NHS
National Patient Safety Agency

Safe Medication Practice Report 2007
Council of Europe

Professor David Cousins
Head of Safe Medication Practice
National Patient Safety Agency
National Health Service
London

Patient Safety

Patient safety is the freedom from accidental injury in health care

Background To Report

- Medication errors are the most common single preventable cause of adverse events in Europe
- The Council of Europe Committee of Experts on Pharmaceutical Questions established the Expert Group on Safe Medication Practices in 2003.
- Group tasked to review medication safety and to prepare recommendations to specifically prevent adverse events caused by medication errors in European health care.
- Multidisciplinary healthcare professionals
- Representatives from European Countries

Objectives of Report

Provide information to:

- enhance awareness of medication errors across the European countries and recognition as an important system-based public health issue;
- provide guidance for reducing medication errors and preventable adverse drug events
- help European health authorities, governments and regulatory agencies, pharmaceutical companies, organisations and professional societies, health professionals and patients selecting top safety practices for implementation both at

Report Overview

- Introduction: provides the scope of the report
- Chapter I: explores how to prevent errors by learning from medication errors
- Chapter II: outlines how to measure and evaluate medication safety
- Chapter III: explains how the design of medicinal products used in Europe can be developed to improve the in use -safety of medicinal products
- Chapter IV: describes methods for improving safe medication practices
- Chapter V: explores how medicine information practices contribute to medication safety

Table 1: Main results of national multi-centre studies on adverse effects

Studies	Year of data collection	No of patients	Stays with at least one serious adverse event	Adverse drug events		
				Part of adverse events	preventable	death
Harvard Medical Practice Study (HMPS) [3,4]	1984	30,195	3.7%	19.4%	17.7%	
Quality Australian Health Care Study (QAHCS) [5]	1992	14,179	16.6%	10.8%	43.0%	8.0%
Thomas et al. (UCMPS) [6]	1992	14,732	2.9%	19.3%	35.0%	
Schioler et al. (Denmark) [7]	1998	1,097	9.0%			
Davis et al. (New Zealand) [8]	1998	6,579	12.9%	15.4%		
Vincent et al. (United Kingdom) [9]	1999	1,014	10.8%			
Canadian Adverse Events Study (CAES) [10]	2000	3,745	7.5%	23.6%		
French Adverse Event Study (ENEIS) [11]						
- prospective study in hospitalised patients	2004	8,574	6.6‰	19.5%	31.0%	
- cause of hospitalisation			4.0%	38.7%	47.0%	
Spanish Adverse Event Study (ENEAS) [12]	2005	5,624	9.3%	37.4%	34.8%	

Table 2: The incidence of medication errors in Europe

Stage in the medication use system	Ambulatory care	Hospital settings	Comments
Prescribing	**7.5%**	**0.3 - 9.1%**	% of medication orders
Dispensing	**0.08%**	**1.6 - 2.1%**	
Administration	Not available		Direct observation studies
		49.3%	- intravenous medicine doses prepared on wards
		5.1 - 47.5%	- traditional floor stock or ward stock systems
		2.4 - 8.6%	- ward stock system with original prescription and daily ward visits by pharmacists
		7.2 - 9.1%	- patient prescription distribution systems
		10.5%	- unit dose drug distribution manual system
		2.4 - 9.7%	- unit dose drug distribution computerised or automated systems

Table 3: The cost of preventable adverse drug events in European countries

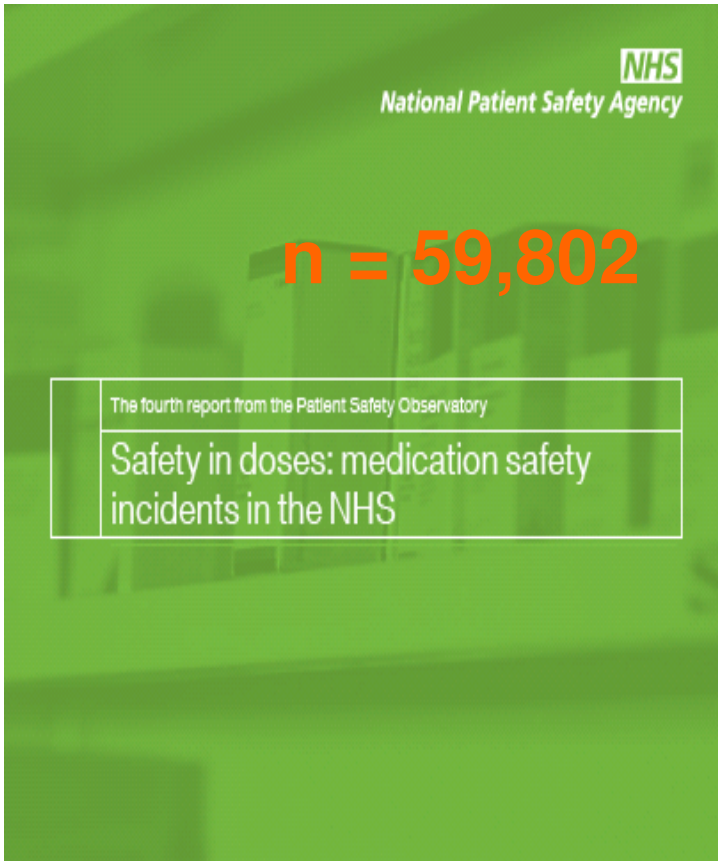
Country	Additional hospital cost per preventable adverse drug event	Estimate of the national annual cost
Spain	€ 3 000	
Germany	€ 3 700	€ 400 million
United-Kingdom		€ 706 million (72% preventable)
France		€ 636 million (38% preventable)

Figure 2: MERS Co-ordination at supranational European level

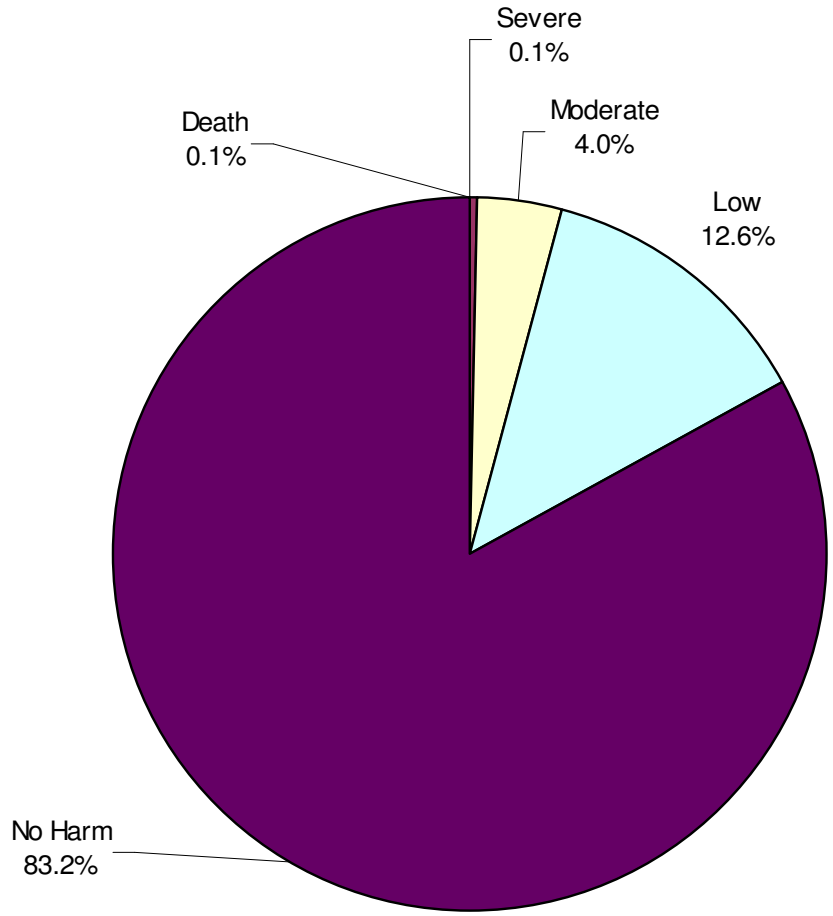
NHS
National Patient Safety Agency

NPSA Patient Safety Observatory Report
Medication Safety Incidents
January 2005 – June 2006

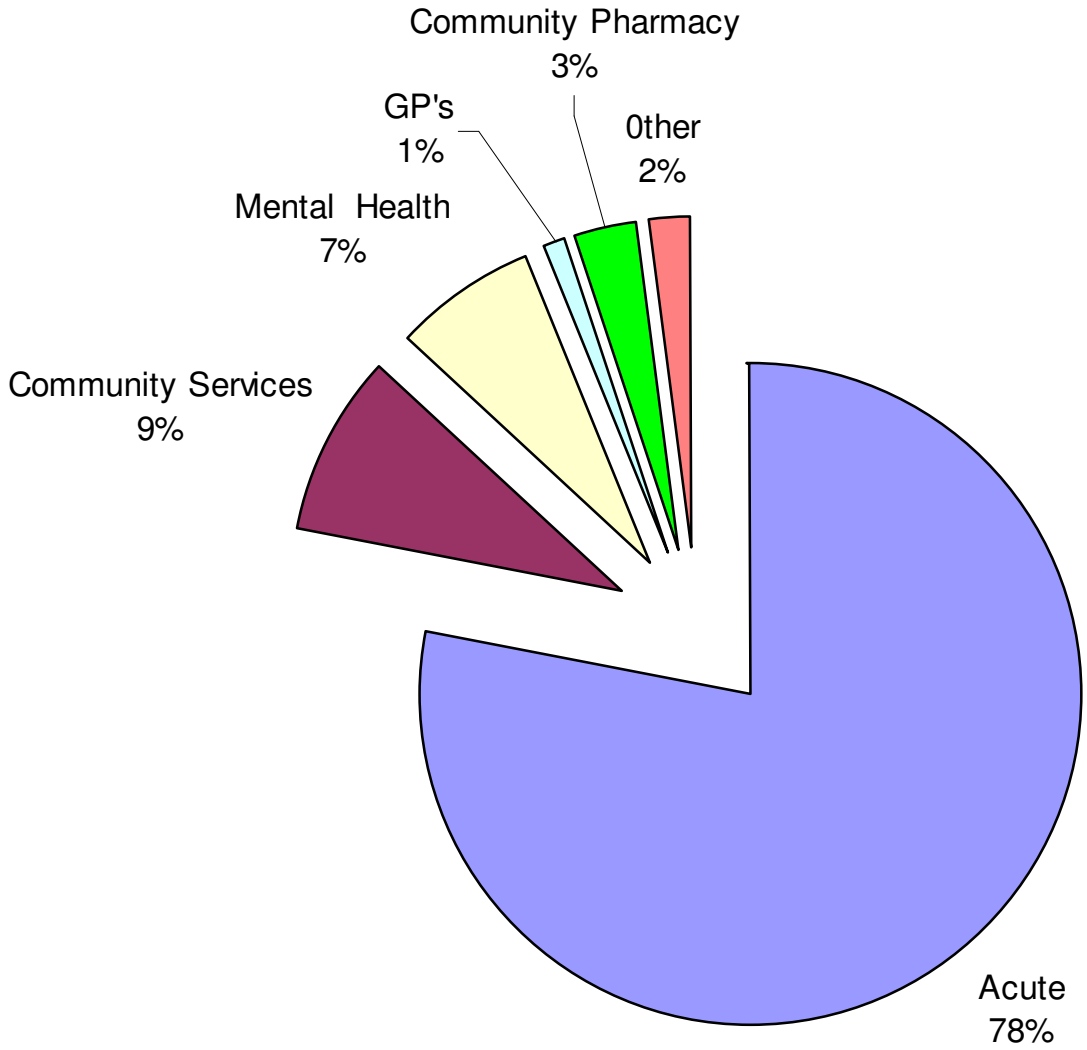
- National Centres for Safe Medication Practices should publish annual reports to identify
- risks and methods that have been used effectively to manage these risks.
- The information should be collated at European level and should be used to inform the external assessment
- of health care organisations.



