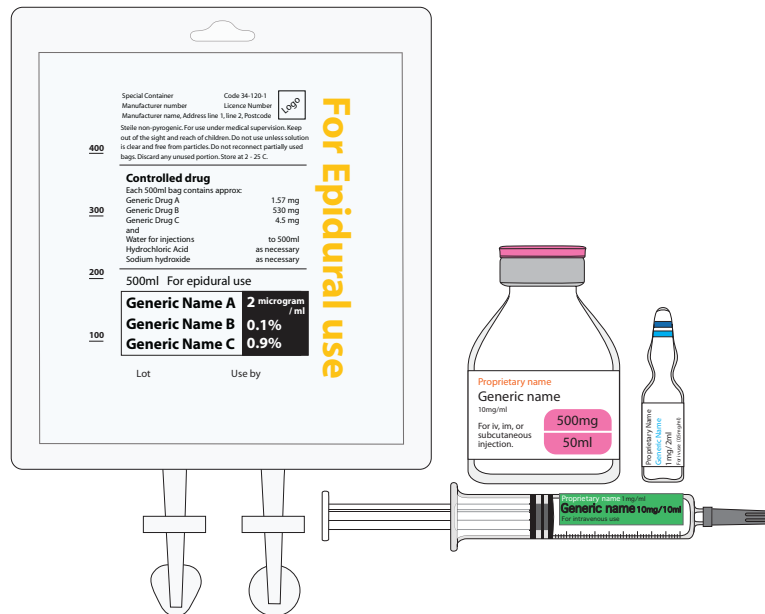


Design for patient safety

A guide to labelling and packaging of injectable medicines

Edition 1
2008



About this publication

This booklet is one of a series of design publications produced by the National Patient Safety Agency (NPSA).

Other publications in the *Design for patient safety* series:

NPSA in collaboration with the Helen Hamlyn Centre, Royal College of Art: *A guide to the graphic design of medication packaging* (second edition) (2007)

Future ambulances (2007)

The design of infusion devices (in progress)

NPSA in collaboration with Lucid Design:
A guide to the design of dispensed medicines (2007)

A guide to the design of the dispensing environment (2007)

Research and methodology

This publication is based on the results of a design research collaboration between the NPSA and the Helen Hamlyn Centre (HHC) at the Royal College of Art, London.

The study was carried out over a one-year period by Sally Halls, a postgraduate specialist in medical design, working to a brief set out by the NPSA and the HHC. Existing design guidance was reviewed and consultations were undertaken with experts in graphic and information design, and design for patient safety. Technical support was provided throughout the project by David Cousins, Head of Safe Medication Practice, NPSA.

A wide range of stakeholders contributed to the research, including patients, healthcare professionals, NHS organisations, the Medicines and Healthcare products Regulatory Agency (MHRA) and pharmaceutical industry personnel.

Observational research was undertaken in clinical environments, such as critical care areas, wards and pharmacies. The outcome was a design rationale to enhance patient safety and a fully illustrated set of design considerations with both good and bad examples.

Contents

Foreword	2
Introduction	3
Advisory panel	5
Previous recommendations	6
Use of colour	8
User testing	10
1 General recommendations	13
2 Ampoules	41
3 Vials	53
4 Pre-filled syringes	63
5 Infusion bags	71
Purchasing for safety	88
References	90
Further information	91

Foreword

I welcome this publication, which is part of a series of design guides produced by the National Patient Safety Agency (NPSA). The guides provide examples of how professionals who dispense and administer medicines can put into practice the advice of Dr Keith Ridge, Chief Pharmaceutical Officer for England, on taking an overview of safe systems and how medicines are used in practice.

Organisations, managers and healthcare workers involved in procuring, dispensing and administering medicines should use this booklet as a resource to introduce new initiatives applicable to their own disciplines to minimise harm from medicines. Humans are fallible and so healthcare inevitably carries risks, but systems that needlessly expose patients to harm are not acceptable.

Other industries have recognised design as an effective tool to improve the safety, effectiveness and efficiency of their activities; this booklet shows the importance of graphic design.

The healthcare industry has been collectively slow in using design to improve safety, but is now integrating the lessons from examples of its own best practice with those of other industries.

New factors will influence the dispensing process, such as electronic prescription services, automation technologies and enhanced pharmacy services. In the meantime, those who administer drugs, be they patients, carers or nurses, will welcome the recommendations that result in clear identification of the contents of containers of drugs.

Those of us who administer potent drugs in difficult and urgent situations, and have a history of care in identification of drugs, will particularly welcome the guidelines that advise a label on an ampoule should give priority to showing what is the active constituent and its amount. The recommendation that labels could be peeled from ampoules and attached to syringes also has merit.

Both the NPSA and the authors of this guide, in particular Sally Halls, postgraduate specialist in medical design, deserve praise.



John Curran

**Immediate Past Vice-President
Royal College of Anaesthetists**

Introduction

Between January 2005 and June 2007, the National Patient Safety Agency (NPSA) received 59,000 reports of patient safety incidents involving medicines.

Those involving injectable medicines accounted for 25 per cent of all the medication incidents, and 58 per cent of the most serious incidents; those that resulted in death or serious harm to the patient.¹

Research has shown that a third of reported medication incidents may be caused by confusion over packaging and labelling.²

The NPSA issued *Patient safety alert 20: Promoting safer use of injectable medicines*³ in March 2007, which recommended healthcare organisations risk assess injectable medicine products and processes, and take action to reduce risk.

Recommended actions included the use of 'purchasing for safety' policies; that healthcare procurement groups should procure injectable medicine products that have design features that make them safer to use in practice.

The Department of Health has recognised the importance of design in improving patient safety,⁴ and there has also been design guidance from both the Medicines and Healthcare products Regulatory Agency (MHRA) and the NPSA.^{5,6}

Design for patient safety: a guide to labelling and packaging of injectable medicines is the first guidance published that focuses on the safe design of the labelling and packaging of injectable medicine products in particular. Products include small ampoules, vials, pre-filled syringes and large infusion bags.

This publication illustrates how graphic design can be used to change and improve current packaging design practice.

It is intended as a best practice guide to be used by packaging designers and pharmaceutical companies, as well as a reference guide for those involved in the procurement of medicines in the NHS.

These guidelines are intended for all injectable medicines in use in England and Wales, including unlicensed specials (manufactured both by hospital pharmacy departments and commercial manufacturers), clinical trial supplies and parallel imported medicines.

It is increasingly being recognised that healthcare user requirements concerning labelling and packaging will exceed that required by current EU Medicines Regulations. In a recent Council of Europe report on safe medication practice, it was stated that:

"Current European Medicines Regulations concerning naming, packaging and labelling for pharmaceutical products provide inadequate safeguards for patients. Medication errors frequently occur in Europe because of sound-alike or look-alike drug names, similarities in packaging and labelling appearance, and unclear, ambiguous or incomplete label information.

There is little recognition of the importance of the human factor principles in selection and design of drug names, labels and packages in order to minimise the potential for error and enhance medication safety, neither within the pharmaceutical industry nor among the medication regulatory agencies.

The current designs for labelling and packaging prioritise industry concerns, such as ‘trade dress’, instead of considering the context where the pharmaceutical product has to be used.

It is not patient-centred, but, rather, relies on an assumption of perfect performance by healthcare professionals and by patients.

It is recommended that European Health Authorities take steps to update European Medicines Regulations used both by the European Medicines Agency (EMA) and National Medicines Agencies to include design features for packaging and labelling of medicine products that take into account human factors and favour safe use in practice.”⁷

Many of the design practices shown in this book are easy to implement. That said, it is recognised that manufacturers may face difficulties in incorporating some of the measures.

This book outlines exemplary packaging designs, creating solutions that can be worked towards and implemented in the not too distant future. For example, the use of auto-id technologies such as 2D data matrix barcodes cannot be used until the necessary infrastructures are in place. However, it is only through looking towards the future that we can plan for these changes, and implement a smooth transition.

Advisory panel

Richard Bateman	Quality Assurance Specialist Pharmacist, London Eastern and South East Specialist Pharmacy Services, Guy's and St Thomas' Hospital NHS Foundation Trust
Prof Roger Coleman	Professor of Inclusive Design and Co-founder, Helen Hamlyn Centre, Royal College of Art
Prof David Cousins	Head of Safe Medication Practice and Medical Specialties, National Patient Safety Agency
Rachel Dean	Senior Graphic Designer, Royal National Institute of Blind People
Sarah Eastham	Principal Pharmacist ITU, Anaesthetics and Theatres Pharmacy Department, St Mary's Hospital NHS Trust
Alan Haskins	Specialist in pharmaceutical primary packaging and associated medical devices
David Hunter	Consultant Anaesthetist, Royal Brompton Hospital and Harefield NHS Trust
Colum Menzies Lowe	Former Head of Design and Human Factors, National Patient Safety Agency
Darragh Murphy	Pharmacy procurement, St Mary's Hospital NHS Trust
Jan MacDonald	Head of Information Quality, Medicines and Healthcare products Regulatory Agency
Howard Stokoe	Principal Pharmacist, NHS Purchasing and Supply Agency
Shakira Watts	ITU Nurse Educator, ITU, St Mary's Hospital NHS Trust
Jeff Willis	Deputy Head of Communication Art and Design Department, Royal College of Art

Previous recommendations

In 2004, the NPSA commissioned a project from the Helen Hamlyn Centre, Royal College of Art, on the graphic design of medication packaging, with a focus on patient packs of oral medicines (tablets and capsules).

Conducted by Research Associate Thea Swayne, the study established good practice design principles that ensured maximum differentiation between packs and improved the conveyance of key information to the patient. This resulted in the publication of *Information design for patient safety – A guide to the graphic design of medication packaging*, which built upon the packaging guidelines of the MHRA.⁵ The recommendations were published in 2006 and revised in 2007.⁶

The key recommendations from this publication are collated in the diagram opposite, for reference. Please note that this represents a basic summary of the recommendations. For a more detailed understanding, please refer to the published document.⁶

It should be noted that there is a different emphasis on the use of proprietary and generic names between this publication on injectable medicines and the previous one concerning oral medicines. This is due to the nature of the different users: injectable medicines are predominantly handled by healthcare professionals, who prescribe, dispense and administer medicines predominantly using the generic name. Oral medicines are usually handled by patients, who may prefer to use the proprietary name. Therefore, in this publication, emphasis has been consistently placed upon the generic name, which is the name predominantly used in practice by healthcare professionals in England and Wales.

Emphasise generic medicine name
Emphasise the difference between look-alike/sound-alike medicine names

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

Use colour differentiation to highlight information
Use opposing, meaningless colours

Align text to the left

Differentiate between strengths of the same medicine
Do not add trailing zeros to numbers

Orientate text in 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 squash 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

Proprietary Name
Generic Name
Solution for injection in a cartridge
100 units/ml

5 x 3ml cartridge
Proprietary Name
Generic Name
Solution for injection in a cartridge
100 units/ml

For subcutaneous use
100 units/ml

Proprietary Name
Generic Name
Solution for injection in a cartridge
100 units/ml

Proprietary Name
Generic Name 100 units/ml
100 units/ml

Place dispensing label here

Store in a refrigerator. (2 C to 8 C)
Store in the outer carton in order to protect from light.
Once in use the cartridge may be used for up to 4 weeks.
Store out of the sight and reach of children.
1 ml contains 100 U (14.2 mg) of insulin detemir, rDNA, mannitol, phenol, metacresol, zinc acetate dihydrate, disodium phosphate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections

Proprietary Name
Generic Name
100 units/ml

Batch:
Use before:

2 52448 43237

Use of colour

Colour can help differentiate between medicines. However, total reliance on colour to do this can lead to mistakes. This is because colours look different in different lighting conditions; people have different perceptions of colour; and colour blindness means some people see colours differently.

Colour should not therefore be relied upon as the sole differentiator, and designers should incorporate additional graphic elements to help differentiate between medicines.

If a single colour is used for a whole range of medicines it can be difficult to identify a specific product. This is compounded if medicines with similar names are stored next to one another.

If a patient is prescribed a number of medicines with the same colour packaging, there is an increased risk of product mis-selection.



Colour coding

A colour coding system allows people to memorise a colour and match it to a function. However, creating a shortcut for identifying a medicine without having to read the label can lead to mistakes. No colour coding system could differentiate between all 12,000 medicines authorised in the UK. Furthermore, in the absence of a national or international colour code, any UK system could become a barrier to international trade.

Guidelines for syringe labelling in critical care

In 2003 the Royal College of Anaesthetists, Association of Anaesthetists of Great Britain and Ireland, Faculty of Accident and Emergency Medicine, and Intensive Care Society established a convention for syringe labelling in critical care areas.⁸ This system assigns a colour to various therapeutic classes of medicines. The colours are used on pre-printed labels, which have the generic medicine names printed on them and are used to label the syringes once the medicines have been drawn up.

On a tray with a small number of critical care syringes, this system assists anaesthetists to quickly label and safely identify these injectable medicines.

However, when presented with a cupboard stocked with a larger range of injectable medicines, many from the same therapeutic group, colour coding is not a sufficient tool for product identification. It is therefore not feasible to extend this colour coding system to commercially produced and manufactured medicine packaging.

Colour differentiation

Colour differentiation is the recommended method to help to minimise selection errors. It uses colour to make features on a medicine pack stand out or to help distinguish one item from another. The chosen colour is not associated with a particular feature. It is important that there is no pattern in the colour scheme.

User testing

Packaging design should take into account the needs and capabilities of the widest possible range of potential users and, in particular, older and partially sighted users.

As the user in this case is not the patient, but the healthcare professional, whilst older and partially sighted users need to be considered, they need to be considered within the framework of people who dispense, prepare and administer drugs.

Pharmaceutical companies should develop their own methods for testing their packaging on users.

