Medicines & Healthcare products Regulatory Agency

MHRA

# FDA/IMSN Joint Summit on Labelling and Packaging – Special Warnings

Jan MacDonald

June 2018


10,000 killed b
medical errors
FATAL ERROR
families find
dead relatives
Suspicio
yard deat
SPINE CHI
Claims of cover-up after
fall from operating table
Patients left to die
Poor hospital
medical
mistake and
are blamed
Slandering
doctors and
nurses 'kill
40,000 a year
investigated
or deaths of
140,000 sent to hospital by medical error
10 patients
80,000 victims a year
of wrong medication
get stole
'tip of iceberg'
Baby dies after
Patients put at risk

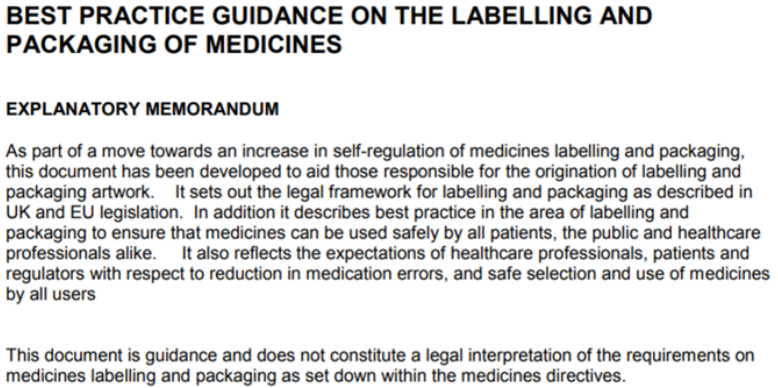

medication
prescription
health
bottle
pharmacy
care
medicine
pill
sickness
person
tablet
pills
therapy
headache
supplement
drug
disease
child
addiction
drugs
cold
cure
dose
healthcare
medicament
industry
treatment
capsule
medical
several
vitamin
many
home
remedy
group
patient
childcare
fever
chemistry
pharmacist
nobody
plastic
syringe
prevention
childhood
symbolism
science
antibiotic
healthy
medicinal
pharmaceutical
doctor
sick
aspirin
flu
pain
placebo
label
container
illness
chemical
hospital
woman
girl
upset
drugstore

# CHM Labelling Group – Key findings

- No substitute for reading the label
- Certain information critical for safe use
- Presentation of information is important
- Similarity in packaging
- Look alike/sound alike names
- Medicines labelling can be improved
- BPGLPM 2012

# Best Practice Guidance on the Labelling & Packaging of Medicines

Available on MHRA Website



**BEST PRACTICE GUIDANCE ON THE LABELLING AND PACKAGING OF MEDICINES**

**EXPLANATORY MEMORANDUM**

As part of a move towards an increase in self-regulation of medicines labelling and packaging, this document has been developed to aid those responsible for the origination of labelling and packaging artwork. It sets out the legal framework for labelling and packaging as described in UK and EU legislation. In addition it describes best practice in the area of labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. It also reflects the expectations of healthcare professionals, patients and regulators with respect to reduction in medication errors, and safe selection and use of medicines by all users

This document is guidance and does not constitute a legal interpretation of the requirements on medicines labelling and packaging as set down within the medicines directives.

# Critical Information

Name of medicinal product

- followed by common name(s)