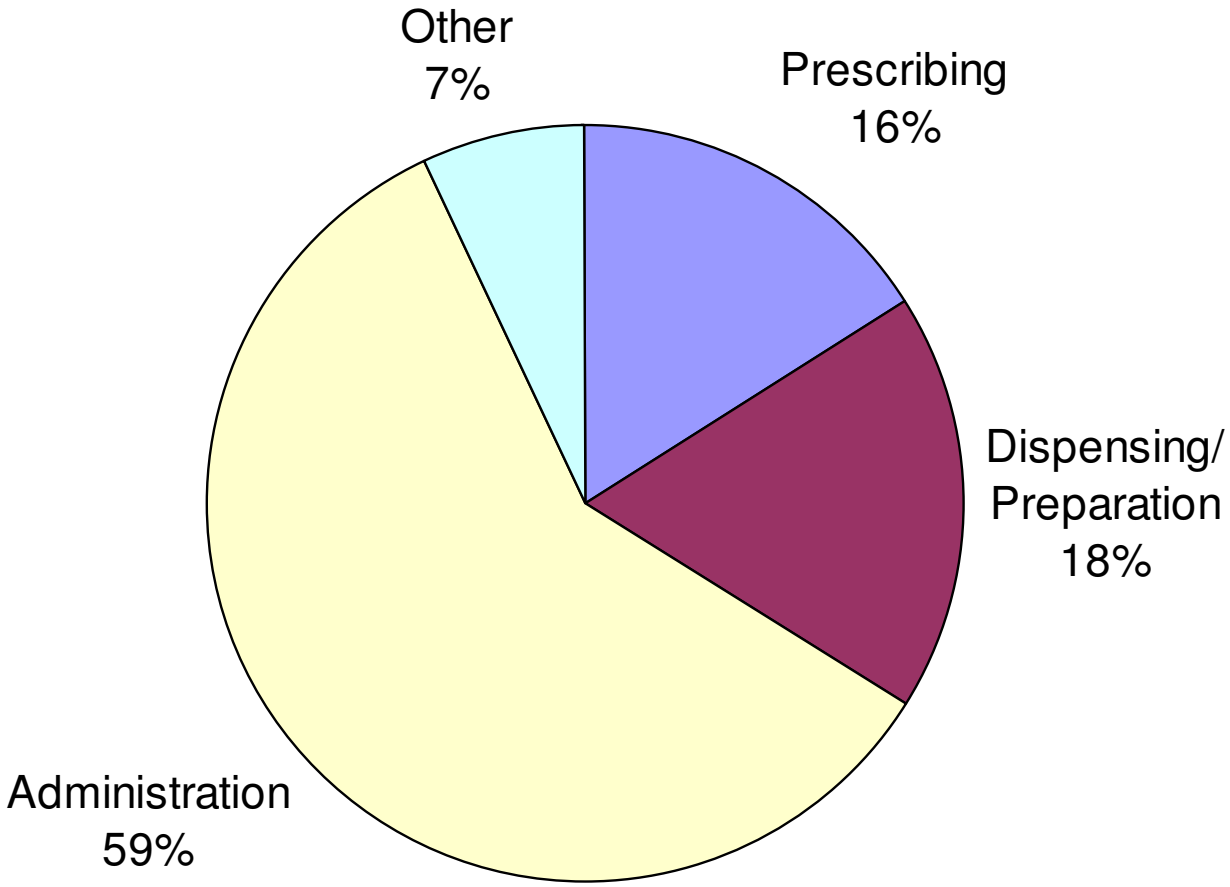
NRLS Medication Incidents – Reported Degree of Harm



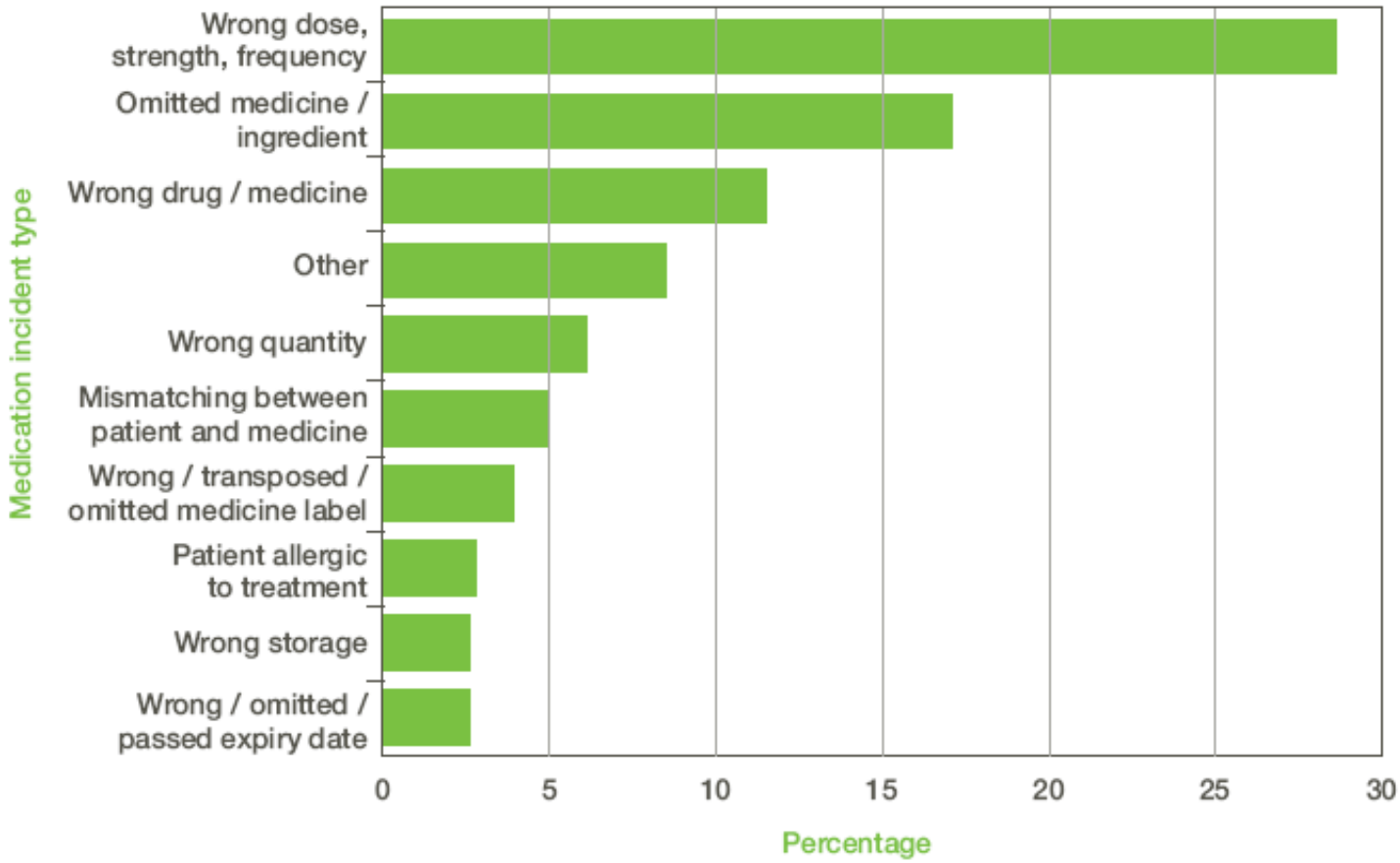
NRLS Medication Incidents – Care Setting



NRLS Medication Incidents – Stage



The 10 most common types of medication error reported to the NRLS



European Medicines Regulations

- 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

The Importance Of Human Factors

- 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

- The current design 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

Recommendations for machine readable codes on medicinal products

It is recommended that :

- EU medicines regulations should be updated to include design features for packaging and labelling of medicine products that take incorporate human factors and promote safe use in practice.
- Include a requirement, that packaging and labelling be subject to human factor assessment and user testing to be undertaken by the manufacturers.

Recommendations for machine readable codes on medicinal products

- Continuing the current non-standardised and unregulated use of machine readable code son medicinal products is likely to increase risks for patients in Europe.
- These codes are expected to be used more frequently in clinical practice in the future. Inaccurate, confusing or unreadable codes or codes not included in health care databases may pose risks.
- Machine readable codes need to be standardised and considered together with other labelling information in the course of the marketing authorisation procedure of medicinal products in order to ensure patient safety and to prevent new risks.

Recommendations for machine readable codes on medicinal products

- European medicine regulations should include requirements for machine readable codes.
- As an important element, the medicine regulations should require that pharmaceutical companies provide unit dose medicines with a bar code.

Recommendations for machine readable codes on medicinal products

- With a view to full benefit for patient safety by this technology, it is recommended that the following changes are made to European medicines regulations:

- all medicinal products marketed in Europe should have an EAN-13 code bar containing the GTIN on the primary medicine container as a minimum requirement with an implementation period of two years;

Recommendations for machine readable codes on medicinal products

- have a data matrix bar code or RFID chip on both the primary container and unit dose with an implementation period of five years.
- The GTIN, batch number and expiry date should be encoded; include a unique serial number if the medicine is at risk of being counterfeit.