The following example of user testing is developed from *A guideline on the readability of the label and package leaflet of medicinal products for human use*.⁹

Aim

There are a number of core tasks that are critical for the safe use of pharmaceutical packaging. The aim is to assess how users find the information they need and how they then interpret this information. The test should be able to highlight any undesirable outcomes and determine the best combination of design elements.

Method

Test on a minimum of 20 people and a range of users, including patients as appropriate. The test method should include product selection from a range of other injectable medicines products and other strengths and formulations of the same medicine. Consideration should also be given to asking the users to prepare the injectable medicines in a syringe or infusion bag as directed by the manufacturers' literature. This will vary for each product. Manufacturers should carry out testing. Designers should be involved.

Participants

Start by testing the products on 10 critical users who are likely to encounter problems. This test should include users with lower visual abilities and reduced cognitive and dexterous functions. If a user becomes confused, note how they deal with the difficulty. If a user does not understand a question, avoid giving the answer. Instead, ask them what they think it means.

Testing procedure

Test one user at a time, allowing at least half an hour for each person. They can be asked about using more than one medicine pack, but do not ask more than 15 questions in a single session. Two questions concerning the same information should not follow one another.

Ask users to carry out their normal routine for reading information on/in packaging:

- 1 Observe and write down what they do.*
- 2 Ask users to write down in their own words what they did.*
- 3 Ask questions that might extend the information gathered.*
- 4 Ask specific questions about the legibility of particular design elements on the packaging.*
- 5 Determine if specific information about the packaging can be found quickly and easily.*
- 6 Determine if information on the packaging is understandable and informative.*
- 7 Ask users to find a particular piece of information and explain it in their own words. This will reveal how well they understand the information. If this involves a physical activity such as mixing something together, they should be asked to do this and actually go through the procedure on the package.*

Results

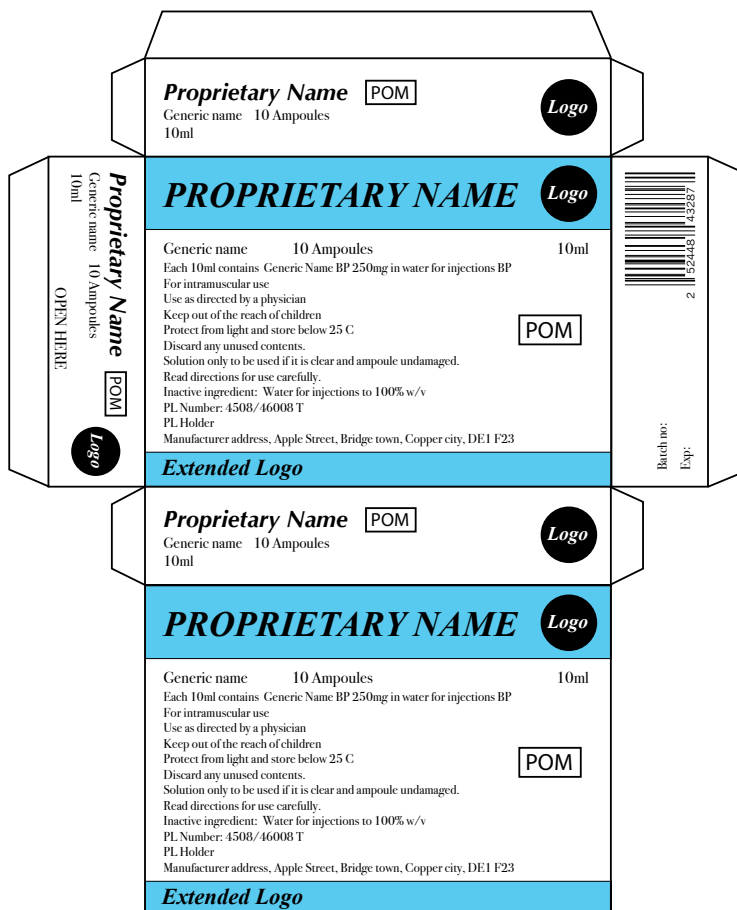
Reviewing the data should reveal any major problems with the legibility of information on the packaging. At this stage it is possible to redesign or rewrite the information before further testing. Once satisfactory data has been obtained from 10 users, a further 10 should be tested. The objective is to have at least 16 users out of 20 able to answer each question correctly. It may be necessary to clarify the performance of the questionnaire, which may include rewriting and remodelling the questions to achieve a better level of performance.

General recommendations

1.1 Key information panel

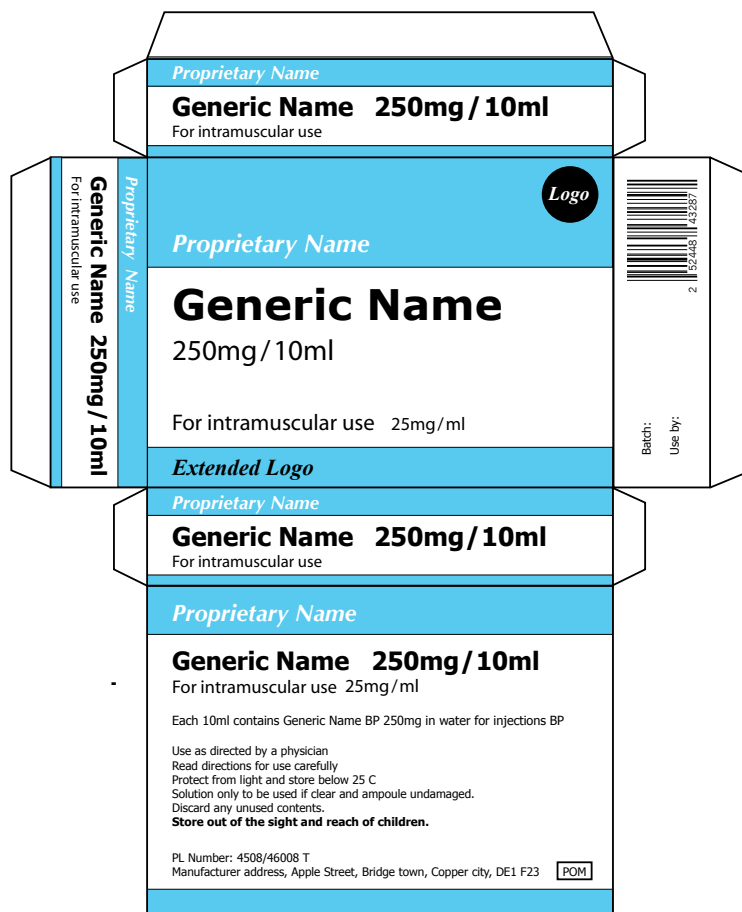
Issue

- Information is often printed on packaging in a dense block using text in a small font. Key information becomes difficult to find.



Recommendations

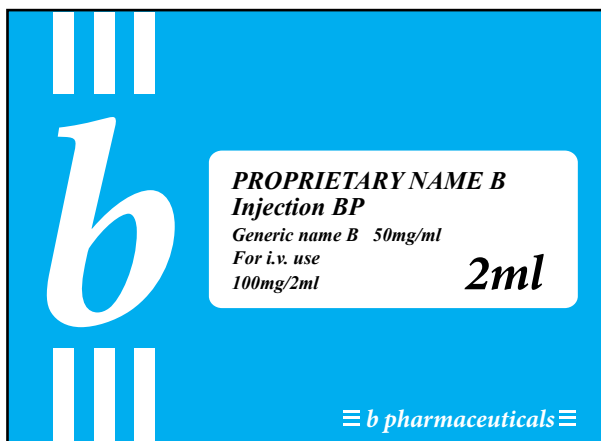
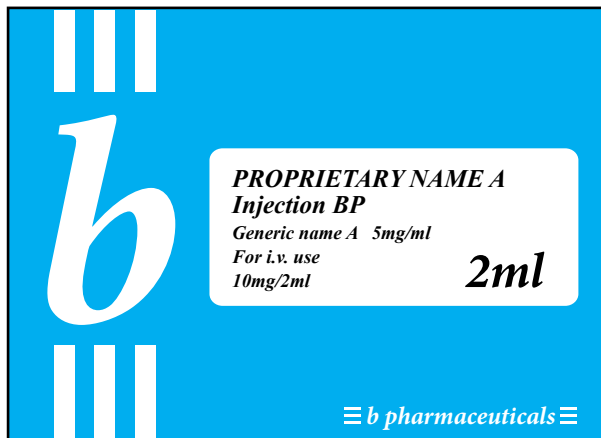
- Create a front panel that features only the key information. Subsequent information can be shown on the back panel.
- Key information consists of:
 - Non-proprietary drug name
 - Strength of the medicine:
 - > total quantity in the container (larger font); and
 - > strength per unit volume (smaller font).
 - Administration route(s)
 - Warnings



1.2 Use of colour

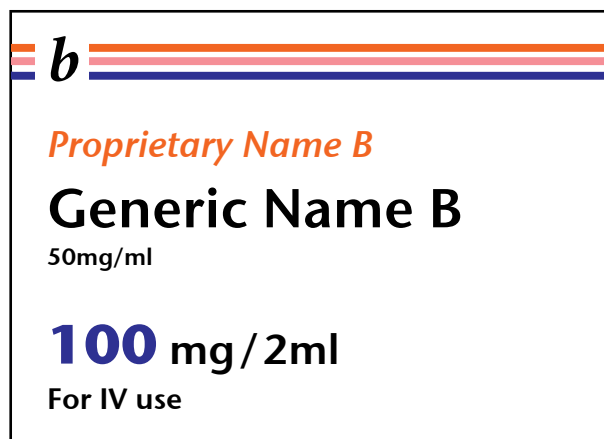
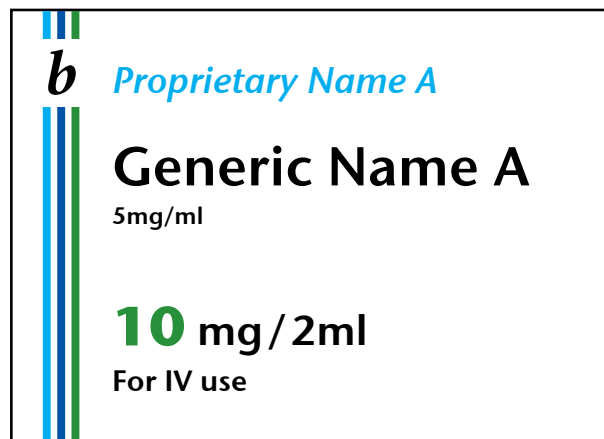
Issue

- Colour and design may be used as a branding tool to identify a manufacturer rather than emphasising a particular drug or dosage. This may cause picking errors where the wrong medicine or dose is selected.



Recommendations

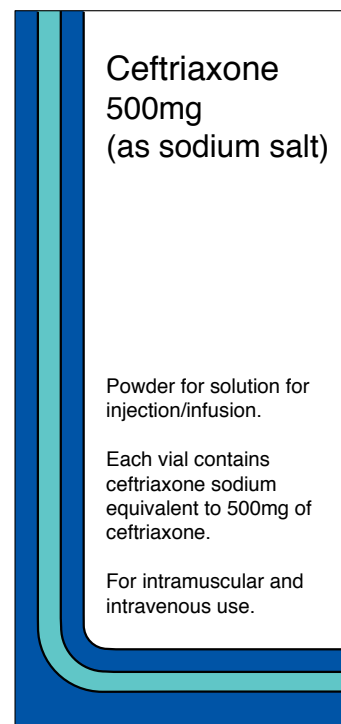
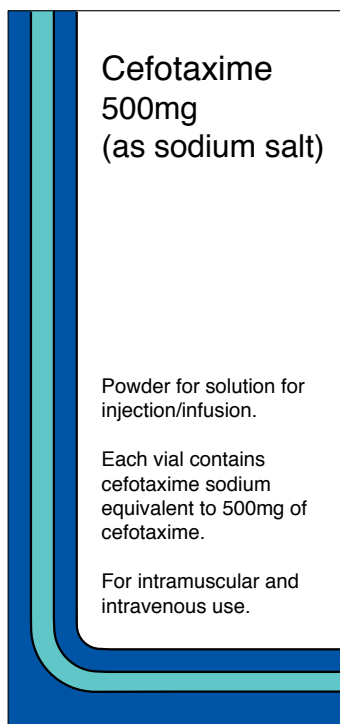
- Use colour to highlight key differences in information: the drug name, the quantity or concentration.
- Apply the colour scheme consistently throughout the primary and secondary packaging.



1.3 Similar drug names

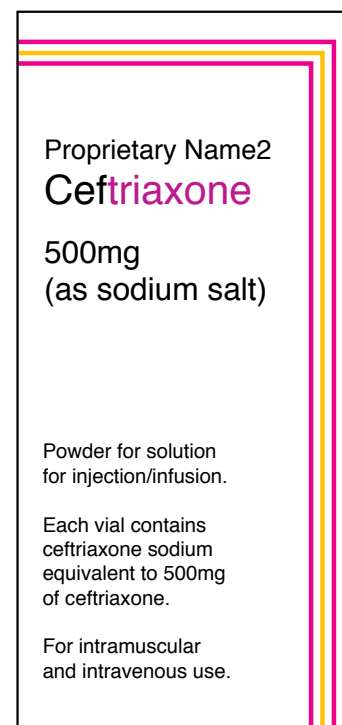
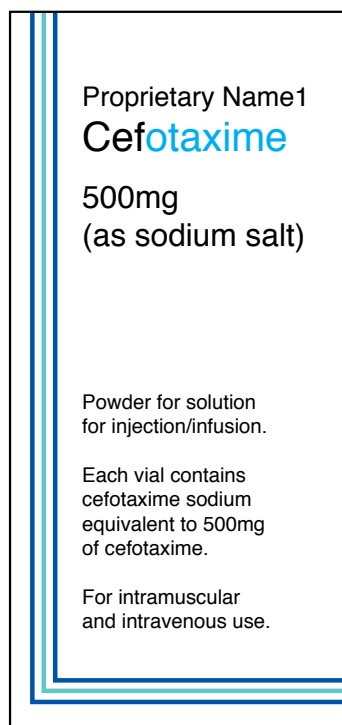
Issue

- Similar names can be easily mistaken for each other, especially with smaller labels which require small font sizes.