Strength

Route of Administration

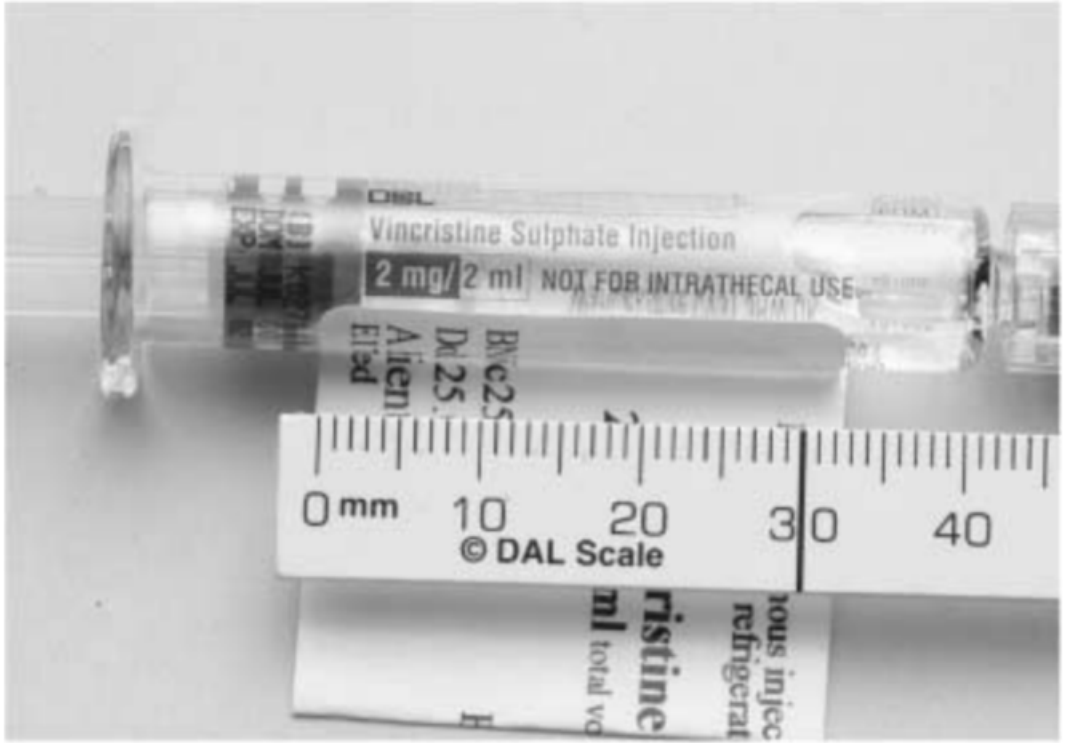
Posology

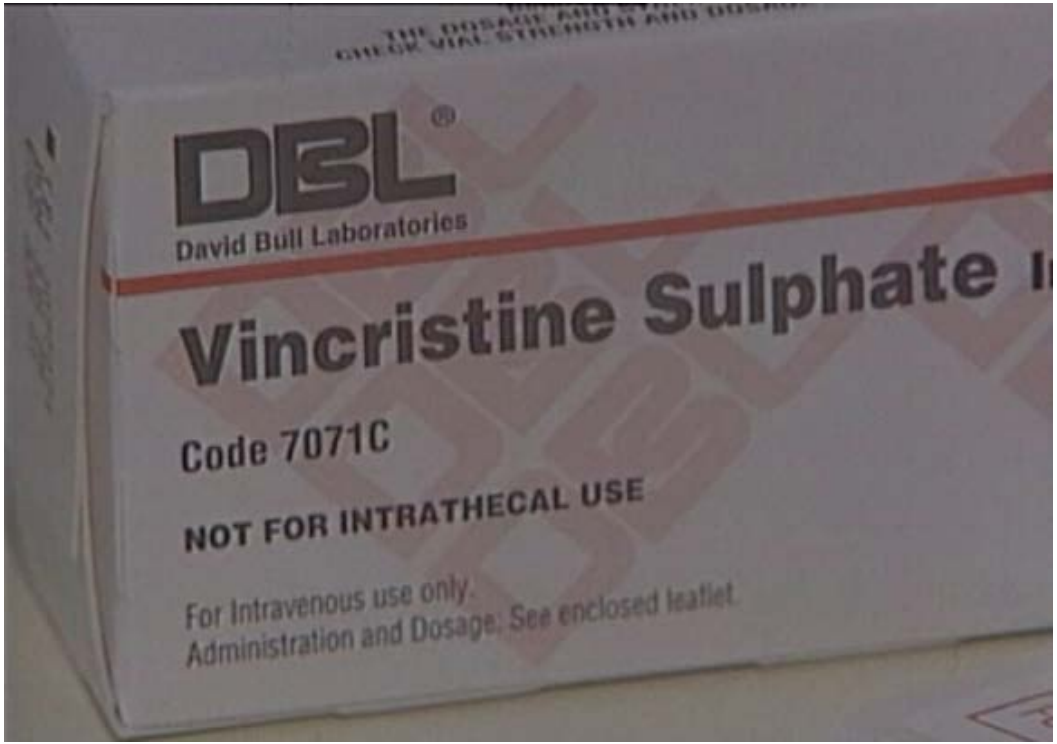
Warnings

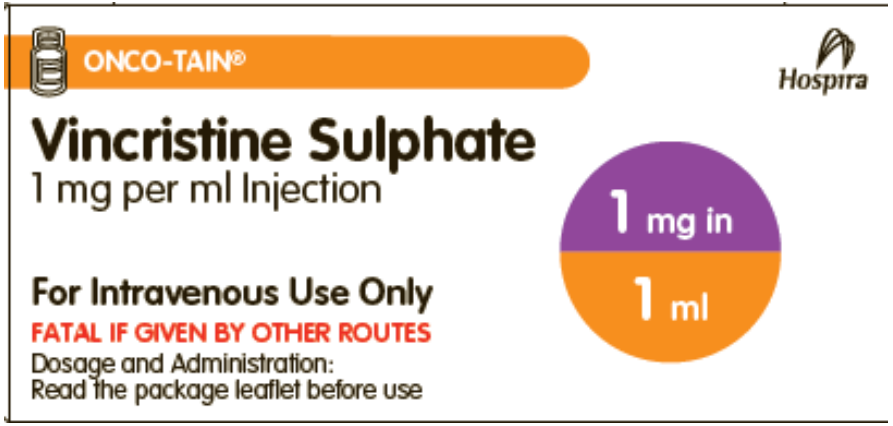
# Case study – Vinca alkaloids

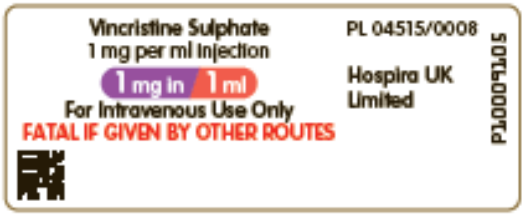
- Patient prescribed cytosine ***intrathecally*** and vincristine ***intravenously*** as part of chemotherapy course.
- Drugs were prepared ready for administration by the pharmacy department.
- Both syringes were sent to the ward in the same clear plastic bag.
- Syringes were labelled with the patient's name, the drug name, and the dose.
- Clinician gave both drugs via the intrathecal route instead of administering the vincristine intravenously as prescribed.
- The patient subsequently died.

Source: Toft 2001

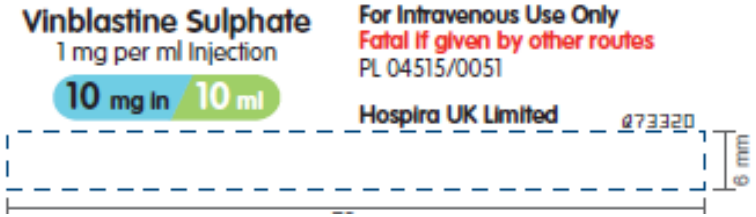

Vincristine Sulphate Injection
2 mg/2 ml NOT FOR INTRATHECAL USE
0 mm 10 20 30 40
© DAL Scale


DBL®
David Bull Laboratories
Vincristine Sulphate
Code 7071C
NOT FOR INTRATHECAL USE
For Intravenous use only.
Administration and Dosage: See enclosed leaflet


ONCO-TAIN®
Hospira
Vincristine Sulphate
1 mg per ml Injection
1 mg in
1 ml
For Intravenous Use Only
FATAL IF GIVEN BY OTHER ROUTES
Dosage and Administration:
Read the package leaflet before use


Vincristine Sulphate
1 mg per ml Injection
1 mg in 1 ml
For Intravenous Use Only
FATAL IF GIVEN BY OTHER ROUTES
PL 04515/0008
Hospira UK Limited
SOTL0001d


ONCO-TAIN™
Hospira
Vinblastine Sulphate
1 mg per ml Injection
10 mg in
10 ml
For Intravenous Use Only
Fatal if given by other routes
Dosage and Administration: Read the package leaflet before use


Vinblastine Sulphate
1 mg per ml Injection
10 mg in 10 ml
For Intravenous Use Only
Fatal if given by other routes
PL 04515/0051
Hospira UK Limited
Ø73320
6 mm