EFPIA Supply Chain Integrity Initiative

- Use of data matrix bar codes
- Enabling anti-counterfeiting and other patient safety safeguards

MHRA
Medicines and Healthcare products Regulatory Agency

NHS
National Patient Safety Agency

Safer practice notice

07

N

Notice

29 April 2005

Immediate action	☐
Action	☑
Update	☐
Information request	☐

Reference: NPSA/2005/7

Ensuring safer practice with Repevax® and Revaxis® vaccines

There have been a number of reported patient safety incidents and near misses involving Repevax® and Revaxis® vaccines, where staff have mistakenly given the wrong vaccine. This is due to similar product names, labelling and packaging.

New packaging is due shortly. This notice highlights this change to healthcare professionals, and provides a guide as to how they can minimise risk in the short-term.

Action for the NHS

NHS acute trusts (including foundation trusts), primary care organisations and local health boards in England and Wales should take the following steps immediately:

1 Ensure procedures are in place to check the correct vaccine has been selected for the individual patient concerned on each and every administration.

2 Raise awareness of the proposed changes to the packaging with all staff involved in childhood immunisations (see page 3). This may include displaying pictures of the product packaging in all locations where the vaccine is stored or used. To reduce the chances of staff selecting the wrong vaccine, where possible staff should use up stocks in the original packaging style first.

3 Review procedures for risk assessment and management of new vaccine products introduced locally, and strengthen procedures where necessary.

4 Continue to report any patient safety incidents (see page 4).

For response by:
- NHS acute trusts (including foundation trusts), primary care organisations and local health boards in England and Wales

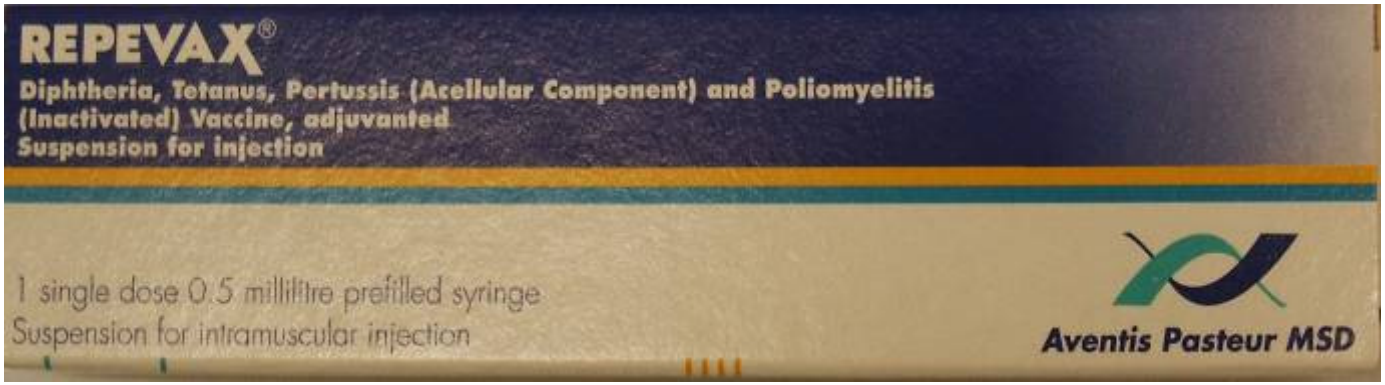
For action by:
- Directors of public health in England and Wales, primary care
- Chief pharmacists in England and Wales, secondary care

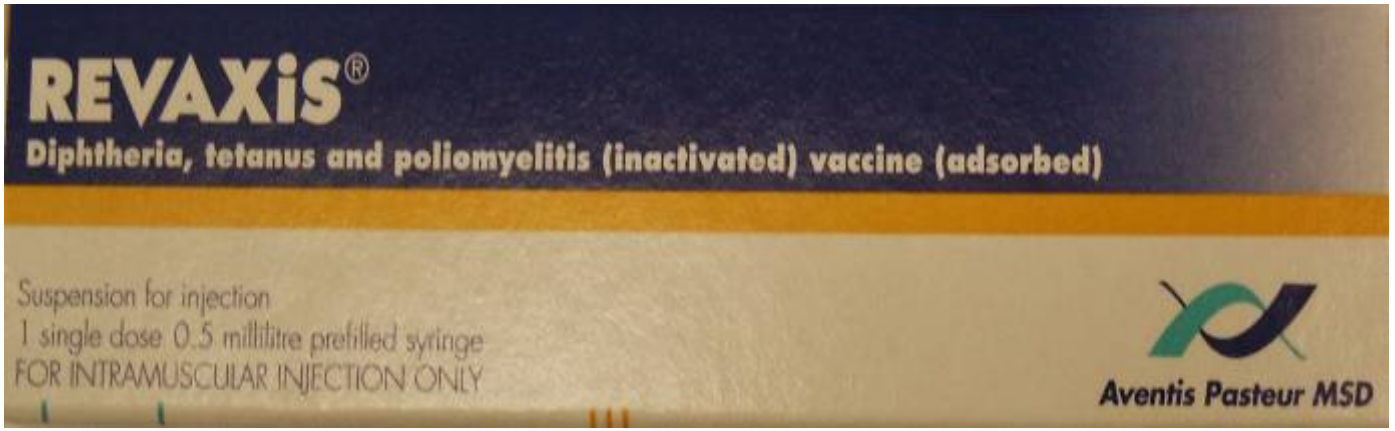
The NPSA recommends that NHS organisations also inform:
- Consultants in communicable diseases
- Medical, nursing and pharmaceutical clinical governance leads
- Risk managers
- Directors of nursing
- Professional leads for school nursing
- District immunisation co-ordinators
- Procurement managers
- Communication leads
- Patient Advice and Liaison Services (PALS) in England
- Claims managers
- Their solicitors
- Patient and public involvement leads

The NPSA has informed:
- Chief executives of acute trusts, primary care organisations and local health boards in England and Wales
- Regional directors of public health of strategic health authorities (England) and regional offices (Wales)
- Healthcare Commission
- Healthcare Inspectorate Wales
- NHS PASA
- Welsh Health Supplies
- NHS Direct
- Royal colleges and professional organisations
- Community Practitioners and Health Visitors' Association (CPHVA)
- Market Authorisation Holders
- Primary and Community Care Pharmacy Network
- Monitor
- Quality improvement leads in Scotland and Northern Ireland
- Independent Healthcare Forum
- Health Protection Agency
- Commission for Social Care Inspection
- Community Health Councils (CHCs) in Wales

NHS
National Patient Safety Agency

Patient Safety Incident Involving Vaccine Products





NHS
National Patient Safety Agency

Safer practice notice 12

N

Notice

25 May 2006

Immediate action	☐
Action	☑
Update	☐
Information request	☐

Ref: NPSA/2006/12

Ensuring safer practice with high dose ampoules of diamorphine and morphine

There have been a number of reports of deaths and harm due to the administration of high dose (30mg or greater) diamorphine or morphine injections to patients who had not previously received doses of opiates. This notice promotes safe practice with these medicines. It is not intended to prevent appropriate clinical use in patients who need them.

Risks

The major risks are:

- Packaging of different strengths of diamorphine and morphine ampoules look the same; the outer carton and ampoule labelling are poorly differentiated; and 5mg, 10mg, 15mg, 20mg and 30mg products have similar appearances.
- Higher strength ampoules of diamorphine and morphine (30mg, for example) stored alongside lower strength products (10mg, for example) in clinical areas in both primary and secondary care.
- Insufficient therapeutic training and understanding on the part of the healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of diamorphine and morphine injections.

Actions for the NHS

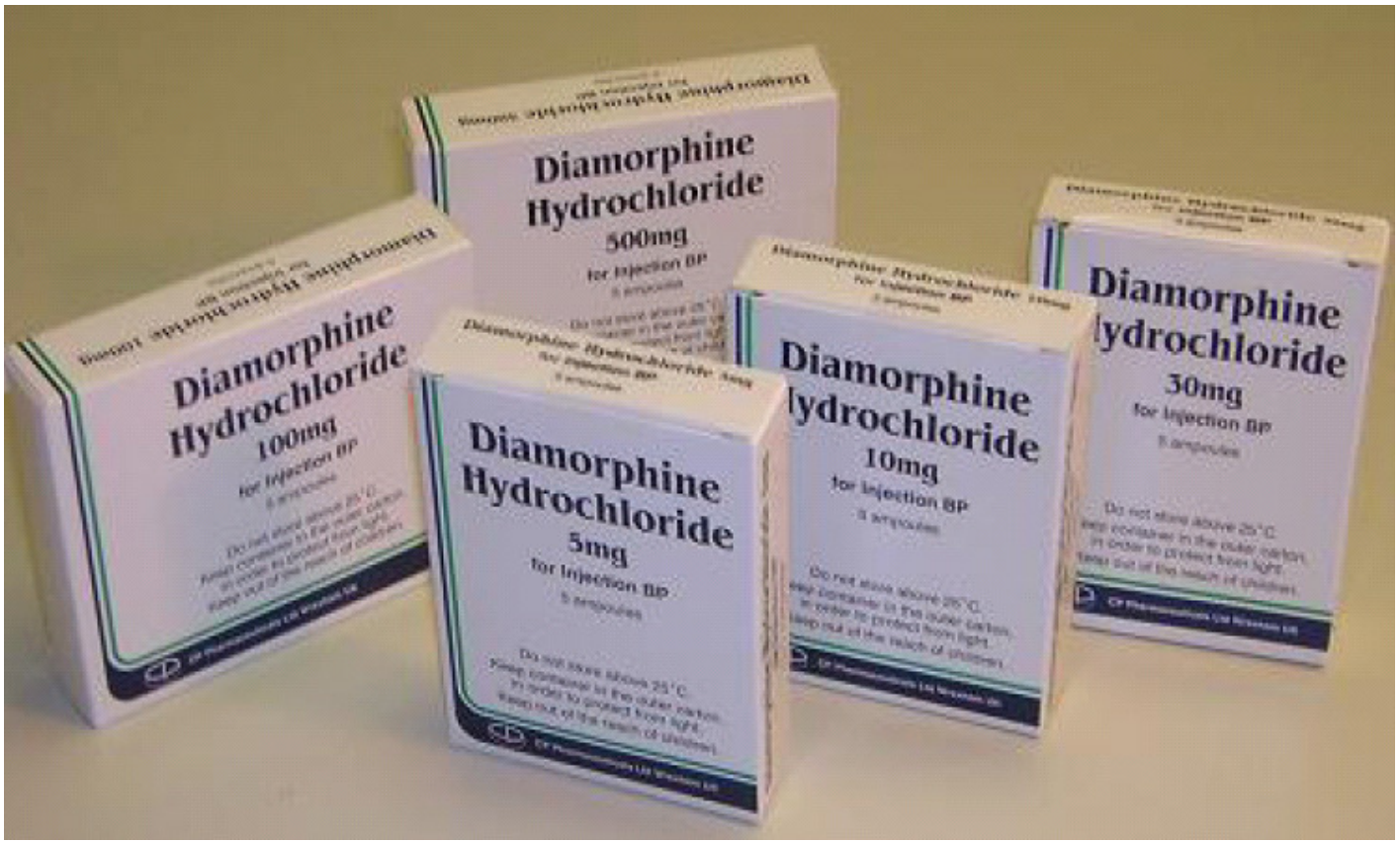
1 Risk assess and have procedures for safely prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections.