Recommendations

- Highlight the differences between the generic drug names. This could be done through the use of colour, tallman lettering or font sizes.¹⁰
- Change the graphic component to ensure an added element of differentiation.



1.4 Strength

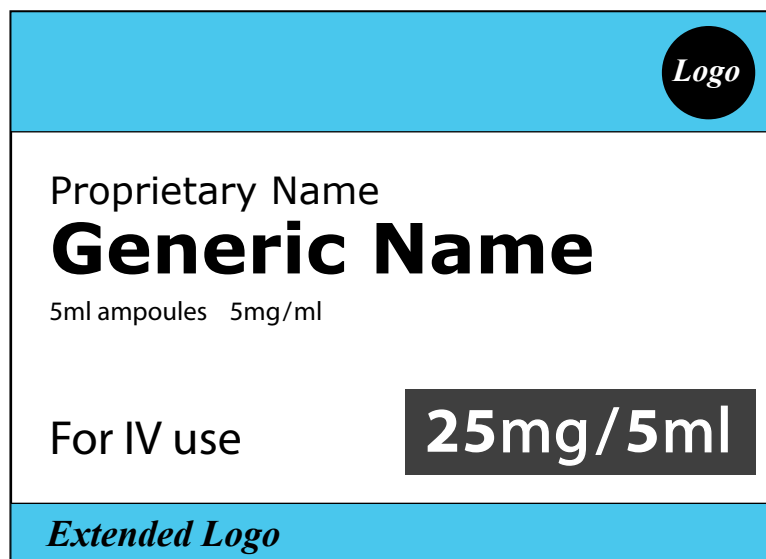
Issue

- It can be misleading if the strength of a medicine is expressed in quantity/unit volume as this can be confused with the total quantity in the ampoule, vial or syringe.



Recommendations

- Express the strength of injectable medicines in quantity/unit volume (mg/ml).
- Include a representation of the full volume strength, i.e. total quantity in total volume (mg/ml). This should be emphasised for single-dose containers.
- Care to be taken with the spacing between mg and ml. Adjust the kerning so as to leave sufficient space around the '/' to achieve maximum legibility.



1.5 Concentration

Issue

- Different representations of concentration can create confusion and complicate dose calculations.¹¹

Logo

PROPRIETARY NAME

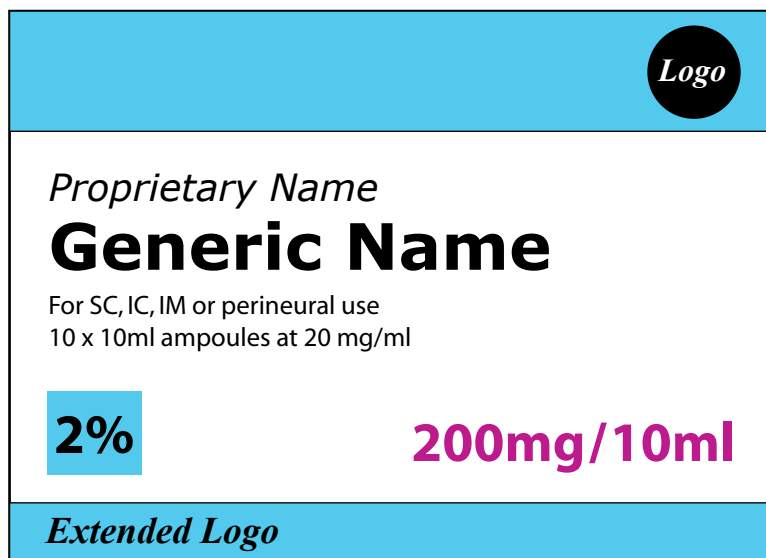
Generic name 2%	20mg/ml	10 Ampoules x 10ml
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Each 10ml contains: Lidocaine Hydrochloride in H₂O 200mg
Excipients: Sodium Chloride, Sodium Hydroxide, Water for injections
For intracutaneous, S.C., I/C., I/M/ or perineural use
Read Directions for Use carefully.
Keep out of the reach of children
Do not store above 25 C.
Discard any unused contents.
Solution only to be used if it is clear and ampoule undamaged.
Read directions for use carefully.
Inactive ingredient: Water for injections to 100% w/v
POM PL Number: 4508/46008 T PL Holder
Manufacturer address, Apple Street, Bridge town, Copper city, DE1 F23

Extended Logo

Recommendations

- Display concentration in total quantity/total volume, even if other units of concentration such as percentage and ratios (for example '1 in 1,000') are also present.
- When using numbers of 1,000 and above, use commas to help prevent misreading.
- Do not superimpose information on other information.



1.6 Administration route

Issue

- Routes which should not be used are stated rather than routes that should.

NOT FOR I.M. OR BOLUS USE

Proprietary Name i.v.

500mg Sterile powder

Generic name
FOR INTRAVENOUS USE.

Each vial contains: 500mg Generic Name,
Lactobionic Acid, Sodium Hydroxide, Ph
Eur, Nitrogen

DO NOT USE DILUENTS CONTAINING
PRESERVATIVES OR INORGANIC SALTS

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

Recommendations

- Make positive statements – use 'do's', rather than 'do not's'.
- Use specific directions and avoid using technical terms that are not well understood, e.g. 'For Parenteral Use' meaning 'For Injection or Infusion'.

Proprietary Name Generic name 500mg Sterile powder
For intravenous infusion Dilute before use Each vial contains: 500mg generic name, lactobionic acid, sodium hydroxide, ph eur, Nitrogen Only use preservative-free and inorganic salt-free diluents. PI number: 458/4600 Manufacturer address, Apple Street, Bridge Town, Copper City, DE1 F23

1.7 Warnings

Issue

- Warnings about unusually high doses or potential allergies, for example, are often not highlighted and become lost in dense blocks of text.

<i>Proprietary Name</i>
<i>4.5g</i>
Generic name Contains penicillin Each 50ml contains: Generic Name 4g and Generic Name 500mg . For injection or infusion as sodium salts. Read directions for use carefully. Keep out of 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 PL Holder Manufacturer address, Apple Street, Bridge town, Copper city, DE1 F23

Recommendation

- Separate warning notices from the main body of text, and highlight the warning.

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.

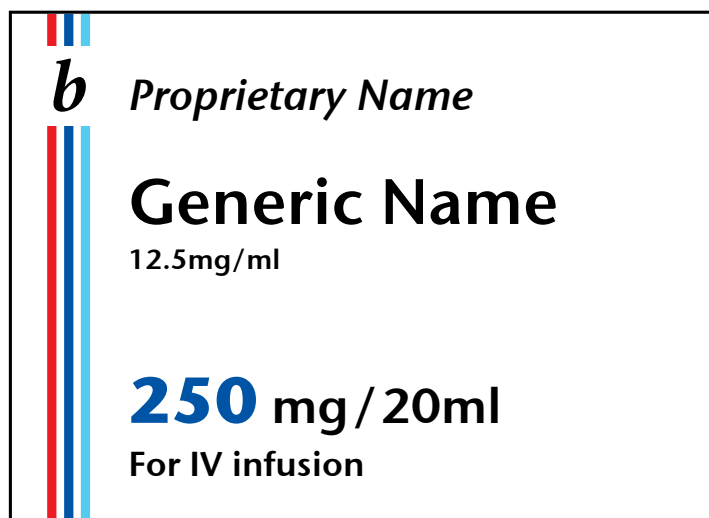
Store out of the sight & reach of children. Store below 25C. Store in the original container. Reconstituted solutions, prepared in sterile conditions may be stored for 24 hours in a refrigerator (2C to 8C).

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

1.8 Medicines for dilution

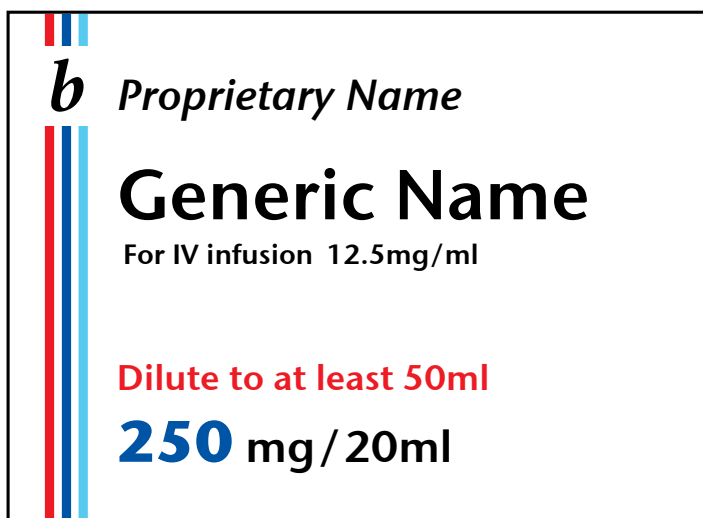
Issue

- Medicines which must be diluted are often not indicated, which may lead to fatal doses being administered.



Recommendation


- Highlight the fact that the medicine requires dilution, and state a minimum dilution volume where appropriate.



1.9 Storage conditions

Issue

- Storage conditions are often not highlighted and may be lost in dense blocks of text. If storage conditions are not followed, medicines may become unusable.

<p>Generic Name 100 Units/ml Solution for injection</p> <p>1 ml contains 100 Units (3.5mg) generic drug. Excipients: generic name, generic name, glycerol, sodium hydroxide, hydrochloric acid, water for injections. Intravenous or Subcutaneous use Keep out of the sight and reach of children. Only use clear and colourless solutions. Read enclosed leaflet before use. Store at 2 C - 8 C (in a refrigerator). Do not freeze. Keep the container in the outer carton in order to protect from light. Do not store above 25 C and protect from direct heat and light.</p> <p>Manufacturer Name Address line 1, line 2, line 3, Postcode</p>	 <p>POM United Kingdom</p>
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Recommendation

- Highlight storage conditions, particularly if the drug requires refrigeration.
- Use positive statements to give directions.

Generic Name

100 Units/ml

For Intravenous or Subcutaneous injection

1ml contains 100 Units (3.5mg) generic drug.

Excipients: generic name, generic name, glycerol, sodium hydroxide, hydrochloric acid, water for injections.

Store in a refrigerator 2 C - 8 C

Keep out of the sight and reach of children.

Only use clear and colourless solutions. Read enclosed leaflet before use.

Keep the container in the outer carton in order to protect from light.

Once in use store below 25 C and protect from direct heat and light.

POM

Manufacturer Name

Address line 1, line 2, line 3, Postcode



1.10 Injectable medicines intended for use by patients (for example, insulin)

Issue

- Some injectable medicines, for example insulin and adrenaline products, are intended for use by patients. These medicines have to be labelled with a dispensing label before they are issued to patients. Dispensing labels may obscure important information such as batch number and expiry date

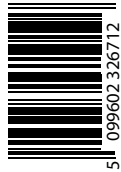
1ml contains 100IU insulin human, with excipients of zinc chloride, m-cresol, sodium dihydrogen, glycerol, sodium hydroxide, water for injections.
For subcutaneous use.

5 099602 326712	GENERIC NAME 100 Units/ml	KEEP OUT OF THE REACH OF CHILDREN	POM
	3ML CARTRIDGES		
	Use 3 times a day as directed		Ireland
	Patient name	ANY PHARMACY	United Kingdom

Manufacturer name
Address line 1
Address line 2
Address line 3

Recommendations

- For injectable medicines that are intended for use by patients, leave a clearly designated blank space that is a minimum size of 70 x 35mm.
- Position the drug name and strength next to this space.
- For injectable medicines that come in a multidose format, such as insulin, it is recommended that the drug strength be represented as quantity/unit volume. This will also help prevent confusion for the patient.
- Braille will need to be present on the packs. Ensure that the use of Braille does not detract from the other design features.

Generic name 100 Units/ml	
GENERIC NAME 100 Units/ml 3ML CARTRIDGES Use 3 times a day as directed Patient name	KEEP OUT OF THE REACH OF CHILDREN ANY PHARMACY
	
1ml contains 100IU insulin human, with excipients of zinc chloride, m-cresol, sodium dihydrogen, glycerol, sodium hydroxide, water for injections. For subcutaneous use.	
Manufacturer name Address line 1 Address line 2 Address line 3	

1.11 Expiry dates

Issues

- Expiry dates may be printed in the middle of bulk text, making it hard to locate.
- Embossed expiry dates can be hard to read, especially in poor lighting conditions.
- The date format and explanatory text can vary and lead to confusion over the exact day of expiry, for example, 'exp', 'use by date', 'use before date'. These may lead to expired medicines being used.

Note

'Exp': means for use up to and until the last day of the specified month.

'Use by': means for use up to and until the last day of the specified month.

'Use before': means for use until the first day of the specified month.



batch: 645981

exp: Mar 08

Recommendations

- Print data in a clearly identifiable location, at the end of bulk text.
- Ink print data where possible. However, manufacturers need to give consideration to medicines which are commonly used in aseptic environments, which will require the embossing of data as well.
- Where possible, display a specific expiry date. Where this is not possible, the explanatory text should say 'use before' for clarity.