# Other Risk Minimisation Measures

- Intrathecal medicines require different considerations in supply, dispensing, storage and administration
- Clinical staff should be accredited if administering via the intrathecal route
- Spinal needles should not be able to connect to IV syringes
- Concentration of vinca solutions to be reviewed


## Using Vinca Alkaloid Minibags (Adult/Adolescent Units)

# Case Study – Strong Potassium Chloride

Drug scandal of the heartbreak families

DAILY MAIL

By DAVID WILLIAMS and STEPHEN GLOVER

TOUGH new rules to control a hospital drug may be introduced following a series of tragic blunders.

One baby died and another suffered severe brain damage after both were mistakenly injected at the same hospital with potassium chloride — a drug used to execute murderers in America.

VICTIM OF HOSPITAL BLUNDER

After the nightmare of little Nicola, more parents tell of tragic mistakes at hospital

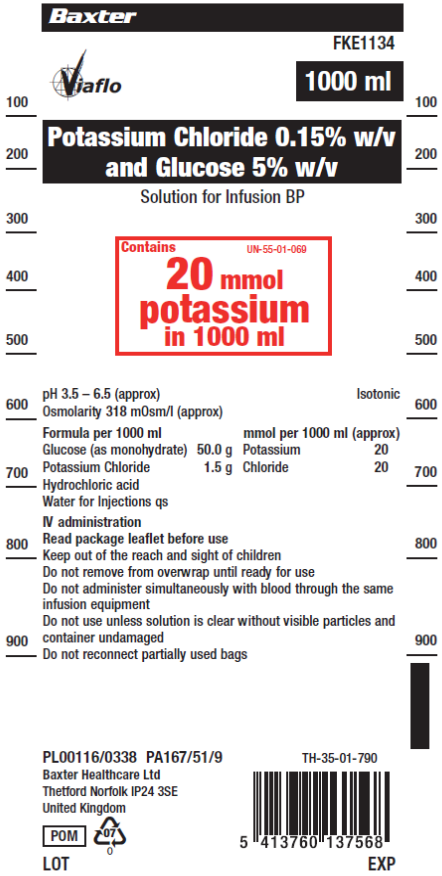
Nurse was suspended after pensioner died from poisonous dose of potassium

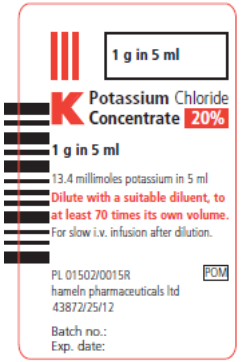
Patient 'unlawfully killed'