2 Review therapeutic guidelines for the use of diamorphine and morphine injectable products for patients requiring acute care, including post-administration observation of patients who have not previously received doses of opiates.

3 Update information concerning the safe use of diamorphine and morphine injectable products as part of an ongoing programme of training for healthcare staff on medication practice.

4 Ensure that naloxone injection, an antidote to opiate-induced respiratory depression, is available in all clinical locations where diamorphine and morphine injections are stored or administered.

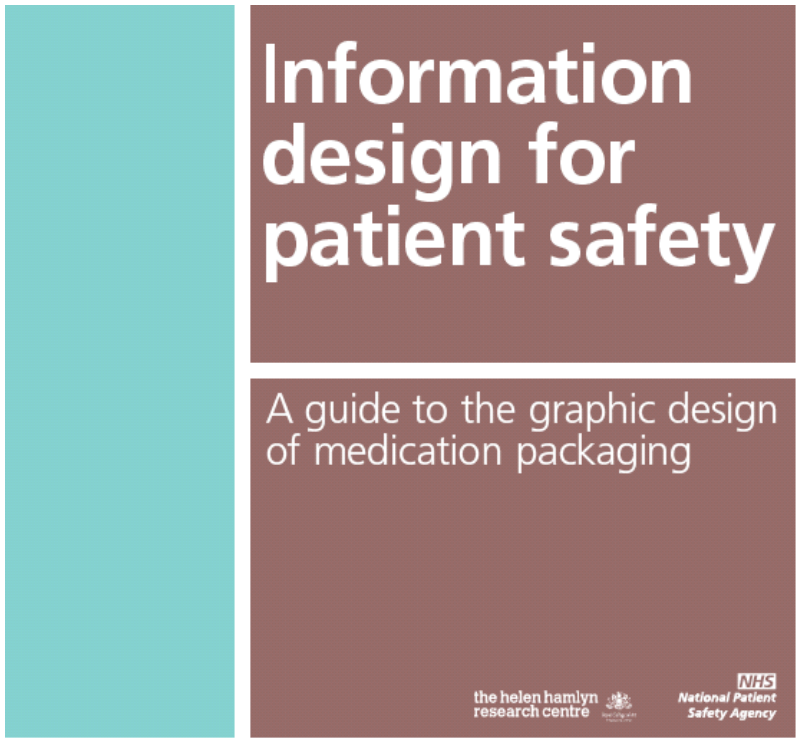
Look-a-like packaging for Diamorphine

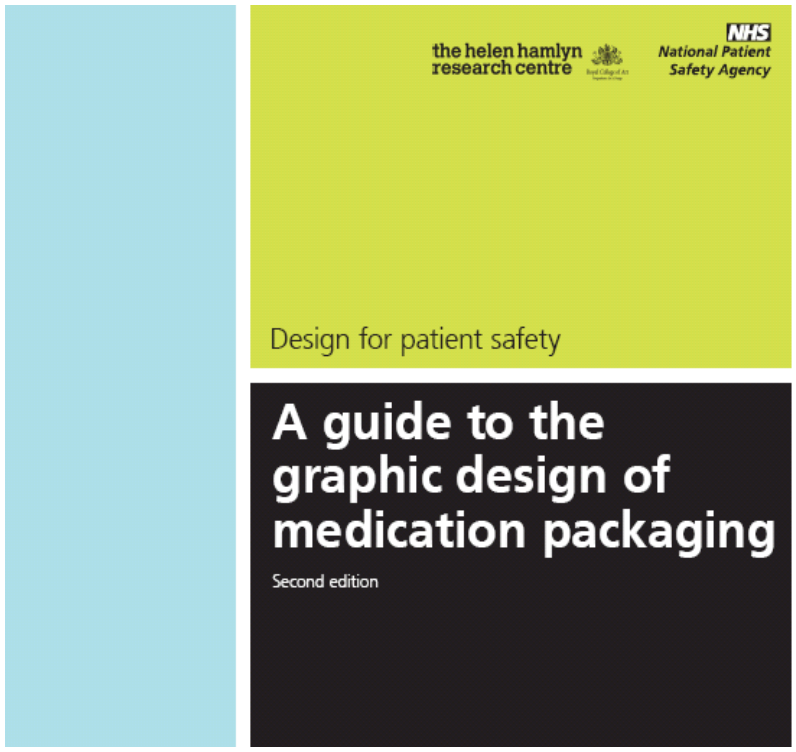


NHS
National Patient Safety Agency

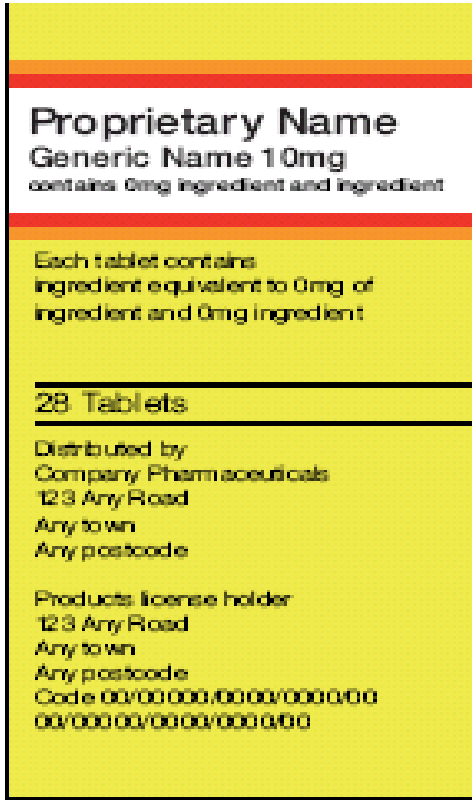
Patient Safety Incident Involving Diamorphine Ampoules

NHS
National Patient Safety Agency

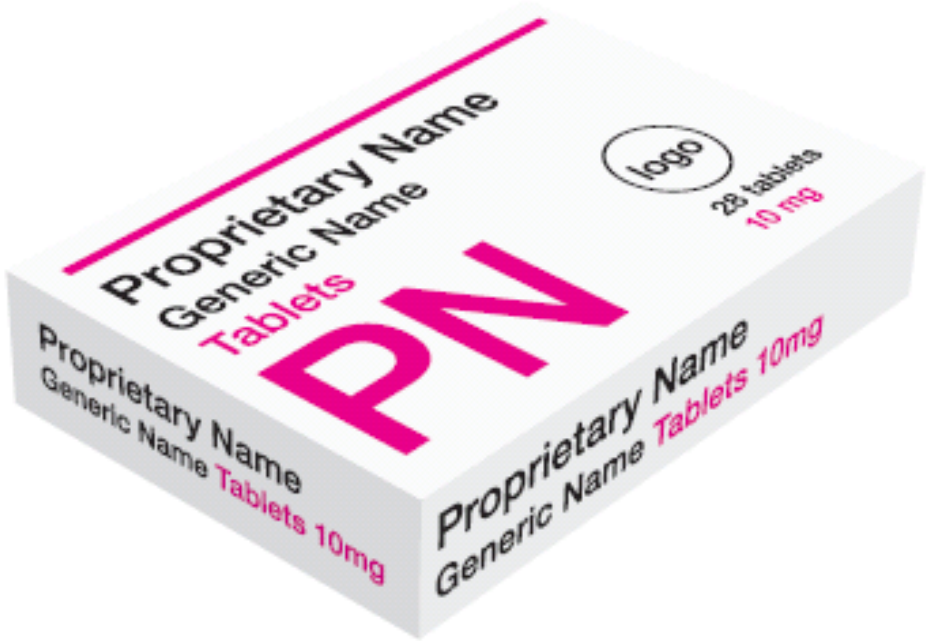




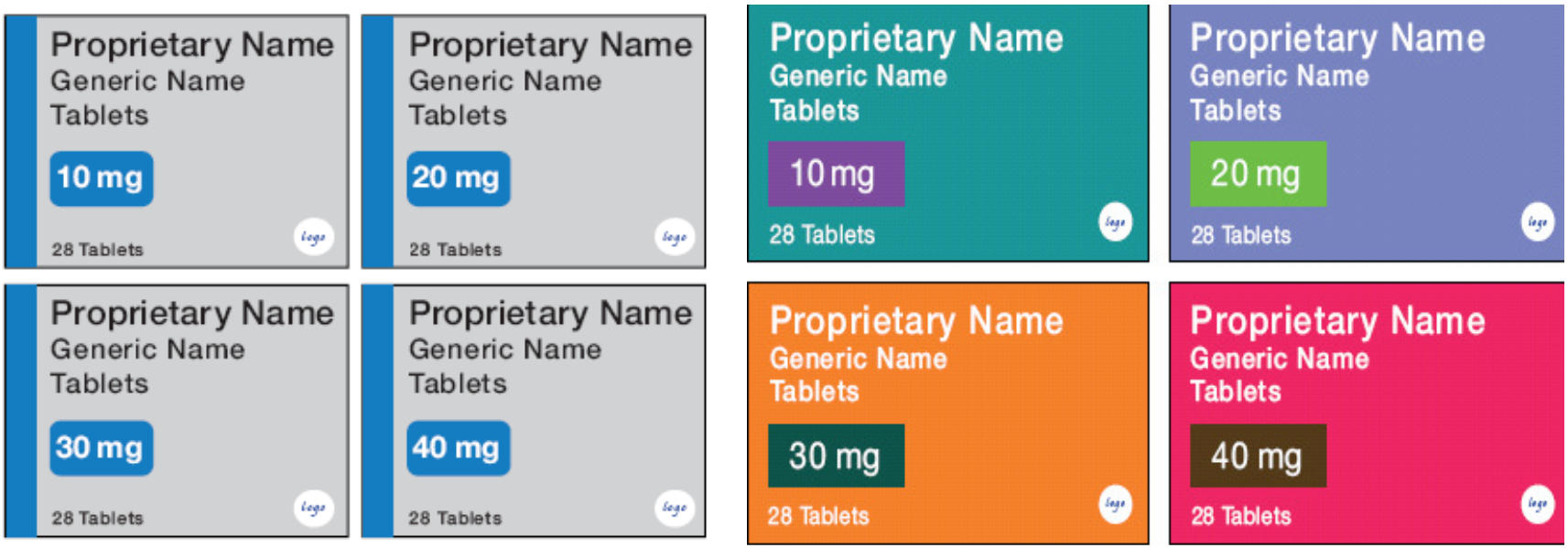
Use Blank Space To Emphasise Critical Information