Batch: **645981**

Exp: **31/3/09**

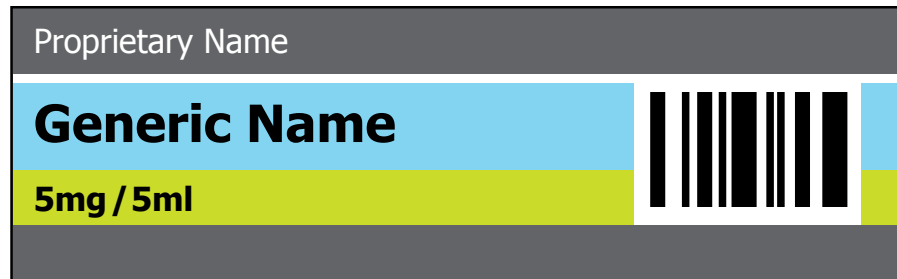
Batch: **645981**

Use before: **Apr 09**

1.12 Barcodes

Issues

- Industry uses 'Pharma' codes (simple linear bar codes) to achieve the necessary level of Good Manufacturing Practice control during manufacturing. The code identifies a version of a printed packaging component.
- Users cannot read or use these codes when the medicines are being dispensed and administered.



Recommendations

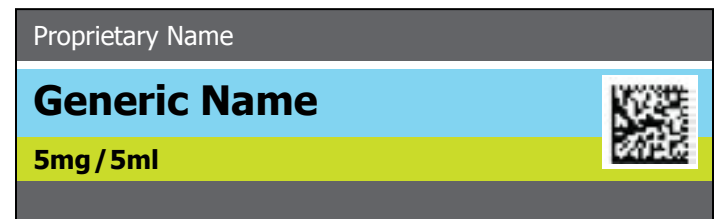
- Hide the manufacturer's barcode on end flaps and ensure that a barcode that can be used in clinical practice is present on the exterior of the pack.

Discussion

As we move towards using auto-id technology, linear bar codes containing the Global Trading Index Numbers (GTIN) will be required on all medicine products within the NHS, with the eventual goal of using GS1 codes.¹²

GTINs and 2D data matrix codes both contain the product name, batch number, expiry and possibly a unique pack identifier. This information can be used by both the manufacturers and the end users.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has recommended the use of 2D data matrix codes, and the Council of Europe report recommends these be implemented on unit packaging, such as ampoules and vials.⁷

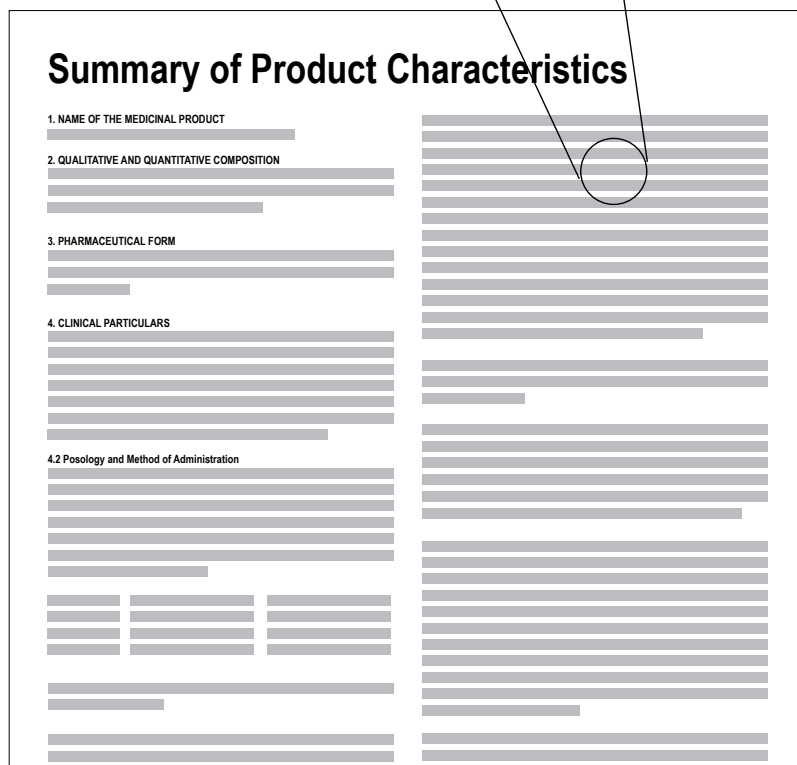
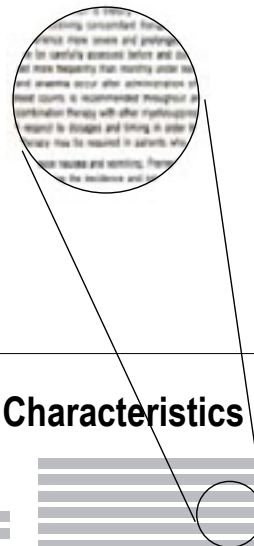


1.13 Technical information

Issues

- EU Medicines legislation only requires a patient information leaflet to be included in a medicine pack. There is no requirement for a Summary of Product Characteristics (SmPC) to be included in the medicine pack.
- Where SmPCs are included in the medicine pack, the technical information to inform the user how to prepare and administer the medicine may be difficult to find and difficult to read.

Actual font size



Recommendations

- All injectable medicines products should contain information about how to prepare and administer doses. This can be provided by including either easy-to-use SmPCs or ‘extra-regulatory information’ in the medicine pack.
- Emphasis should be given to the information that is required by the healthcare practitioner to prepare and administer the medicine safely. Print this in a clear font of at least 10 point size.

Discussion

The provision of extra information should be considered by NHS procurement groups as part of the product specification for the contracting process.

The NPSA has identified the necessary information required for the safe use of injectable medicines.³ This is considered to be the following information (where relevant):

- Concentration of the final solution
- Dilution/flush solution
- Administration rate
- Example calculations
- Stability in solution – expiry times
- Incompatibilities with commonly used mixtures
- Special handling information
- Specialist technical information (e.g. displacement values)

Generic Name 2mg/10ml

Extra Regulatory Information

	IV Bolus	IV Infusion
Concentration of the final solution	x mg/ml	y mg/ml
Dilution / flush solution		100 ml of Sodium Chloride 0.9%
Administration rate	Over 3 to 5 mins	Over 60 mins
Example calculations		70kg adult: Example calculation for a 70kg adult 10kg child: Example calculation for a 10kg child
Stability in solution		24 hours
Incompatibilities with commonly used mixtures	Daunorubicin, doxorubicin, phenothiazines, vancomycin	
Special handling information	Administer by infusion if there is underlying cardiac pathology. Flush: Sodium Chloride 0.9% Sodium content: 0.021 mmol/ml	
Specialist technical information (where relevant)	Tachycardia and hypotension; monitor blood pressure continuously during infusions. Fluid overload likely, restrict fluid intake and check body weight regularly.	

Ampoules

2.1 Text orientation

Issues

- When the medicine name is printed horizontally around the vial or ampoule, similar names can be more easily confused with one another.
- This is particularly important for the smaller ampoules of 1, 2 and 5ml.



Recommendations

- Print the medicine name longitudinally, along the length of the ampoule.
- A good rule of thumb is: if the visible width of the label is less than the height of the label then the name should be printed longitudinally.
- The information that must be present on containers 10ml or smaller is:
 - Medicine name
 - Expression of strength (where relevant)
 - Route of administration
 - Posology (for self medication)
 - Warnings
 - Expiry date
 - Batch number
 - PL number
 - MA holder's name



2.2a Labelling methods

Issues

- Ampoules can be hard to identify when labelled with ceramic printing or clear plastic labels.
- The text may show through from the reverse side making the details difficult to read. This is particularly problematic if the text is oriented horizontally around the ampoule.



Ceramic label/
clear plastic label



Paper label

Recommendations

- Use paper labelling where possible, but ensure an area is left free to allow for inspection of contents.
- If ceramic or clear plastic labelling must be used, highlight key information by inverting the text colour.
- Keep the information to a minimum and reduce overlapping with text from the reverse as much as possible.
- Labels should not come off in use and should be printed with ink that does not run when sprayed with alcohol to disinfect the ampoule surface in the pharmacy or during clinical procedures.



Ceramic label/
clear plastic label

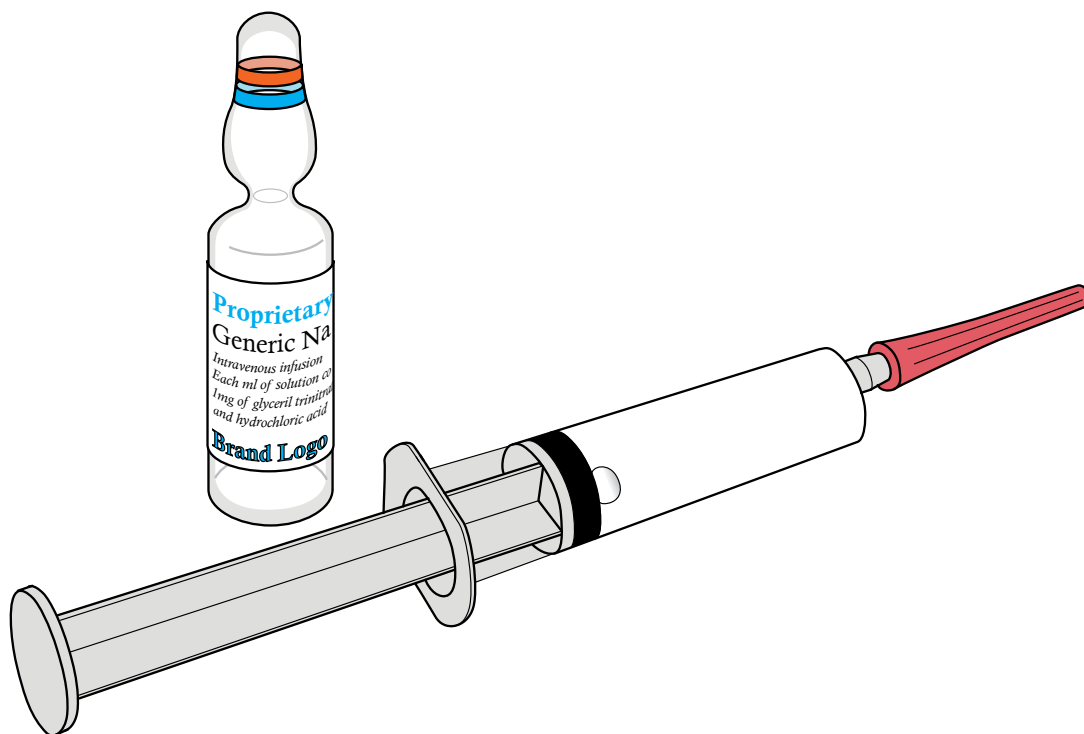


Paper label

2.2b Labelling methods

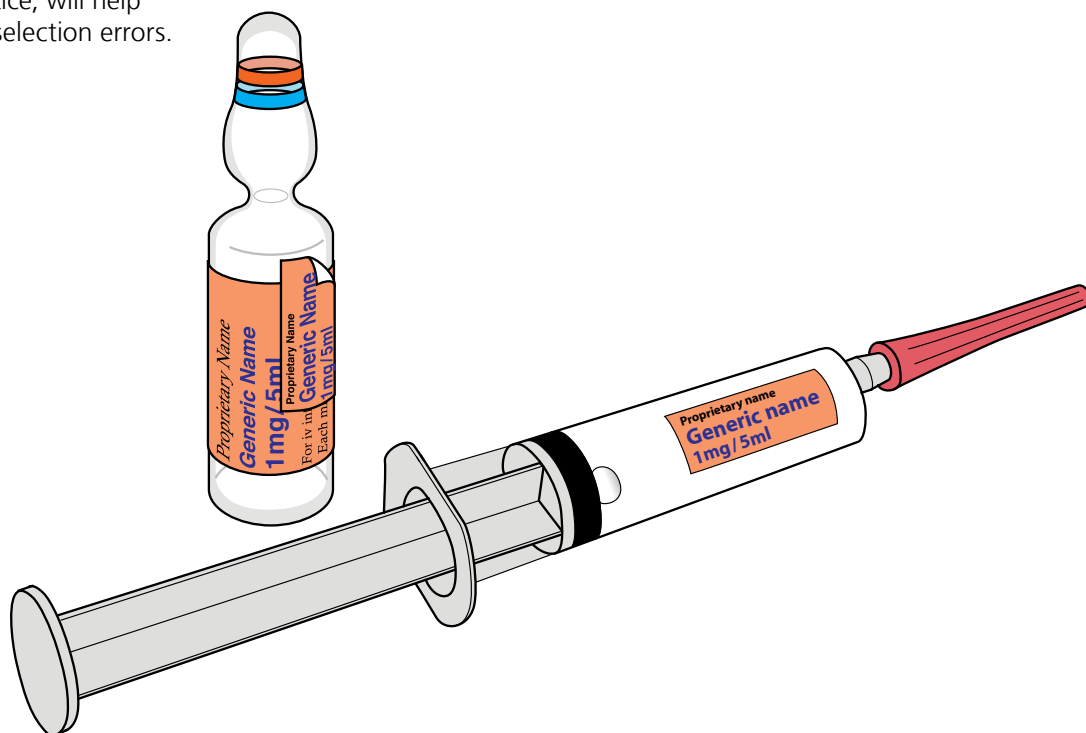
Issue

- One or more syringes may remain unlabelled when filled with medicine in practice, especially if there are no labels present in the area where the medicine is prepared.