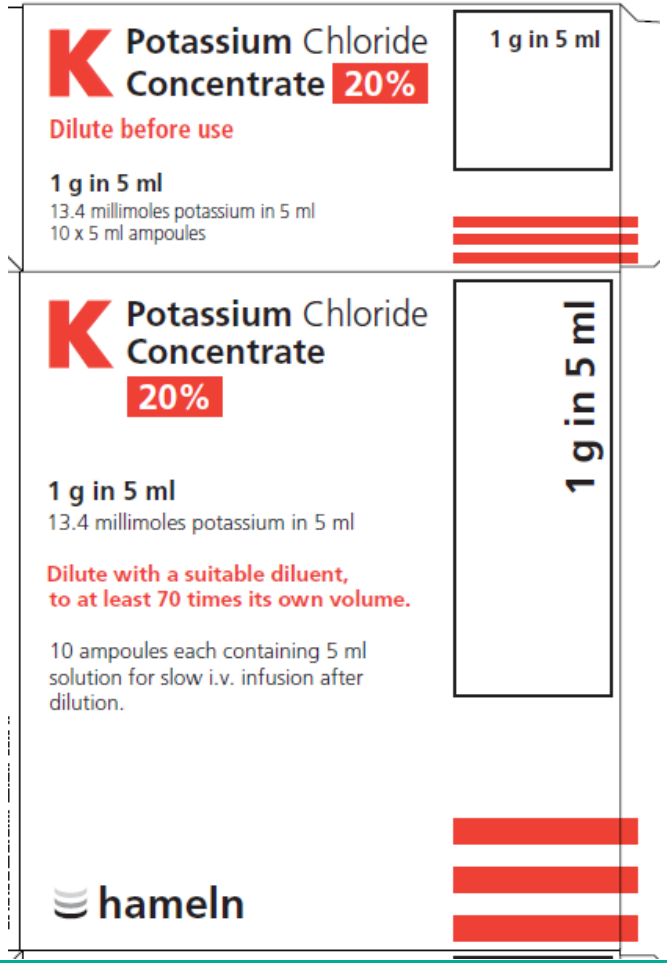
Patient given fatal injection in error

ACCOS+

Nurse fixed a lethal jab


Baxter
FKE1134
Viaflo
1000 ml
Potassium Chloride 0.15% w/v and Glucose 5% w/v
Solution for Infusion BP
Contains
UN-55-01-069
20 mmol potassium in 1000 ml
pH 3.5 – 6.5 (approx)
Isotonic
Osmolarity 318 mOsm/l (approx)
Formula per 1000 ml
Glucose (as monohydrate) 50.0 g
Potassium Chloride 1.5 g
Hydrochloric acid
Water for Injections qs
mmol per 1000 ml (approx)
Potassium 20
Chloride 20
IV administration
Read package leaflet before use
Keep out of the reach and sight of children
Do not remove from overwrap until ready for use
Do not administer simultaneously with blood through the same infusion equipment
Do not use unless solution is clear without visible particles and container undamaged
Do not reconnect partially used bags
PL00116/0338 PA167/51/9
TH-35-01-790
Baxter Healthcare Ltd
Thetford Norfolk IP24 3SE
United Kingdom
POM
07
0
5 413760 137568
LOT
EXP


1 g in 5 ml
Potassium Chloride
Concentrate 20%
1 g in 5 ml
13.4 millimoles potassium in 5 ml
Dilute with a suitable diluent, to at least 70 times its own volume.
For slow i.v. infusion after dilution.
PL 01502/0015R
hameln pharmaceuticals ltd
43872/25/12
POM
Batch no.:
Exp. date:


Potassium Chloride
Concentrate 20%
Dilute before use
1 g in 5 ml
13.4 millimoles potassium in 5 ml
10 x 5 ml ampoules
1 g in 5 ml
Potassium Chloride
Concentrate
20%
1 g in 5 ml
13.4 millimoles potassium in 5 ml
Dilute with a suitable diluent,
to at least 70 times its own volume.
10 ampoules each containing 5 ml
solution for slow i.v. infusion after
dilution.
1 g in 5 ml
hameln

# Other Risk Minimisation Measures

- Strong KCl only held in certain clinical areas
- Accredited prescribers only
- Treated as a controlled drug
- Second check

ORIGINAL ARTICLE

# Evaluation of the implementation of the alert issued by the UK National Patient Safety Agency on the storage and handling of potassium chloride concentrate solution

A J Lankshear, T A Sheldon, K V Lowson, I S Watt, J Wright

*Qual Saf Health Care* 2005;**14**:196–201. doi: 10.1136/qshc.2004.011874

See end of article for authors' affiliations

Correspondence to: Dr A J Lankshear, Department of Health Sciences, Seebohm-Rowntree Building, University of York, York YO10 5DD, UK; al25@york.ac.uk

Accepted for publication 5 April 2005

**Objectives:** To assess the effectiveness of the response of NHS hospital trusts to an alert issued by the National Patient Safety Agency designed to limit the availability of concentrated potassium chloride in hospitals in England and Wales, and to determine the nature of any unintended consequences.
**Design:** Multi-method study involving interviews and a physical inspection of clinical areas.
**Setting:** 207 clinical areas in 20 randomly selected acute NHS trusts in England and Wales between 31 October 2002 and 31 January 2003.
**Participants:** Senior managers and ward based medical and nursing staff.
**Main outcome measures:** Degree of staff awareness of and compliance with the requirements of the national alert, withdrawal of concentrated potassium chloride solutions from non-critical areas, provision of pre-diluted alternatives, storage and recording in accordance with controlled drug legislation.
**Results:** All trusts required that potassium chloride concentrate be stored in a separate locked cupboard from common injectable diluents (100% compliance). Unauthorised stocks of potassium chloride were found in five clinical areas not authorised by the trust (98% compliance). All trusts required documentation control of potassium chloride concentrate in clinical areas, but errors were recorded in 20 of the 207 clinical areas visited (90% compliance). Of those interviewed, 78% of nurses and 30% of junior doctors were aware of the alert.
**Conclusions:** The NPSA alert was effective and resulted in rapid development and implementation of local policies to reduce the availability of concentrated potassium chloride solutions. The success is likely to be partly due to the nature of the proposed changes and it cannot be assumed that future alerts will be equally effective. Continued vigilance will be necessary to help sustain the changes.