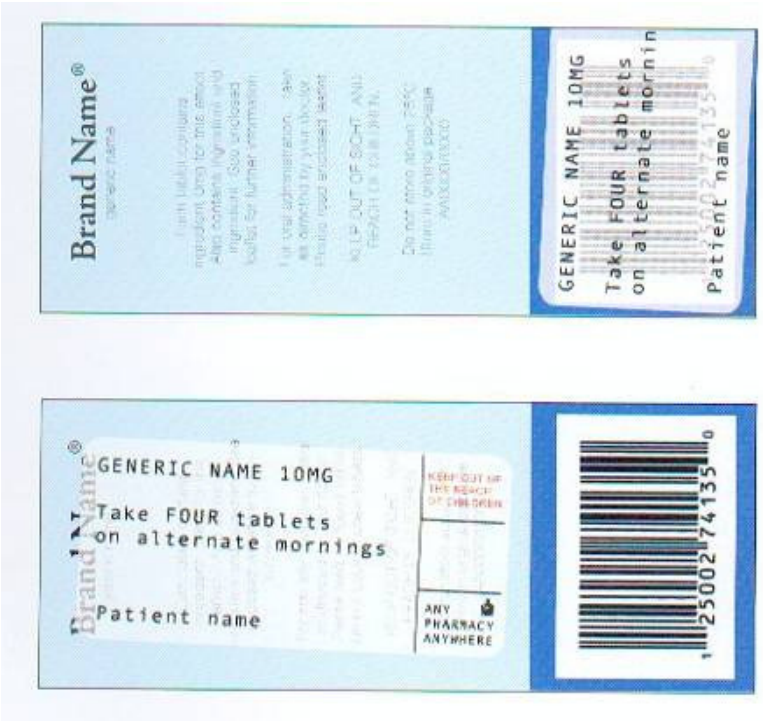
Critical Information In The Same Field of Vision On At Least Three Non-Opposing Faces

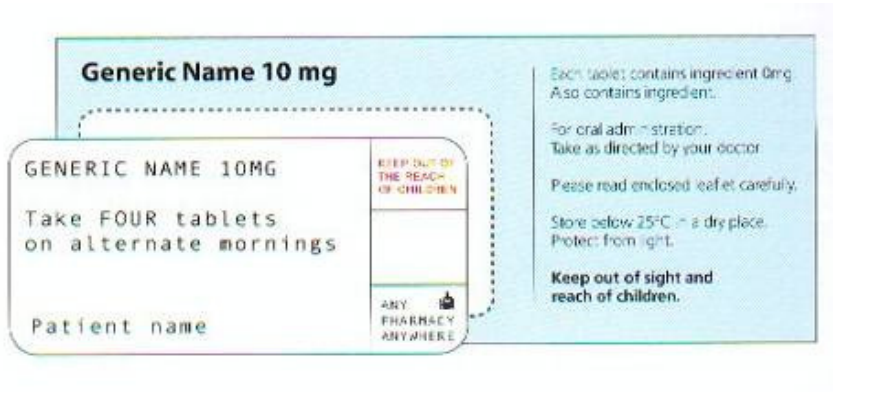


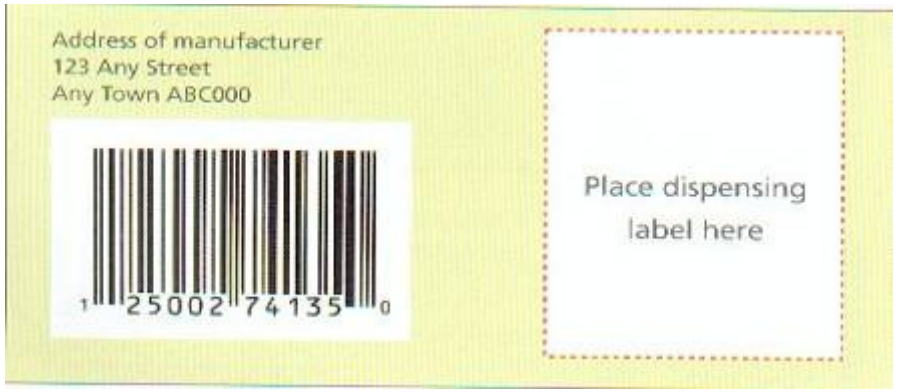
Use Colours To Differentiation to Highlight Information