Recommendation

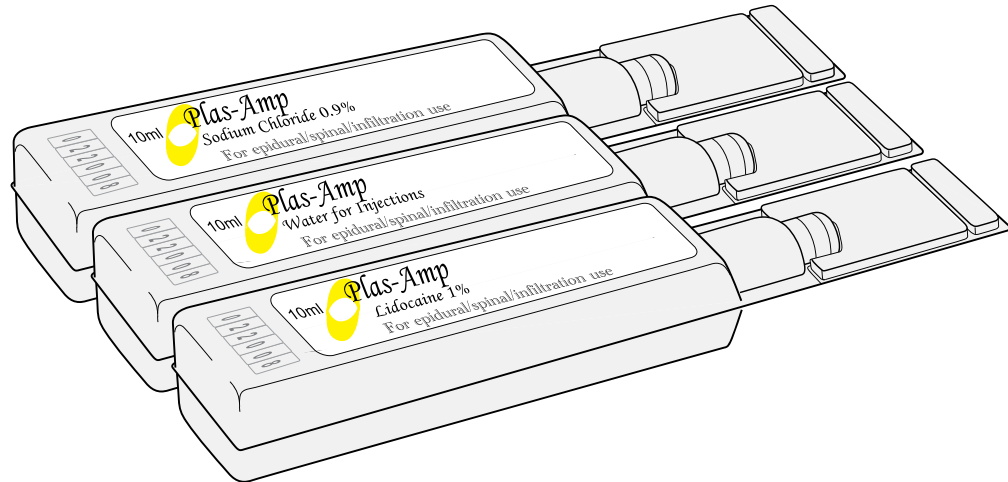
- The NPSA has recommended that all syringes containing medicines are labelled if they leave the operator's hands.³ The addition of a peel-off label on ampoules or vials, which can be transferred to a syringe in practice, will help practitioners avoid selection errors.



2.3 Plastic ampoules

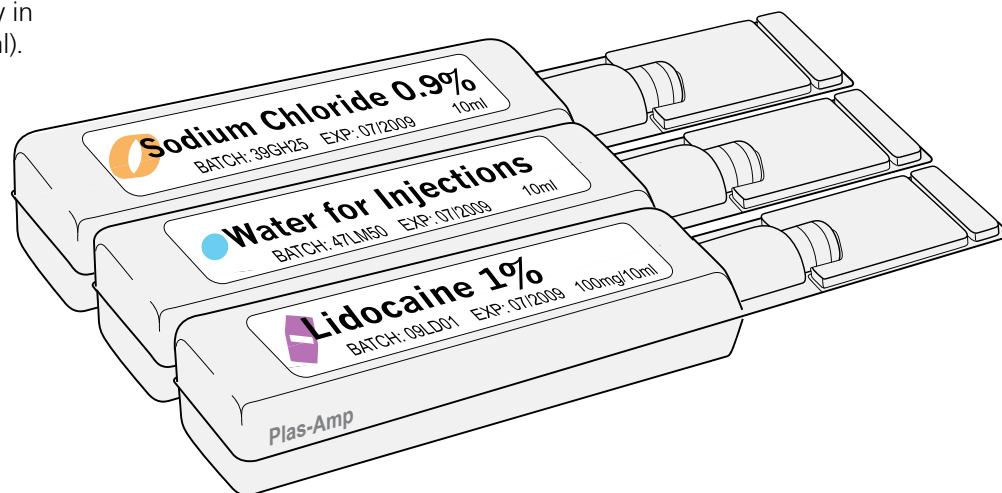
Issues

- Plastic ampoules may look very similar, with minimal differentiation between the labels.
- Confusion may occur because of the undue emphasis on the name of the container type.
- Expiry dates and batch numbers may be embossed, which are hard to read.



Recommendations

- Use a large, clear font.
- Use colour to help to differentiate between products.
- Eliminate or reduce emphasis on the name of the container type/ brand such as 'Plas-Amp'.
- Expiry dates and batch numbers should be easy-to-read and printed on the main body of the container, not on rip-off tabs.
- Where concentrations are shown, they should be expressed as total quantity in total volume (e.g. mg/10ml).



2.4 Secondary packaging

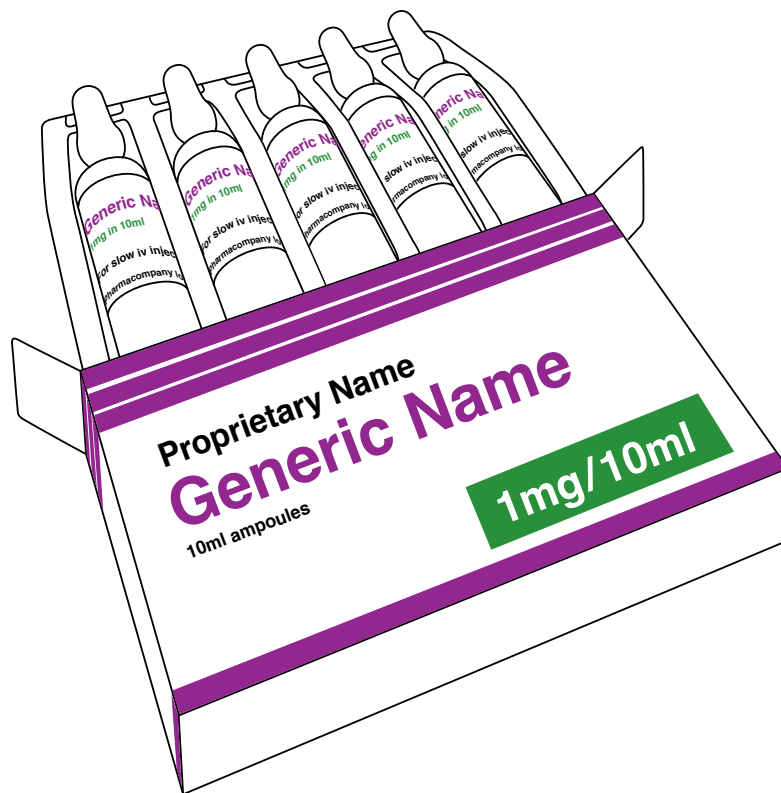
Issues

- Ampoules can be hard to remove from their packaging, especially when gloves are worn.
- This is particularly true for those ampoules that are individually packaged in perforated trays, with hard to use peel-off seals.



Recommendations

- Use open, unsealed trays where possible.
- If sealed trays must be used, ensure that they can be opened very easily.

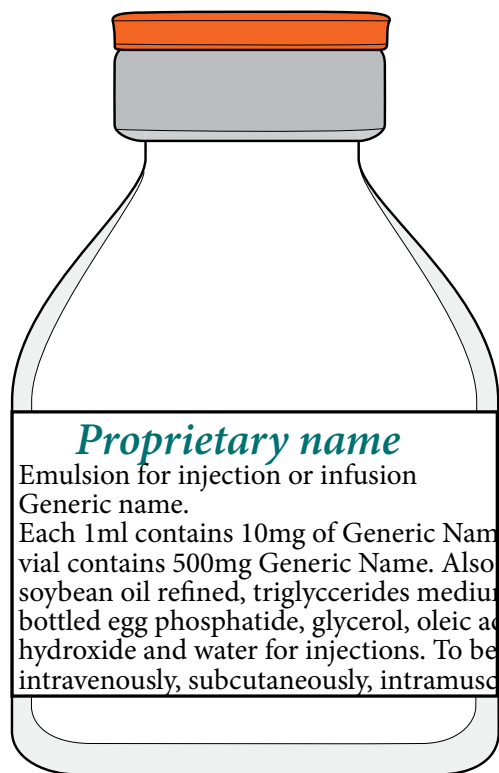


Vials

3.1 Key information panel

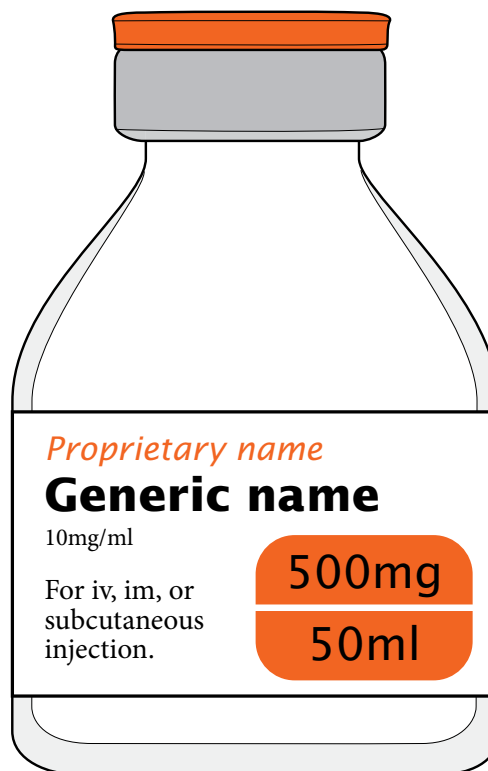
Issues

- Key information can be hard to find in dense text.
- On smaller vials, it may be hard to read generic names in one glance.



Recommendations

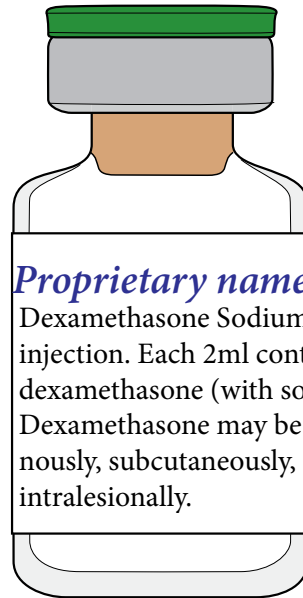
- Create an area which highlights the key information. This area should not be wider than the width of the bottle.
- Use appropriate font size and formatting to enable the generic drug name to be read in one glance.



3.2 Text orientation

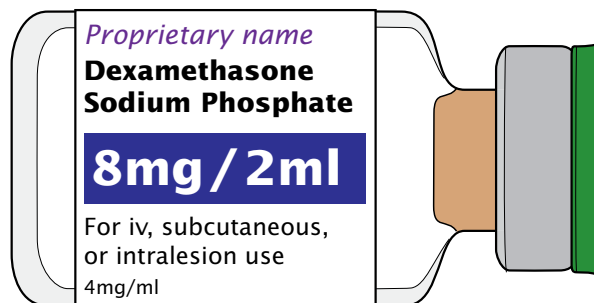
Issue

- When the generic name is printed horizontally around the vial, half the drug name may be hidden round the other side, leading to medicines with similar names being easily confused.



Recommendation

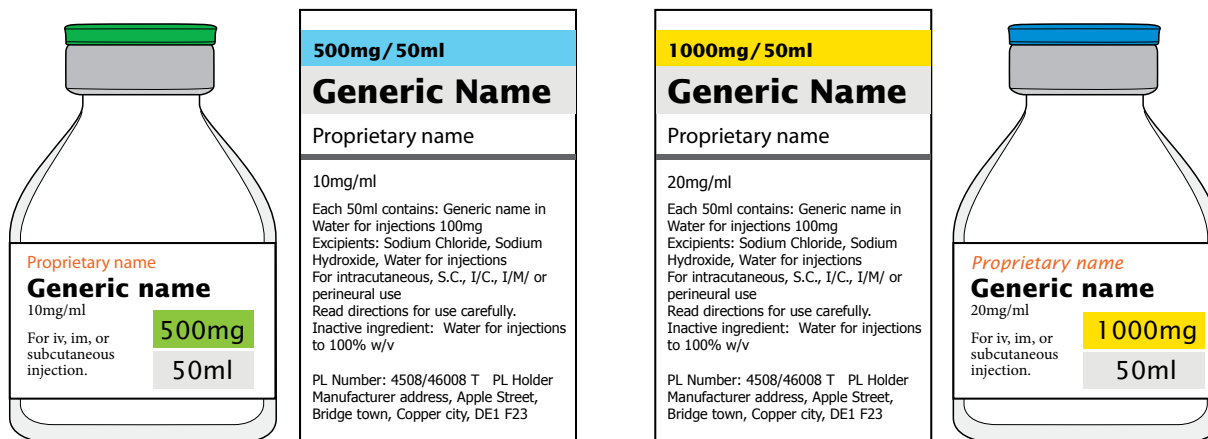
- Use the same rule of thumb as in recommendation 2.1: if the width of the vial is less than the height of the label, then orientate the text longitudinally.



3.3 Colour schemes

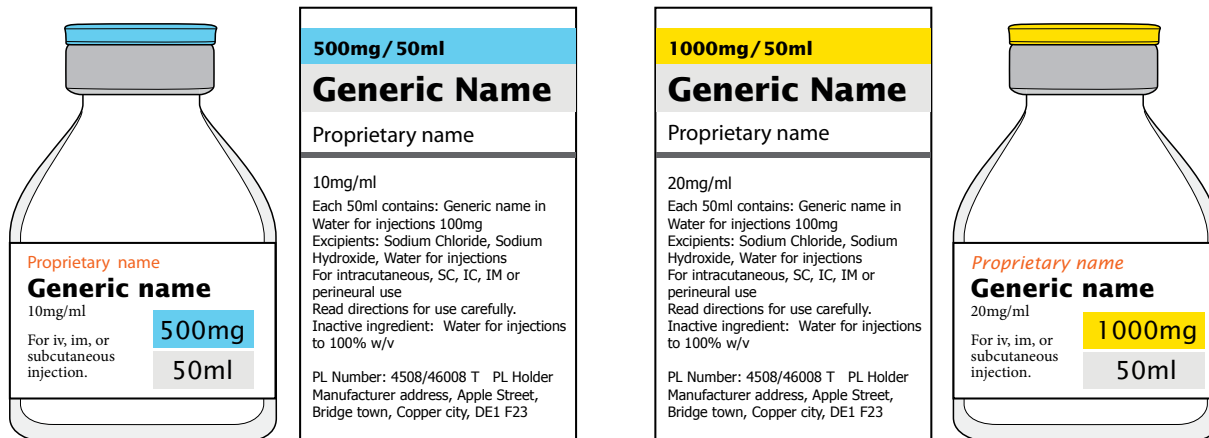
Issues

- Colour schemes applied inconsistently across product ranges from the same supplier may cause confusion.
- Colours used on vial labels can differ from carton labels.