# Case Study - penicillins

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NEWS

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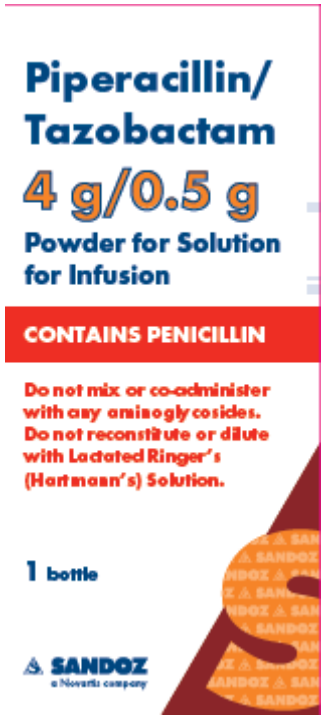
Health

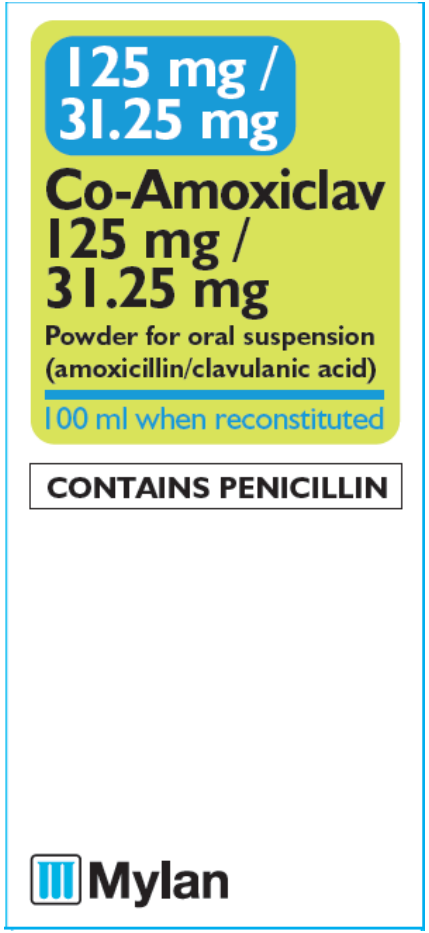
## Severe allergic reactions in surgery 'caused by antibiotics'

14 May 2018 Share


Antibiotics are the main cause of life-threatening allergic reactions during surgery, a new report suggests.


Piperacillin/
Tazobactam
4 g/0.5 g
Powder for Solution
for Infusion
CONTAINS PENICILLIN
Do not mix or co-administer with any aminoglycosides. Do not reconstitute or dilute with Lactated Ringer's (Hartmann's) Solution.
1 bottle
SANDOZ
a Novartis company


Co-fluampicil
250mg/250mg
Hard Capsules
ampicillin/flucloxacillin
Contains Penicillin
For oral use
WOCKHARDT
28 Capsules


125 mg /
31.25 mg
Co-Amoxiclav
125 mg /
31.25 mg
Powder for oral suspension
(amoxicillin/clavulanic acid)
100 ml when reconstituted
CONTAINS PENICILLIN
Mylan