Allocate Space for a Dispensing Label

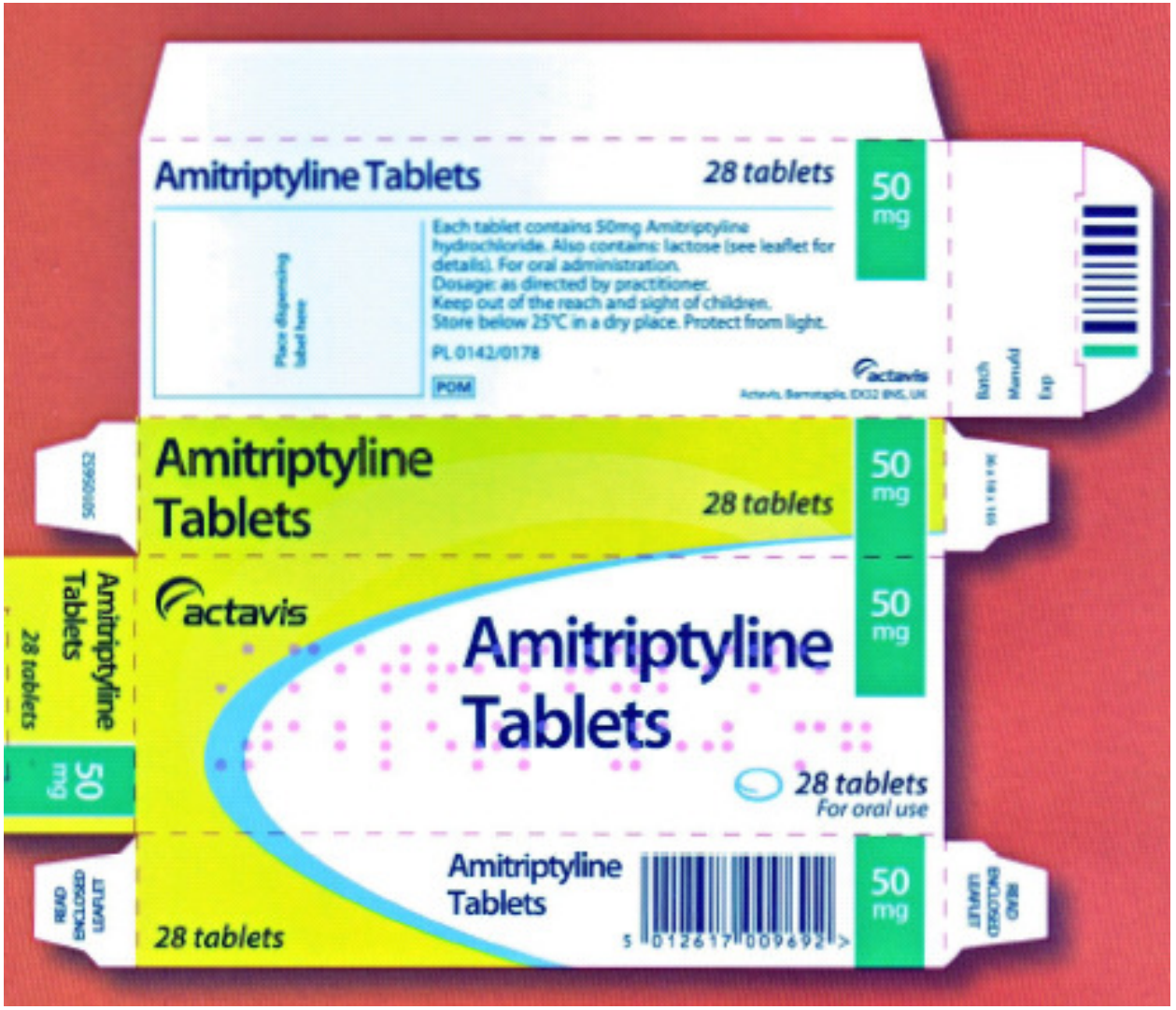






Recently Re-Designed Packaging

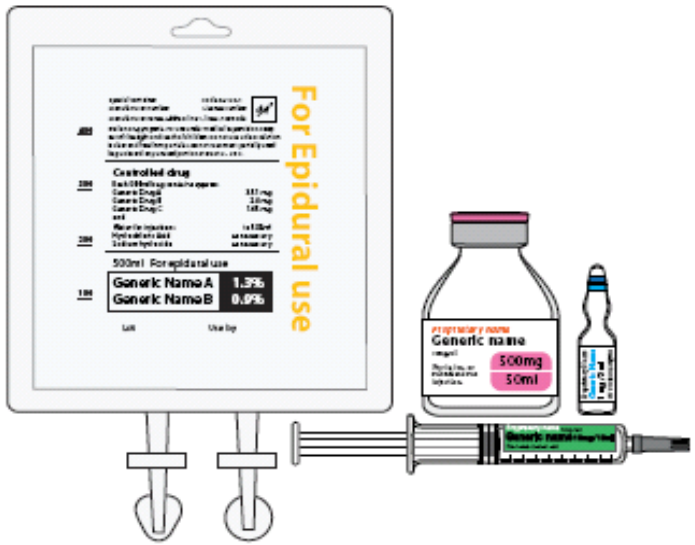
Recently Re-Designed Packaging



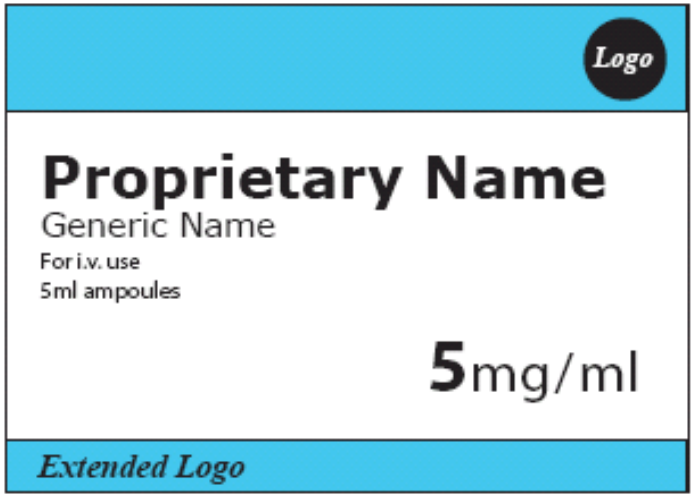
NHS
National Patient Safety Agency

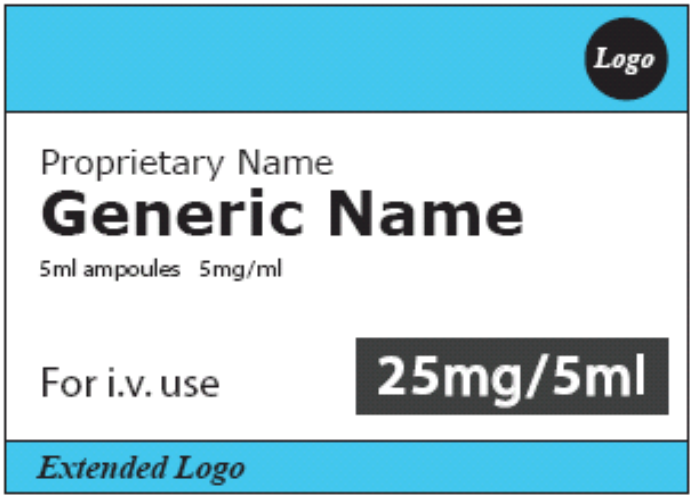
Design for Safety

Labelling and Packaging Guidelines for Injectable Medicines

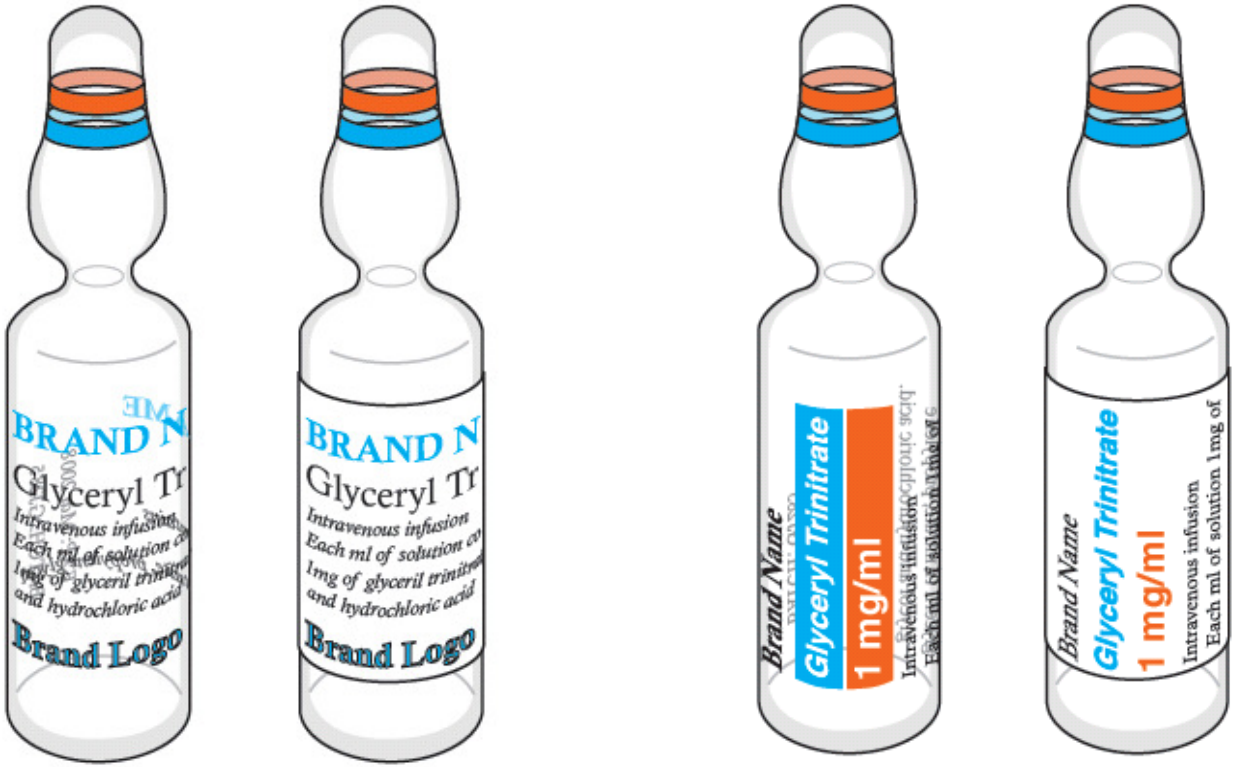


Name and Strength

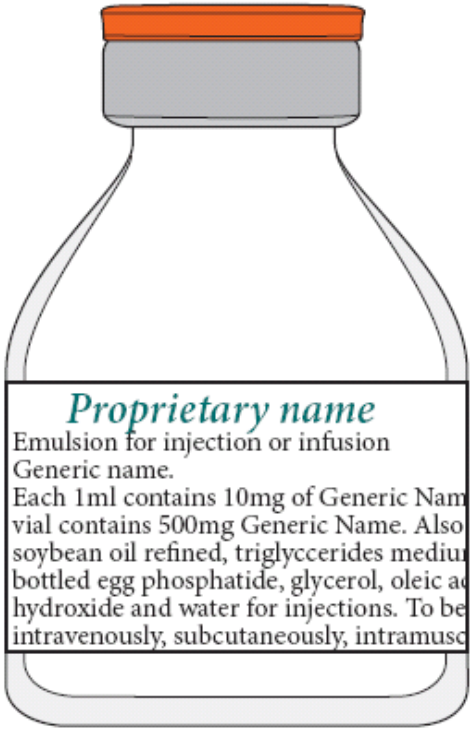


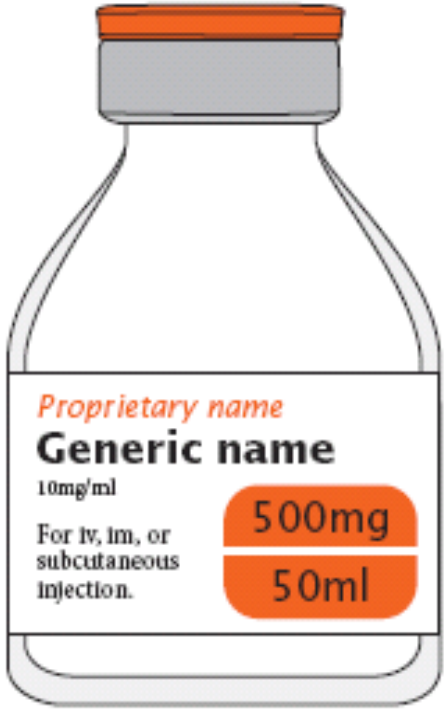


Ampoule Design

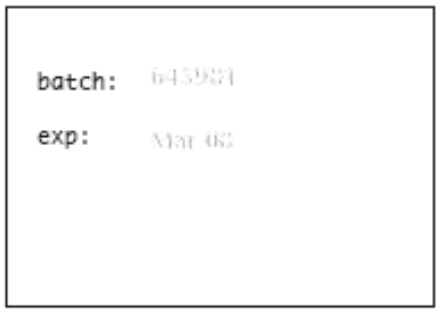


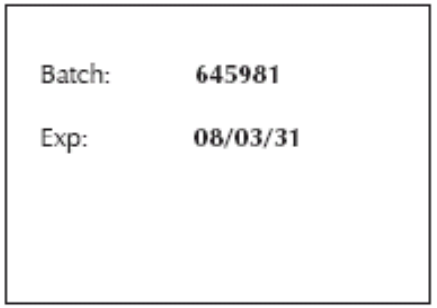
Vial Design

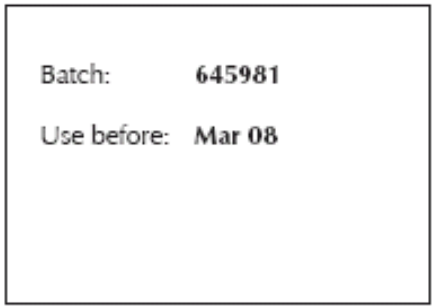

Proprietary name
Emulsion for injection or infusion
Generic name.
Each 1ml contains 10mg of Generic Nam
vial contains 500mg Generic Name. Also
soybean oil refined, triglyccerides mediu
bottled egg phosphatide, glycerol, oleic a
hydroxide and water for injections. To be
intravenously, subcutaneously, intramusc


Proprietary name
Generic name
10mg/ml
For iv, im, or subcutaneous injection.
500mg
50ml

