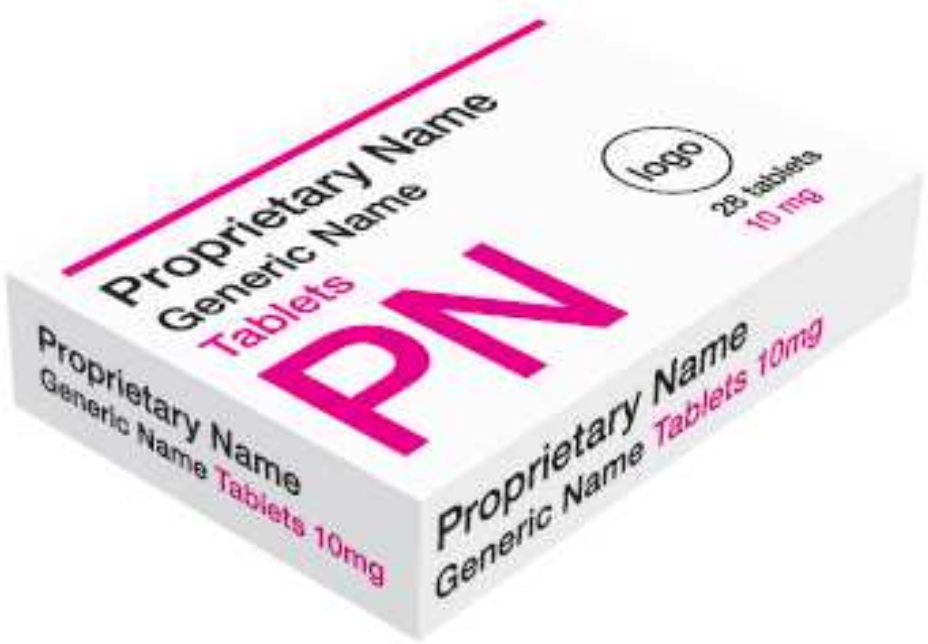
Language (3)


vaccine
Quintarixor
DTP-HepB +Hib
1 Paed. dose. Via IM.
+ 0.5ml Hib diluent/solvant/
solvente Store/Cons 2°C–8°C
Logo
Batch 368EUD10
Exp: 08/2015


DTP-Hib / DTCoq-Hib
Brand name Vaccine
10 doses dosis doses
x 0.5mL
Diphtheria Tetanus Pertussis and Conjugated HaemoPhilus Type B
Store at 2°C tp 8°C
Shake well before use.
For use by UN agencies.
Suspension for IM injection
Vaccin Diftérica Tetánica Pertúsica Adsorbida y HaemoPhilus Typo B Conjugada
Conservar 2°C a 8°C.
Agitar antes de usar.
Para uso de las ONU.
Suspension injectable por via IM
Vaccin Diphtériq Tétanique Perussique Adsorbé et HaemoPhilus Type B Conjugé
Conserver 2°C a 8°C
Agiter avant utilisation.
Pour l'usage des Nations Unies.
Suspension injectable par voie IM
DTP-Hib / DTCoq-Hib
Brand name Vaccine
10 doses dosis doses
x 0.5mL
Store at 2°C to 8°C.
Discard if frozen. Shake well.
Conservar 2°C de 8°C.
Descartar si se congela.
Agitar antes de usar.
Conservar 2°C a 8°C.
Jeter si gelé.
Agiter avant utilisation.

Space for a dispensing label (4)

Medicine name and form (5,6)



Expression of strength (7)
Route of administration (8)

Dosing instructions (9)

Special warnings (10)

Proprietary Name

Generic Name 4.5g

Contains penicillin

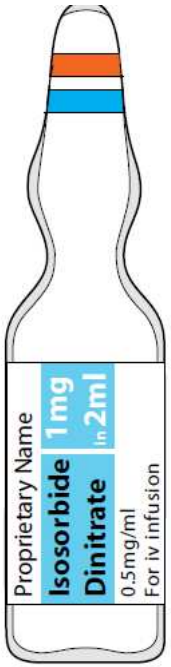
Each 50ml contains: Generic Name 4g and Generic Name 500mg.