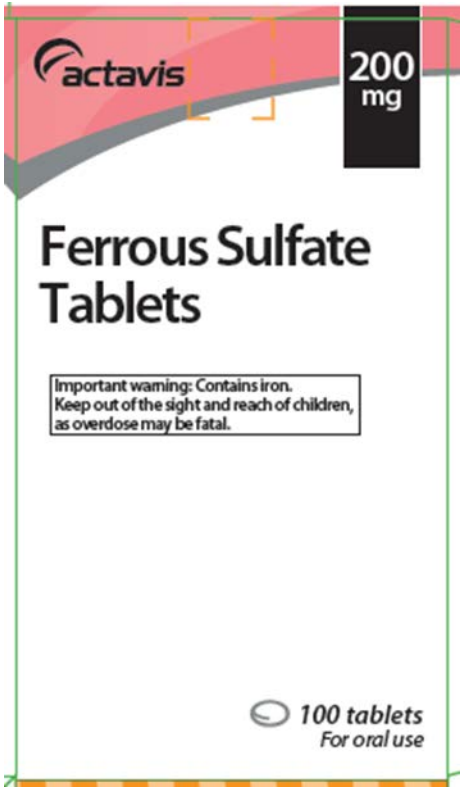
# Other Risk Minimisation Measures

- Patients should carry an ‘alert card’
- Clinicians to take a full history
- Confirmed allergy to be documented



NEW
ADVICE FOR DRIVERS
See leaflet inside
30mg in 1ml
Morphine Sulfate
Injection 30mg in 1ml
CAUTION: HIGH DOSE
Solution for Injection
For intramuscular, intravenous or subcutaneous injection
Protect from light
Please read ampoule label carefully
POM
CD
10 x 1ml ampoules


32 effervescent tablets
Ultramol
Soluble
Paracetamol, Codeine and Caffeine
Can cause addiction
For 3 days use only
For effective
pain relief


actavis
200 mg
Ferrous Sulfate Tablets
Important warning: Contains iron.
Keep out of the sight and reach of children, as overdose may be fatal.
100 tablets
For oral use


100 TABLETS
Hospira
Methotrexate
2.5 mg Tablets
2.5 mg
For Oral Use
Check dose and frequency
Methotrexate is usually taken once a week
Read the package leaflet before use

# Future work

News › Health

## NHS medication errors contribute to as many as 22,000 deaths a year, major report shows

'The long lasting solution to this is a properly funded NHS with enough staff to deliver safe patient care,' NHS leaders say

Alex Matthews-King Health Correspondent | Friday 23 February 2018 01:16 | 15 comments