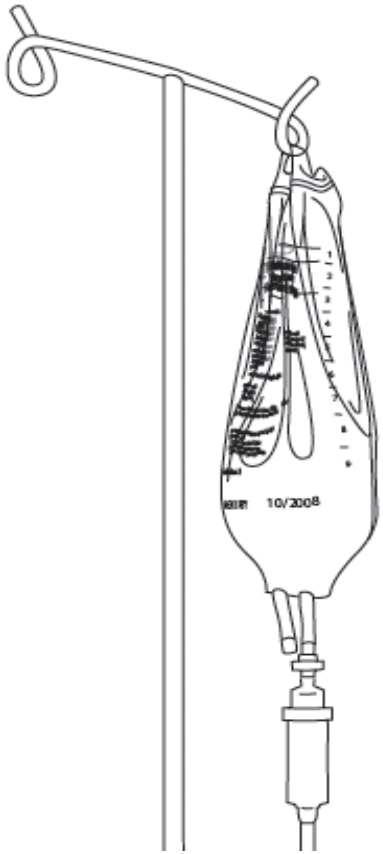
Batch and Expiry

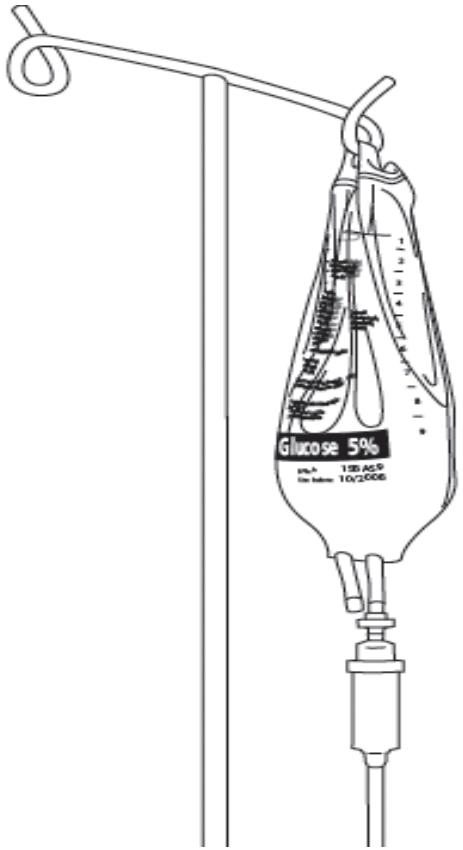




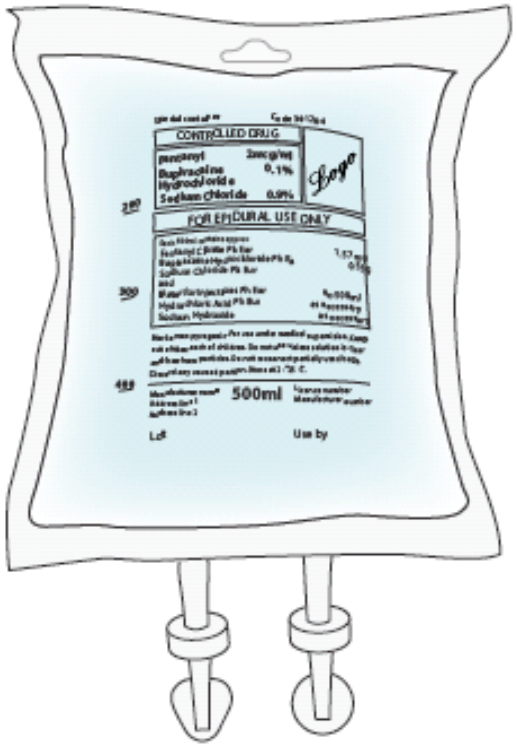


Infusion Design



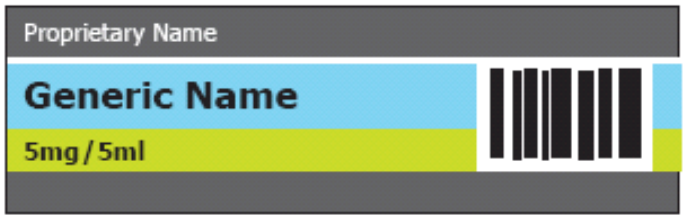


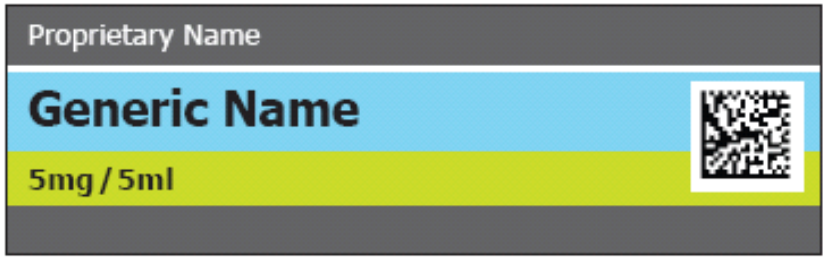
Highlight Route of Administration



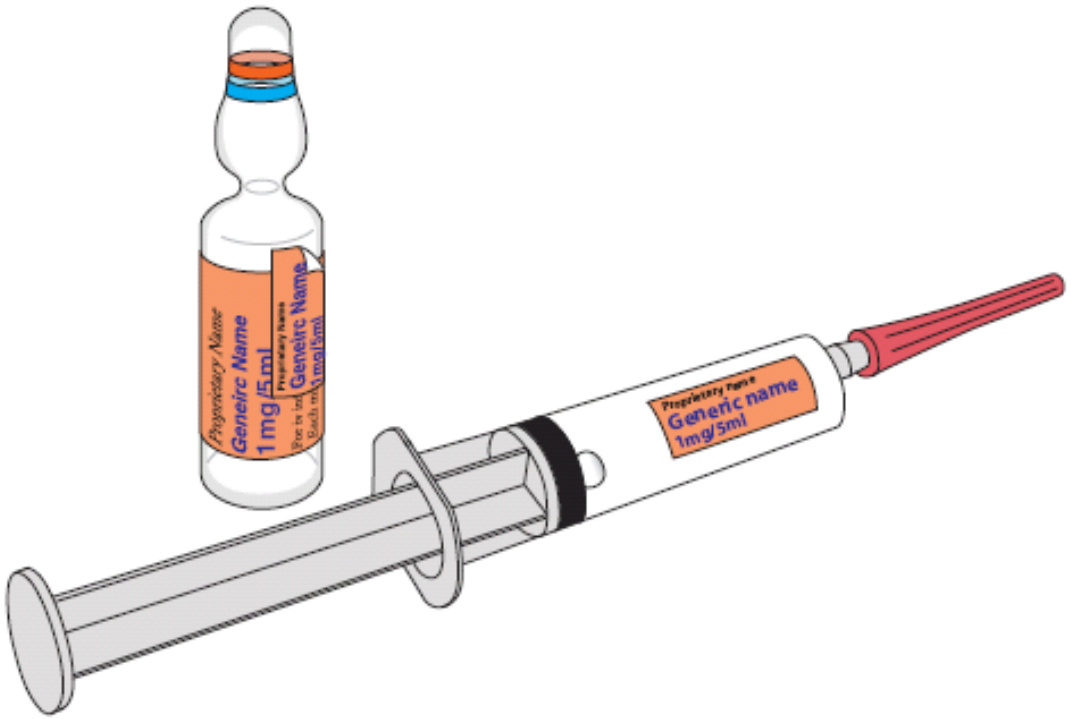
NHS
National Patient Safety Agency

Bar Codes

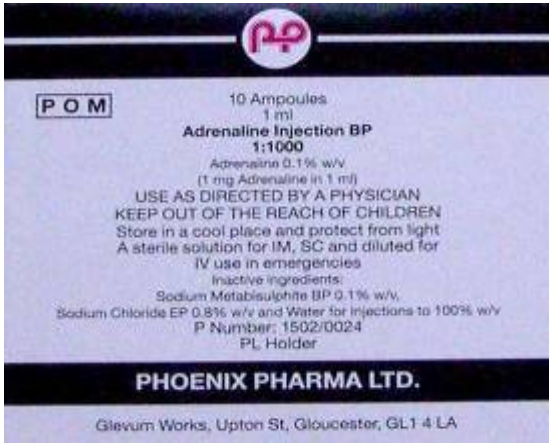


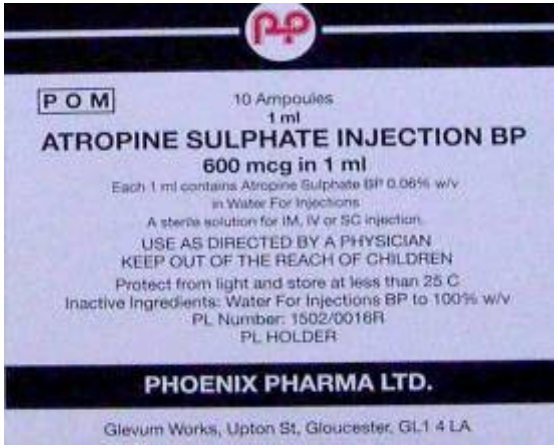


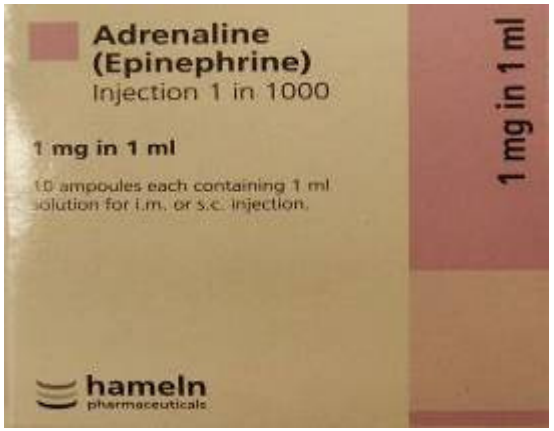
Peelable Ampoule/Vial Labels

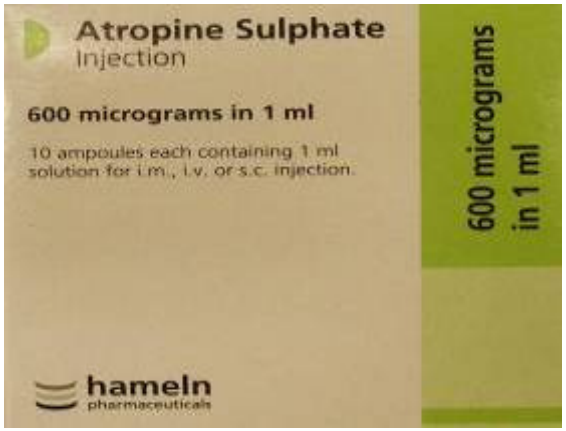


Differentiating Injectable Medicine







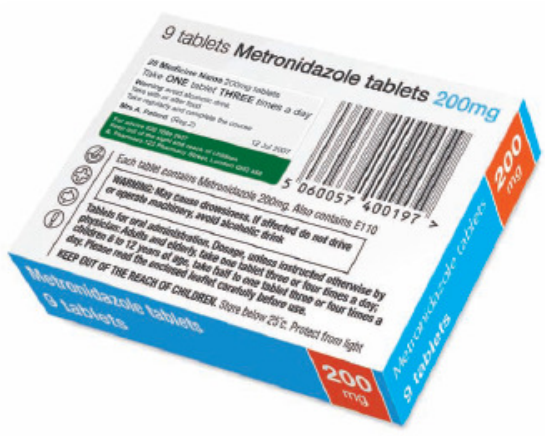


NHS
National Patient Safety Agency

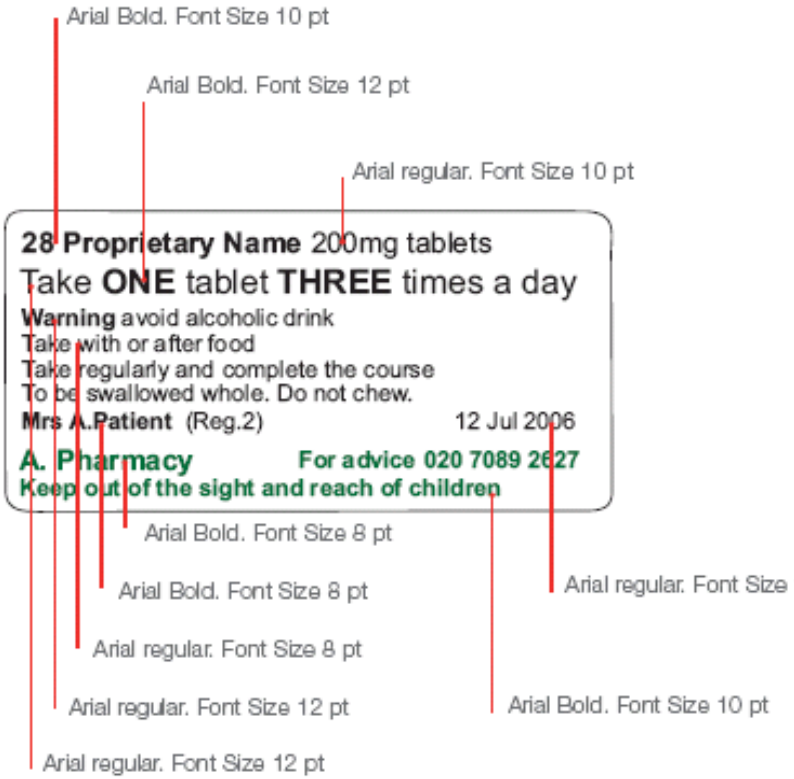
Design for patient safety

A guide to the design of dispensed medicines

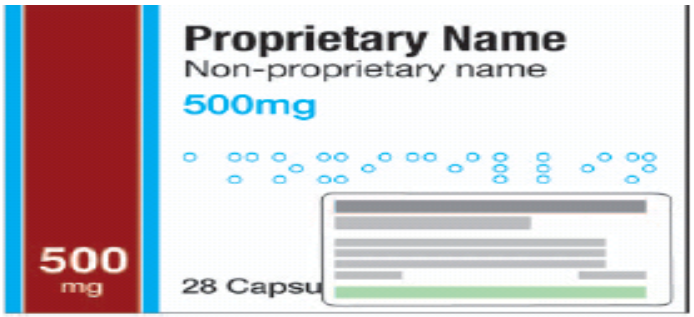
Edition 1