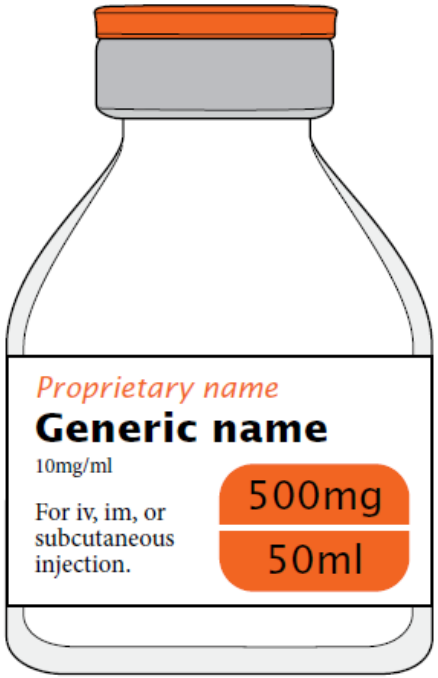
For injection or infusion as sodium salts.
Read directions for use carefully.

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

Format and Design (11)





Use of colour (12)

Machine readable codes (13)

Unit Dose


CHLORPROPAMIDE
100 mg TABLET
N5107920201
Lot 0B207 Exp. 2/02
PKG. BY: UDL, ROCKFORD, IL
CHLORPROMAZINE HCl
100 mg TABLET
N5107951601
Lot 0D737 Exp. 11/01
PKG. BY: UDL, ROCKFORD, IL

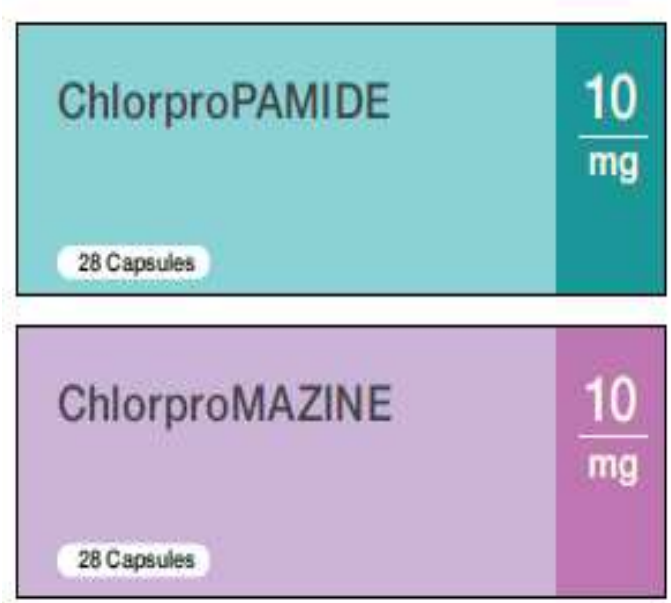
Bulk packs and Child proof tops

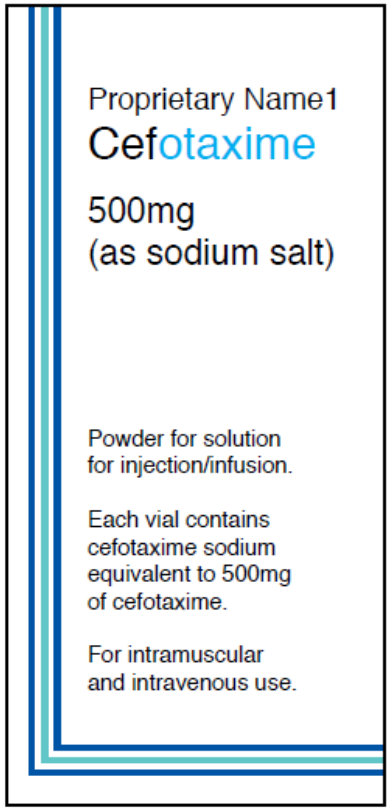
Dosing devices

Naming

- The medicine name should not be liable to confusion with a non-proprietary or proprietary name or an existing product when hand written, 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 Name1
Cefotaxime
500mg
(as sodium salt)
Powder for solution
for injection/infusion.
Each vial contains
cefotaxime sodium
equivalent to 500mg
of cefotaxime.
For intramuscular
and intravenous use.


Proprietary Name2
Ceftriaxone
500mg
(as sodium salt)
Powder for solution
for injection/infusion.
Each vial contains
ceftriaxone sodium
equivalent to 500mg
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