Recommendations

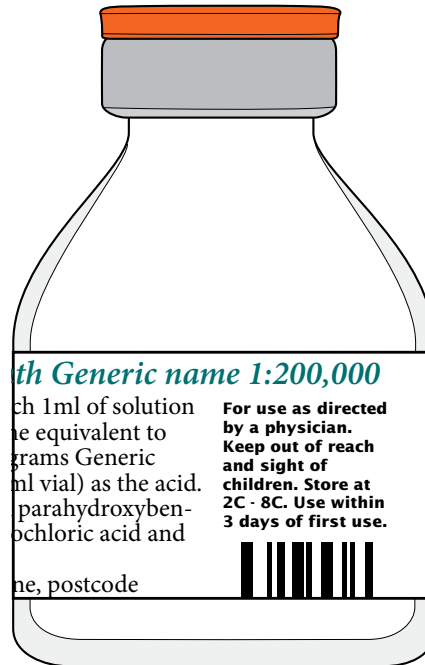
- Match the design of the vial label to that of the carton.
- Where the flip cap is coloured, it should use the predominant differentiating colour that has been used on the label and carton.



3.4 Multi-dose vials

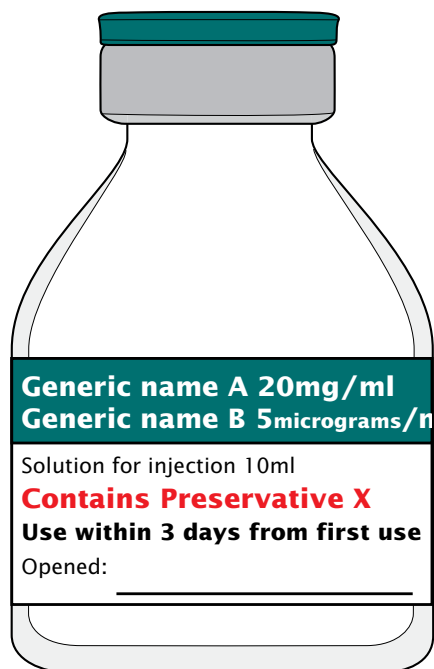
Issue

- Vials intended for multi-dose are not always well labelled, and instructions on shelf-life and use of preservatives are not easily found. This may lead to out-of-date drugs being used, as well as preservatives being administered to those with allergies.



Recommendations

- Highlight shelf-life of product once opened. Leave a space next to it for staff to write the date it was opened.
- Emphasise which preservatives the drug contains.
- For multi-dose vials, drug strength should be represented as quantity per unit volume.

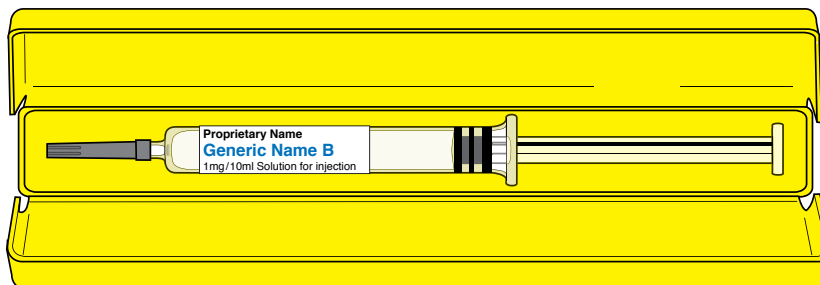
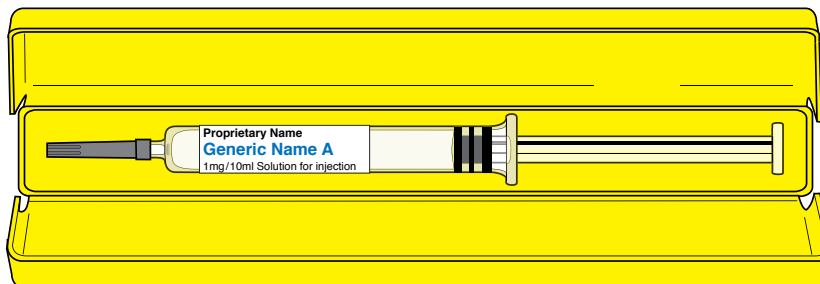
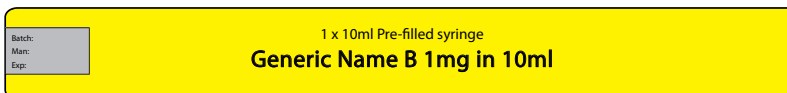
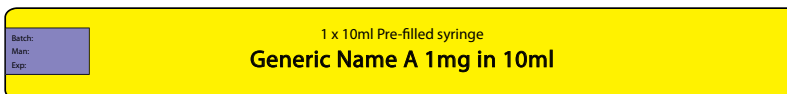


Pre-filled syringes

4.1 Use of colour

Issues

- Pre-filled syringes that may be required during a medical emergency can be easily confused, especially when there is minimal differentiation on the outer packaging.
- Medicines that come in a wide range of concentrations and doses can also be mistaken for each other.
- Outer packaging may be easily re-sealed, after the pre-filled syringe has been removed, leading to a delay in treatment if the empty pack is placed back into stock.

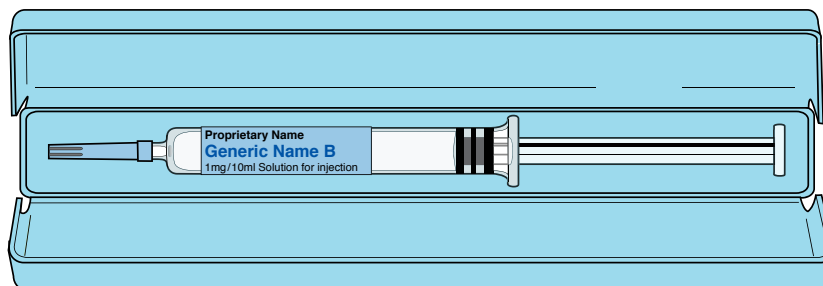
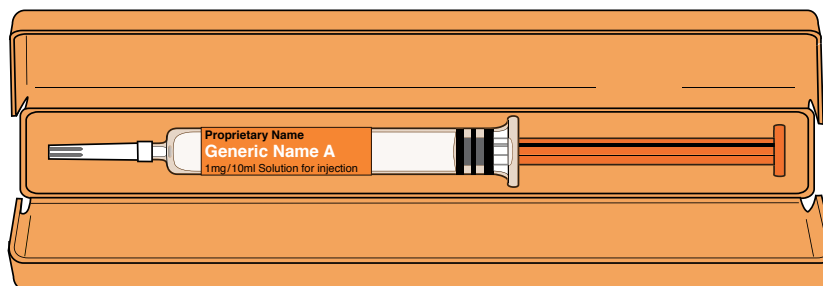
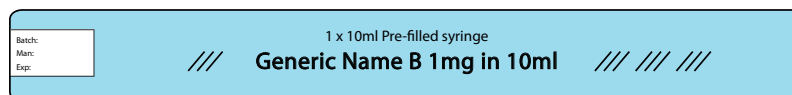


Recommendations

- Vary the design of the secondary packaging, to enable easy identification
- Consider the use of different coloured components, for example, plungers or caps, to emphasise differences.
- Outer packaging once open should not be easily re-sealable and should clearly indicate that the pre-filled syringe has been removed.

NOTE

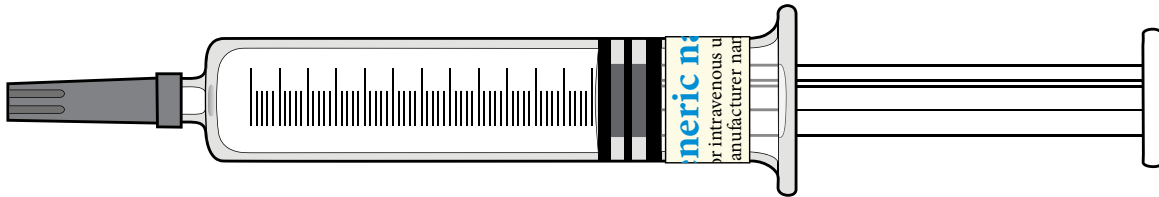
When considering colours, please note that the convention is for purple to denote oral syringes and yellow to denote epidural syringes.



4.2 Text orientation

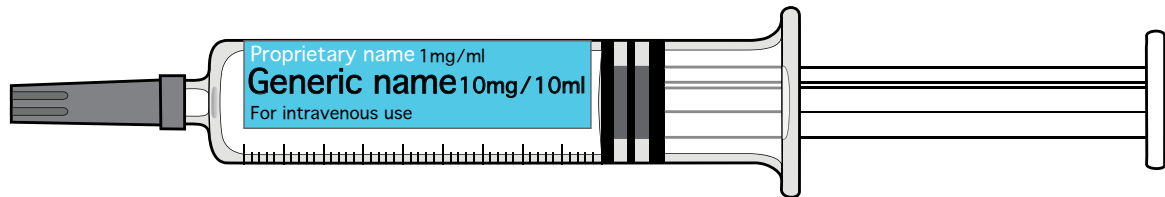
Issue

- When text is orientated around the syringe it necessitates a small font size which can be difficult to read.



Recommendations

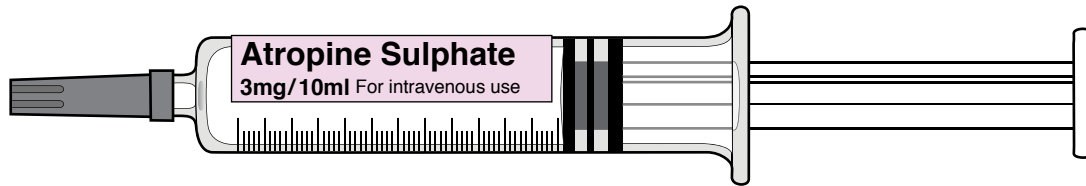
- Orientate text along the length of the syringe.
- Ensure that an area of clear space is left to allow for inspection of contents.
- Invert text colour or use a backing colour to prevent text showing through.
- Volume markings should always be visible and not covered by labels.



4.3 Use of colour and design on syringe labels

Issue

- Some label designs for commercially produced pre-filled syringes may conflict with the critical care syringe label guidelines and cause confusion.

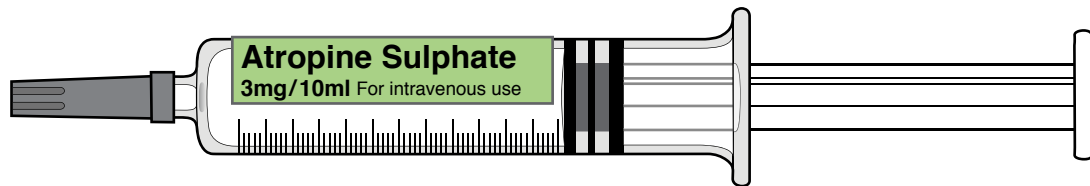


Ephedrine
.....mg/ml

Atropine
.....mg/ml

Recommendations

- Where commercially produced pre-filled syringes are used in resuscitation and critical care areas, consideration should be given to the critical care syringe label guidelines⁸ (see discussion on page 9).
- There should still be a judicious use of colour, in accordance with MHRA guidelines.⁵

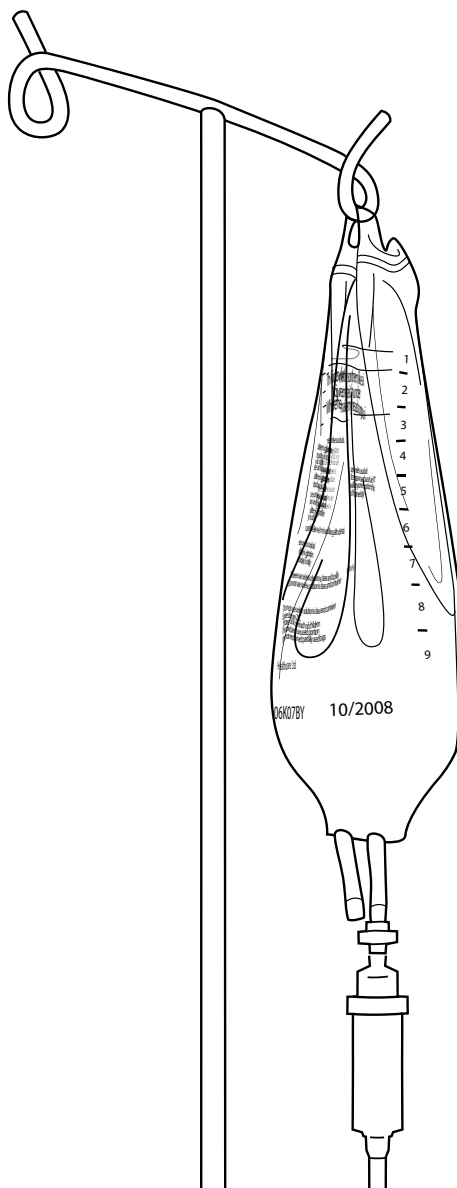


Infusion bags

5.1 Text positioning

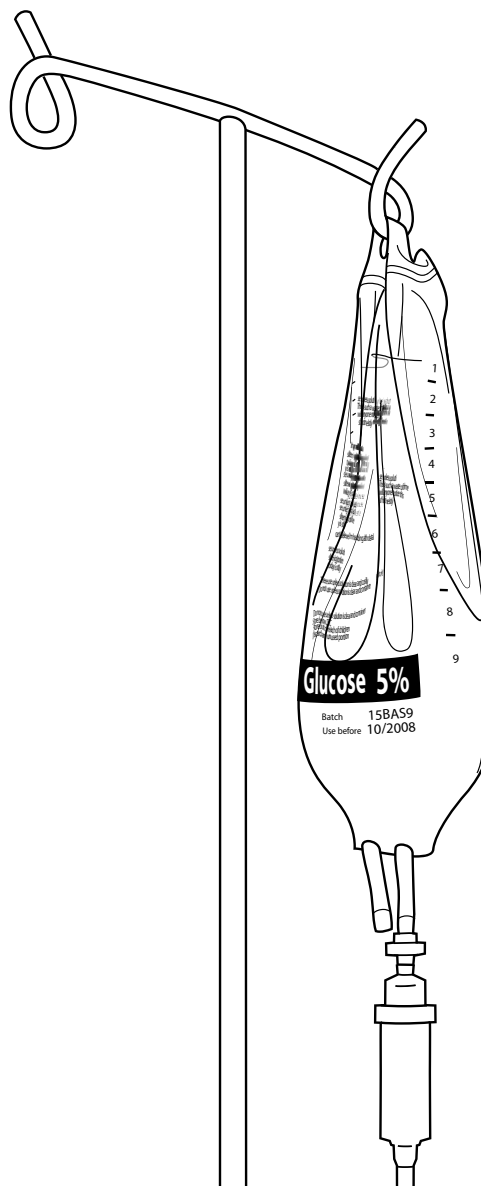
Issues

- Key information regarding the fluid is positioned at the top of the infusion bags. During the administration of the infusion, the bag will collapse in from the top down, making the key information illegible very quickly.
- The spacing of the batch number and expiry date mean that overlables cannot cover both numbers.
- Key information is lost in dense blocks of text.