2007

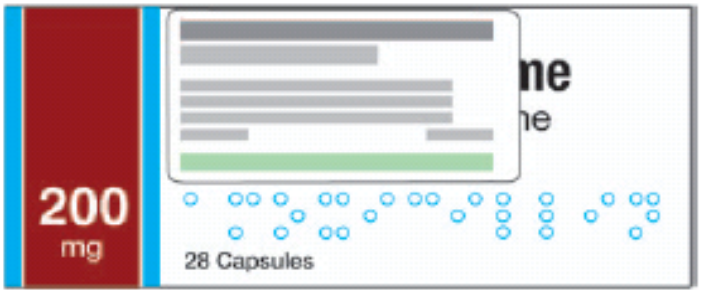


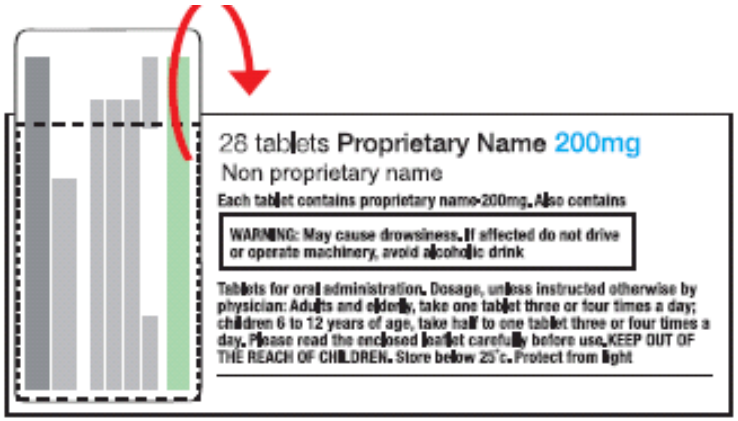
Dispensing Labels

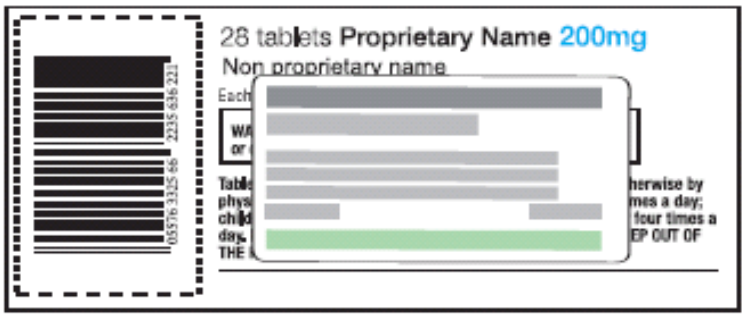


Room For Dispensing Labels

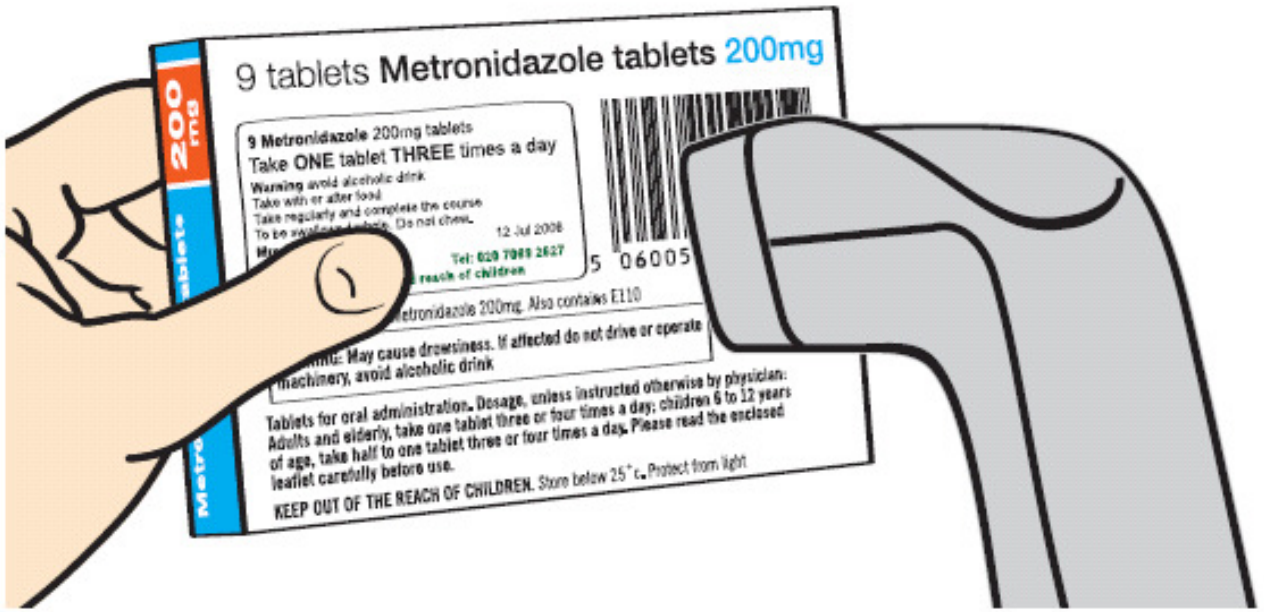




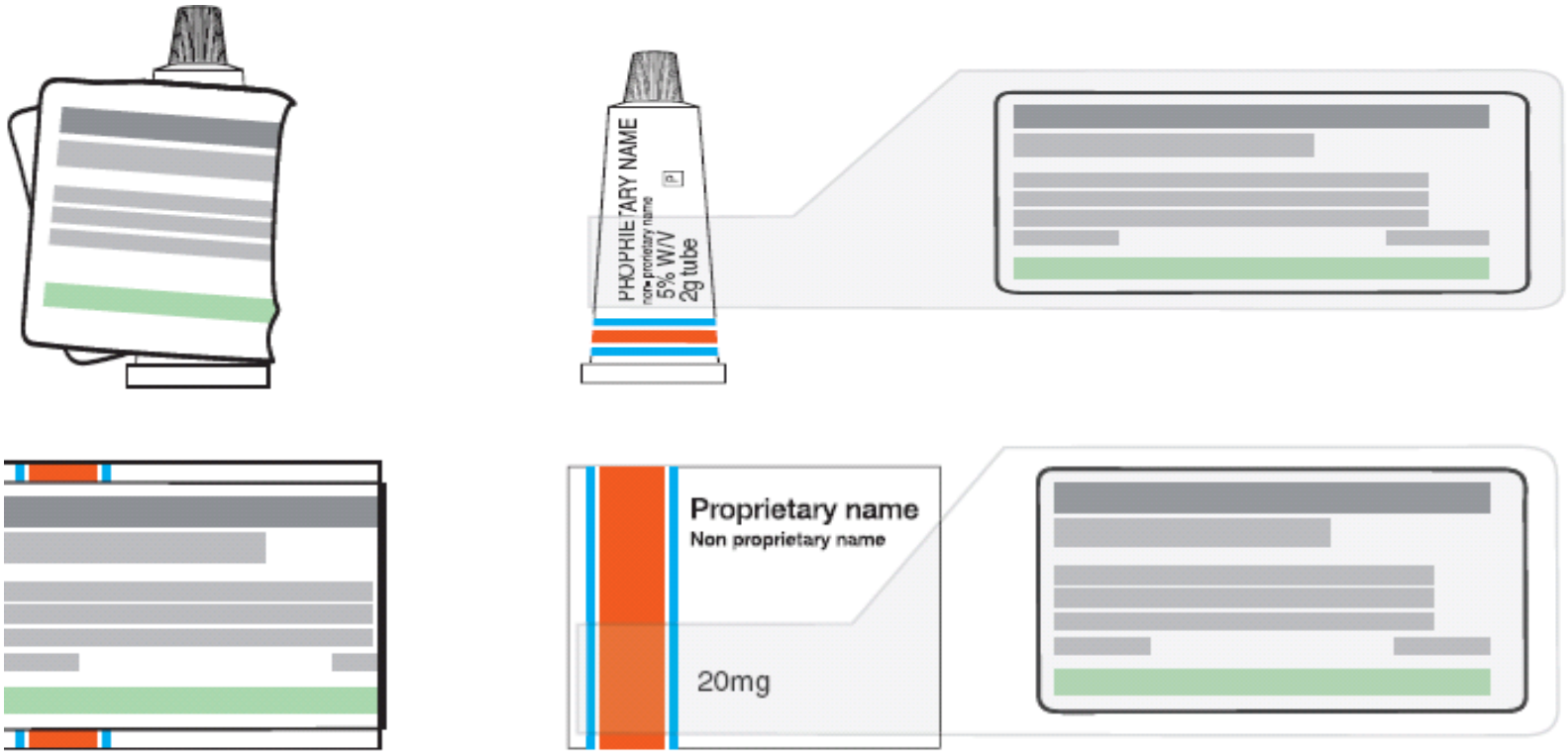




The Use of Bar Codes



Labelling Small Containers



Summary

- Safe medication practice is an important public health issue in Europe
- Current European medicines regulations concerning naming, packaging and labelling for pharmaceutical products provide inadequate safeguards for patients
- The Council of Europe Safe Medication Practice Report Recommends changes in European Regulation to require the use of a GTIN, batch number and expiry date and a unique serial number (where appropriate) on outer packs and unit of use packaging in five years.

More information

www.npsa.nhs.uk