Recommendations

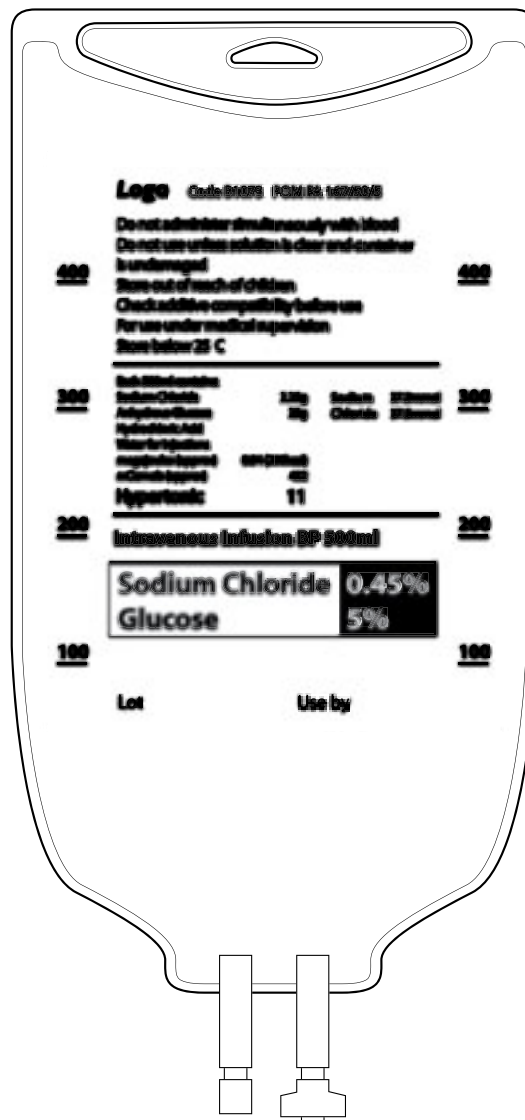
- Reconsider appropriate areas for the placement of key information. Options may be towards the bottom or down the side of the bag.
- Position the batch number and expiry date close together.
- Invert the key information text to draw the eye to it.



5.2 Font

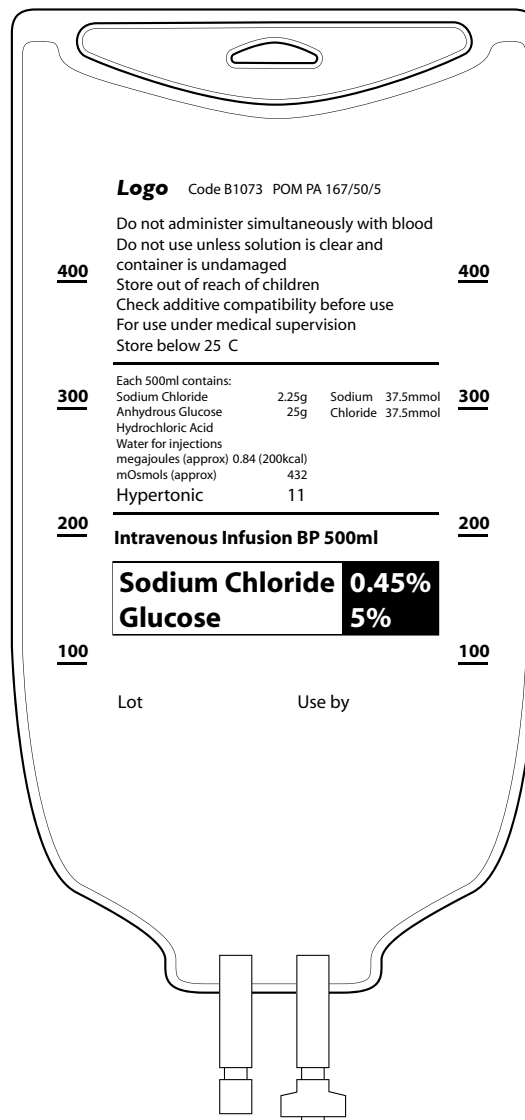
Issue

- Due to the printing methods employed, the ink tends to bleed. This can make text hard to read.



Recommendation

- Choice of font should be carefully considered to ensure adequate spacing between letters and that it remains legible even if the ink bleeds.



5.3 Bag volume

Issues

- For fluids that come in a number of different volumes, insufficient emphasis is given to differentiating between them.
- Emphasising the volume is especially important for fixed size containers that are only partially filled.



Recommendations

- Give emphasis to the volume of the infusion, and position it next to the infusion name.
- Vary other elements of the design to increase differentiation between labels.
- When listing ingredients on infusion bags, the strength should be represented as quantity per container.



5.4 Use of colour

Issues

- Colour is used to highlight important items of information, but is often used in a way that achieves minimal impact.
- The strength of the medicine may be represented in mmol/litre even for infusion volumes of less than 1 Litre.



Recommendations

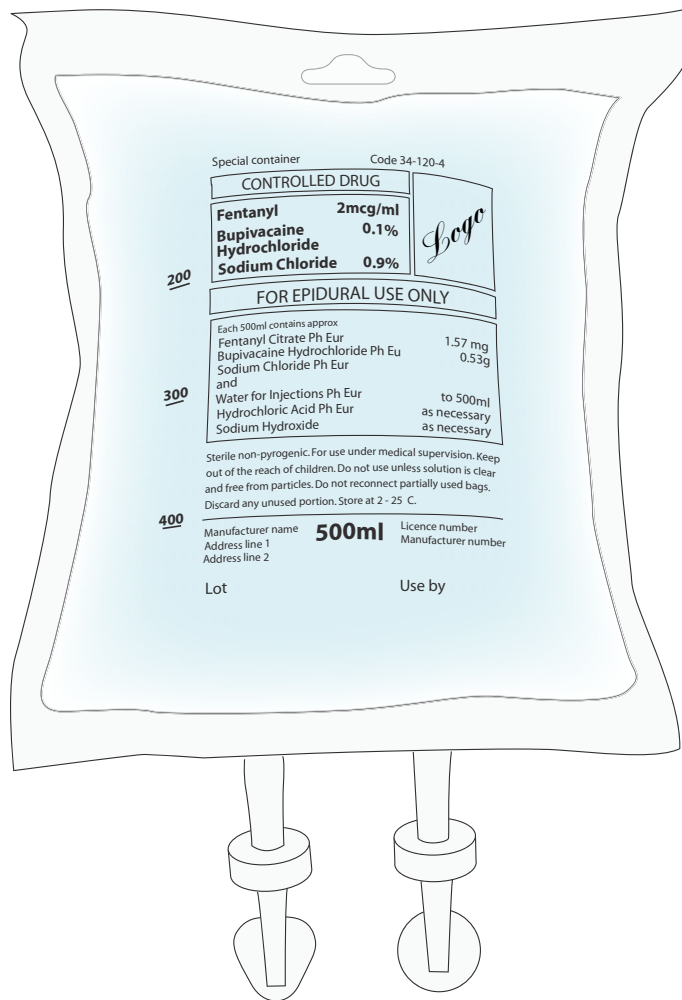
- Consider the judicious use of colour for identified high-risk infusions.
- Use bold blocks of colour that stand out and draw the eye.
- Only use 'approved' or non-toxic inks and adhesives.
- Where the strength of the medicine is expressed in mmol, it should be represented as mmol/ container volume.



5.5 Route of administration

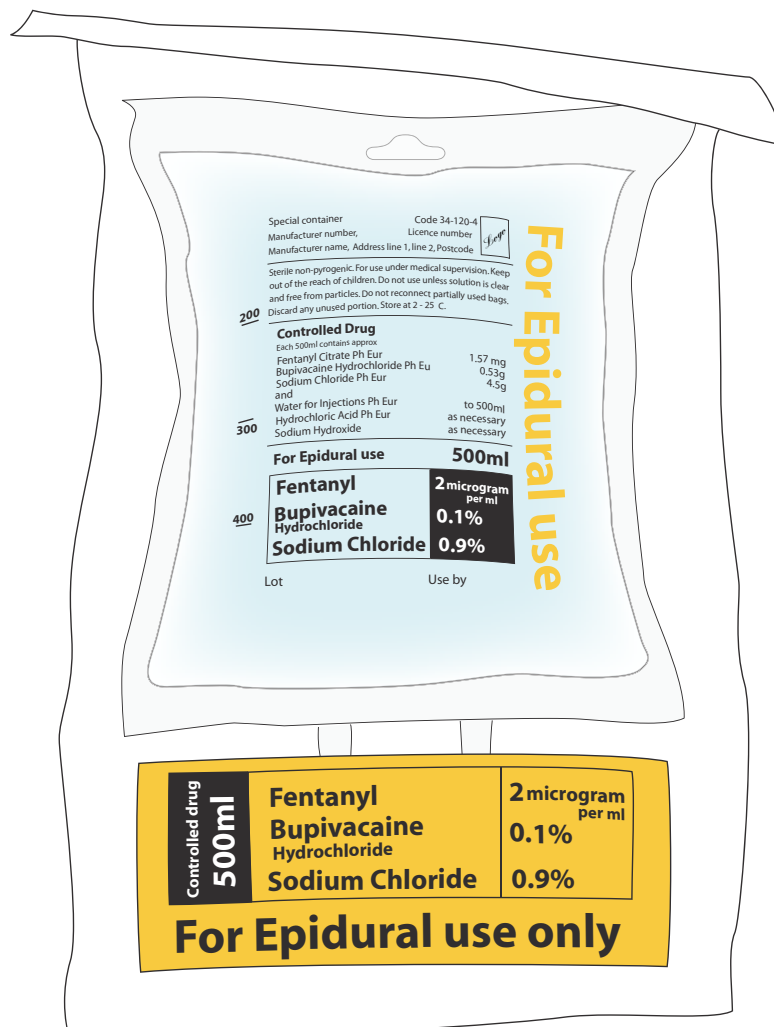
Issue

- If the route of administration is not highlighted, it may be assumed that the infusion should be administered intravenously.



Recommendations

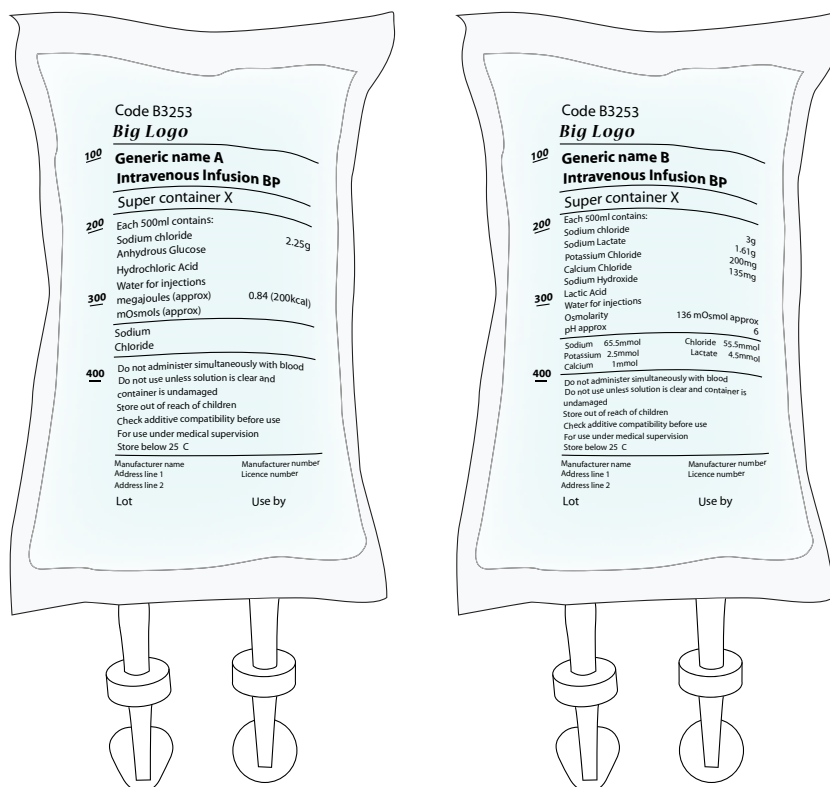
- Highlight the route of administration, particularly if it is different to the norm.
- Epidurals are normally associated with the colour yellow. Consider incorporating this colour into the packaging.
- If printing colour directly onto the infusion bag does not have sufficient impact, consider the use of coloured labels or overwraps.



5.6 Product differentiation

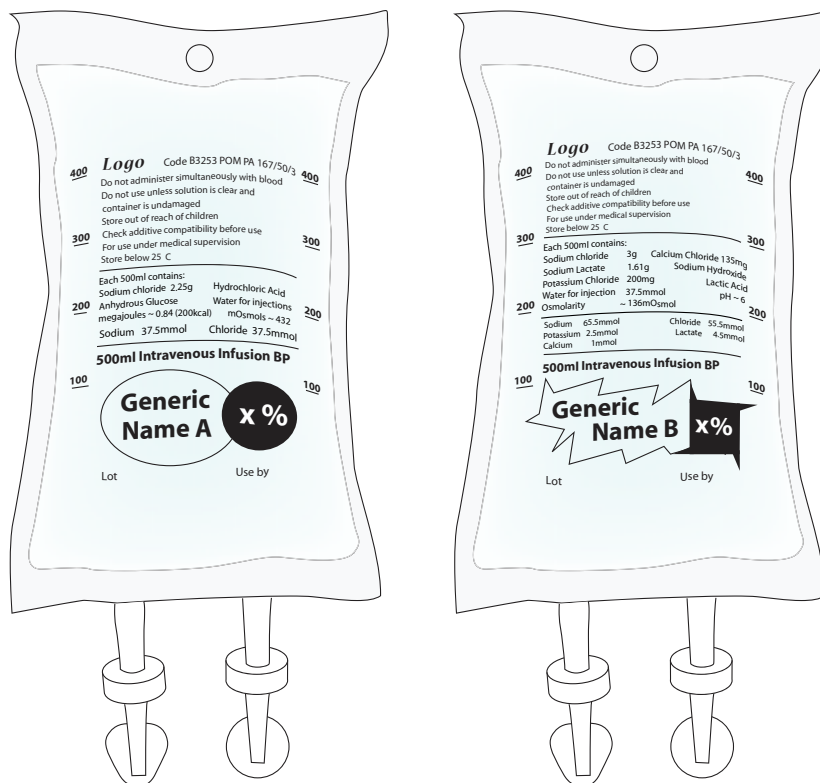
Issue

- Infusion bags can look identical due to the lack of design differentiation between them.



Recommendation

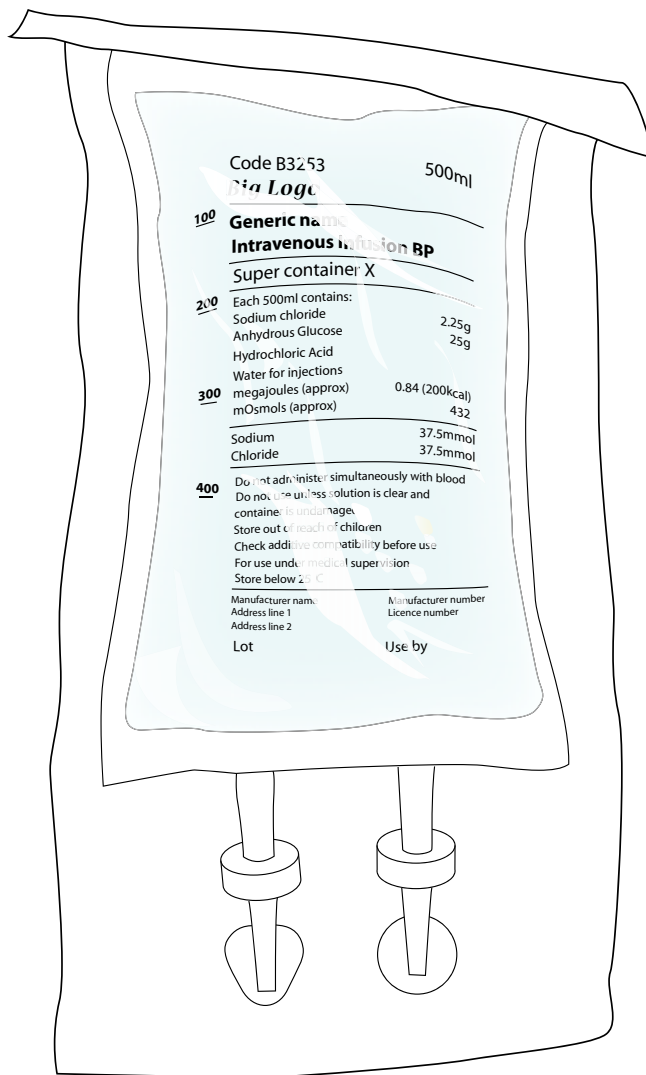
- Ensure there is an additional differentiator as well as the text. For example through the use of colour or, if this is not possible, vary the graphic components.



5.7 Surface finish

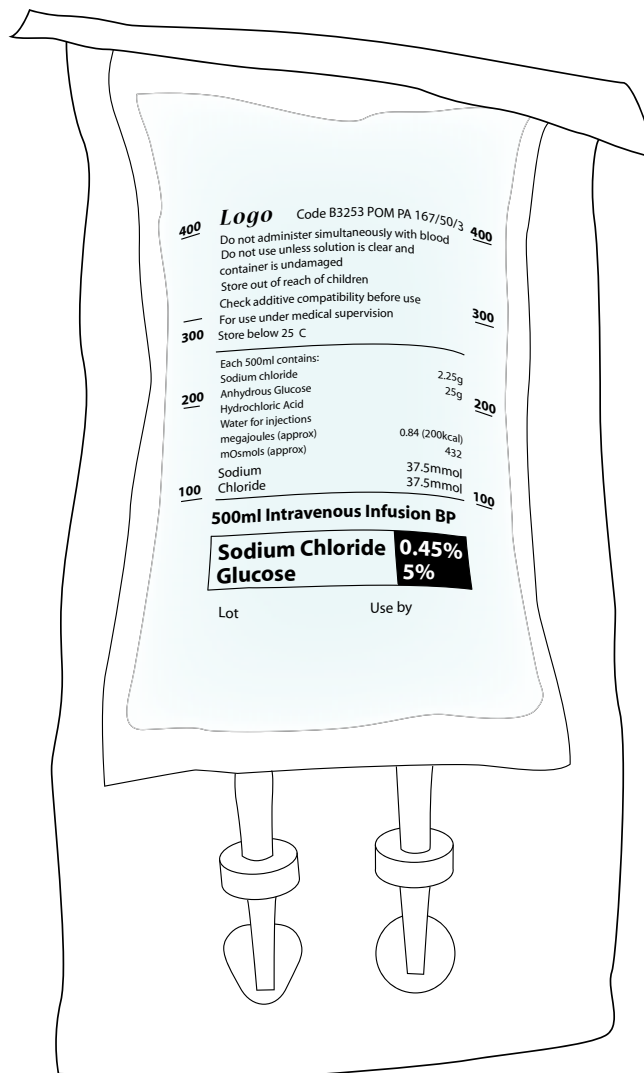
Issue

- Materials used for the fluid bags and overwraps are reflective, and the combination of the two materials can lead to impaired visibility of key information.



Recommendation

- Use matt materials where possible to improve legibility.



5.8 Outer packaging

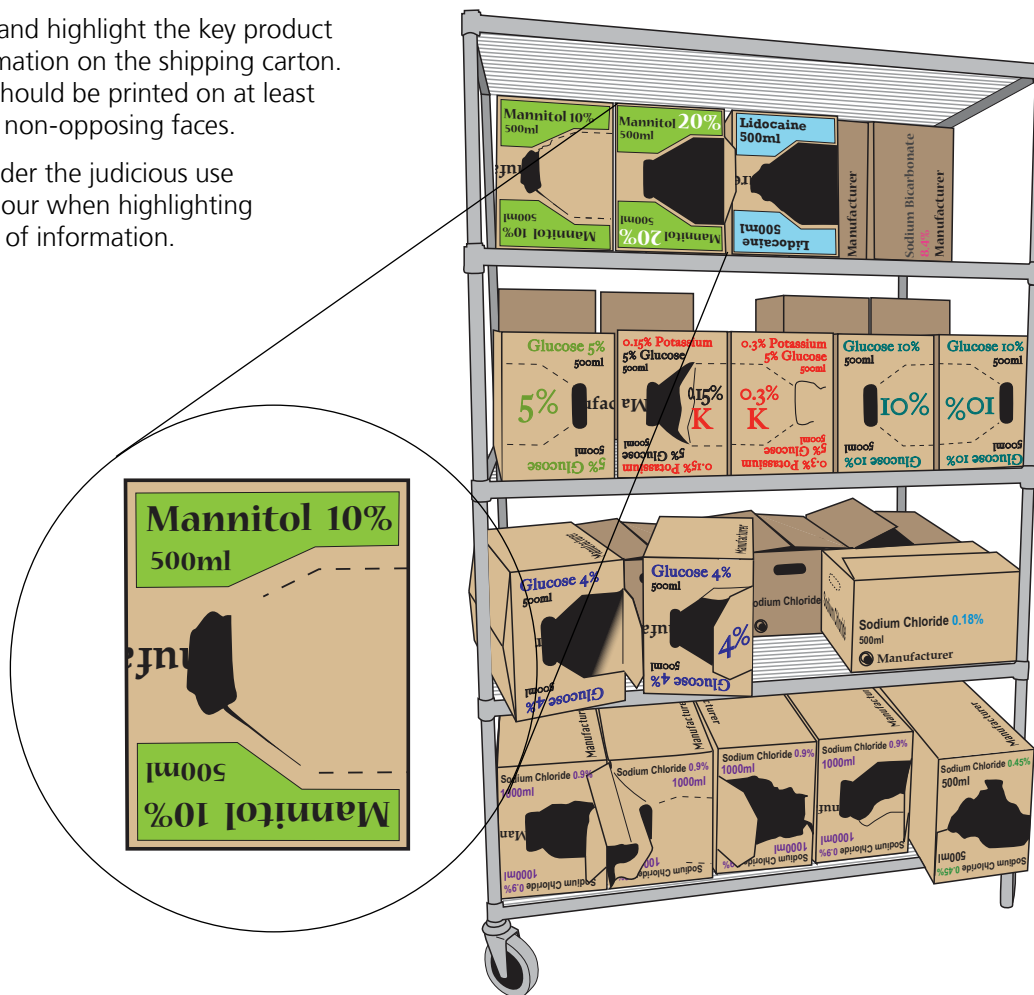
Issue

- Infusion bags are often stored in their tertiary packaging in clinical areas. Poor labelling of this packaging is a recognised reason for mis-identification and picking errors by practitioners.



Recommendations

- Print and highlight the key product information on the shipping carton. This should be printed on at least three non-opposing faces.
- Consider the judicious use of colour when highlighting items of information.



Purchasing for safety

In the Department of Health report, *Building a safer NHS for patients* (2001),¹³ it was recommended to build safety into purchasing policy within the NHS; and to seek input from the world of design to identify new opportunities for improving safety.

In the NPSA *Patient safety alert 20: Promoting safer use of injectable medicines* (2007),³ it was recommended that healthcare organisations should implement a purchasing for safety policy to promote procurement of injectable medicines with inherent safety features.

Purchasing for safety was further defined as procuring presentations and formulations of medicines approved for use in local medicine formularies. In this process, medicine products are reviewed by purchasing and pharmacy groups, and products that are designed in such a way as to promote safer practice are selected. This process does not involve therapeutic substitution.

The NPSA recommends that policies advocate the purchase of injectable medicines that include technical information about how they should be prepared and administered, and are designed in such a way as to promote safer practice. It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied. The NPSA suggests that NHS organisations should work with the pharmaceutical industry to identify new products and formulations that could make practice safer.

NHS procurement groups have described how purchasing for safety methods have been used in practice as part of the medicines contract adjudication in secondary care at local, regional and national procurement processes.¹⁴ The NHS Pharmaceutical Quality Assurance Committee have developed a Medication Error Potential Assessment (MEPA) method.¹⁵

The development of the national Pharma QC database will facilitate the sharing of risk assessment ratings for medicine products across the UK. The roll-out of purchasing for safety methods into primary care is particularly important.

An All-Party Parliamentary Group for Patient Safety was established in 2005.¹⁶ Its first meeting focused on patient safety in the procurement process, including the evaluation of medical technologies, the inclusion of patient safety issues as pre-purchase criterion, the ability of users to make informed risk assessments when buying, and the need for readily-available safety evidence and data to inform procurement decisions.

Subsequent to these discussions, the NHS Purchasing and Supply Agency (PASA) agreed to undertake a research project with pilot sites within the NHS to test purchasing for safety benefits in the area of injectable medicines.¹⁷ The project has the following three overall objectives:

1. To demonstrate that strategic purchasing can reduce clinical risk associated with the administration of injectable medicines.
2. To learn lessons relating to the case of injectable medicines that will be of benefit to trusts and collaborative procurement hubs across the country.
3. To develop an approach that could serve as a model for addressing wider government policy issues through procurement.

The pilot objectives are closely aligned to the recommendations outlined in the NPSA patient safety alerts published in March 2007.¹⁸

The project is due for completion at the end of 2008.



References

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- 4 Department of Health and the Design Council. *Design for patient safety. A system-wide design led approach to tackling patient safety in the NHS.* (2003). Available at: www.edc.eng.cam.ac.uk/medical/downloads/report.pdf
- 5 Medicines and Healthcare products Regulatory Agency. Guidelines on the Labelling and Packaging of Medicines, Guidance Note 25. (2003). Available at: www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007558.pdf
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- 10 The Federal Drug and Food Administration Office of Generic Drugs requested manufacturers of 16 look-alike name pairs to voluntarily revise the appearance of their established names in order to minimise medication errors resulting from look-alike confusion. See: www.fda.gov/CDER/Drug/MedErrors/nameDiff.htm
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Further information

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