## Medication errors in England

# 237 million

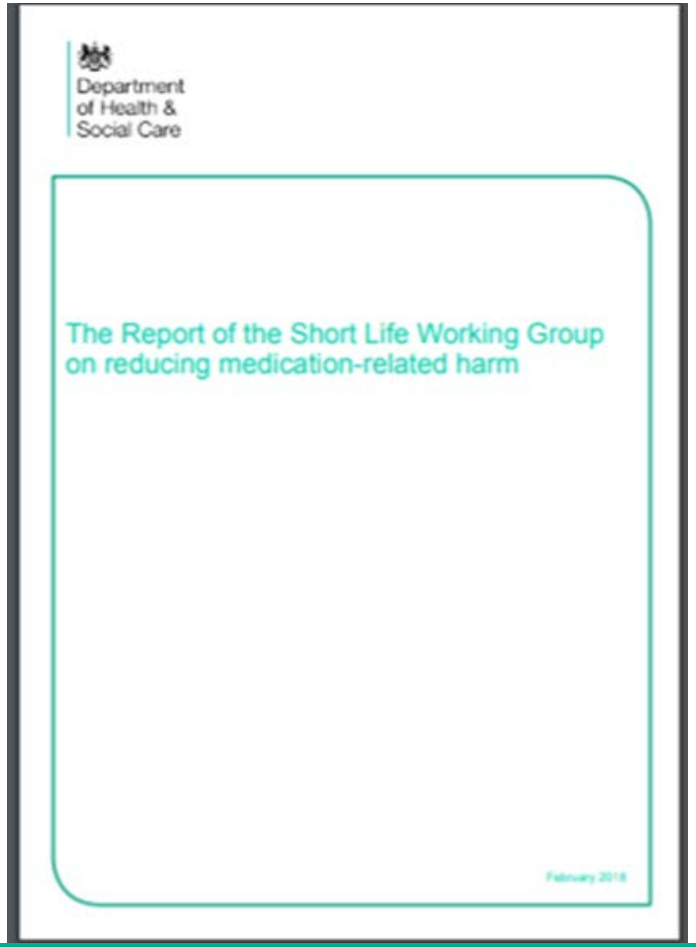
drug mistakes are made each year

**28%** could cause moderate or severe harm

**700** deaths caused by errors

**22,300** more deaths could be related to mistakes

Source: Manchester, York and Sheffield Universities

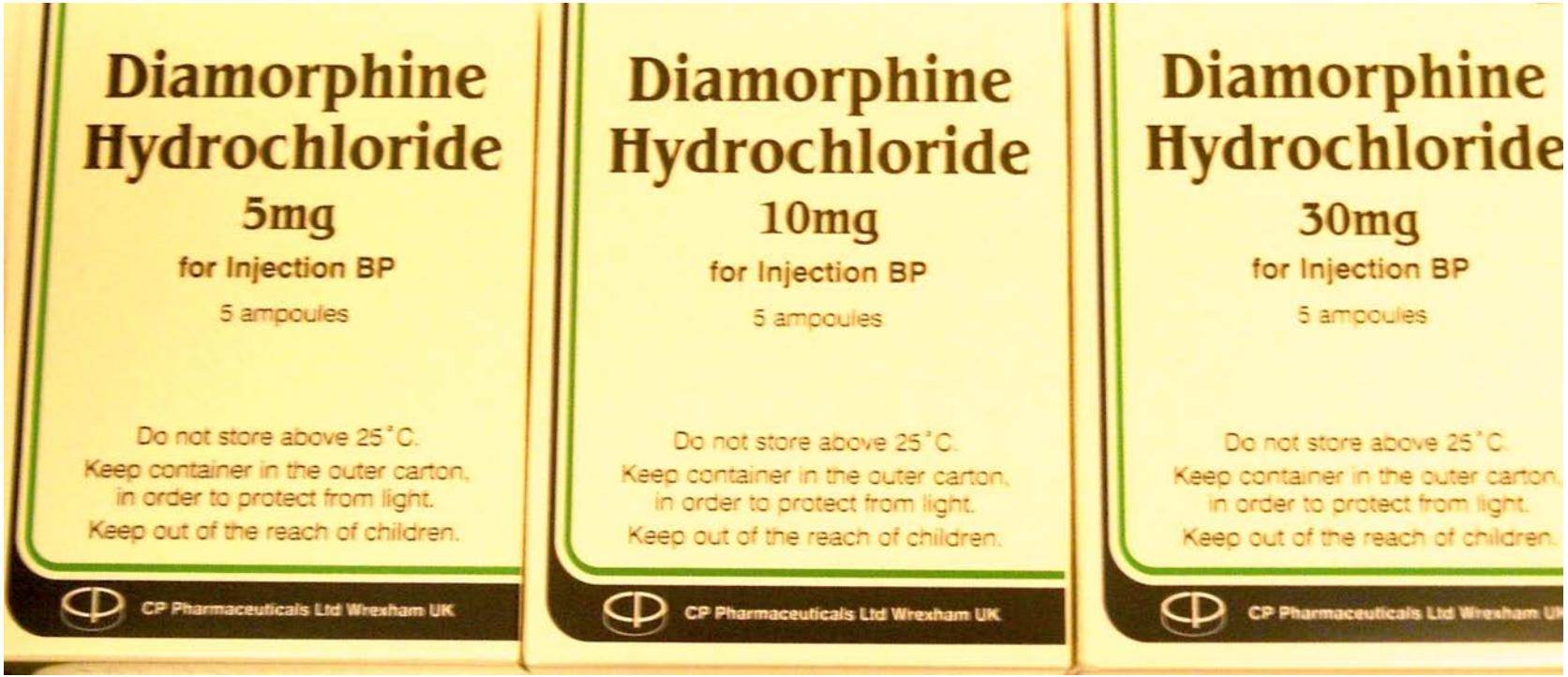

Department
of Health &
Social Care
The Report of the Short Life Working Group
on reducing medication-related harm
February 2018

- Patients – shared decision-making, improved information and empowerment
- Medicines – labelling to contribute to safer use
- Healthcare professionals – reporting and learning; repository of good practice; training
- Systems and practice – e-prescribing; primary care interventions; metrics; research

# Questions

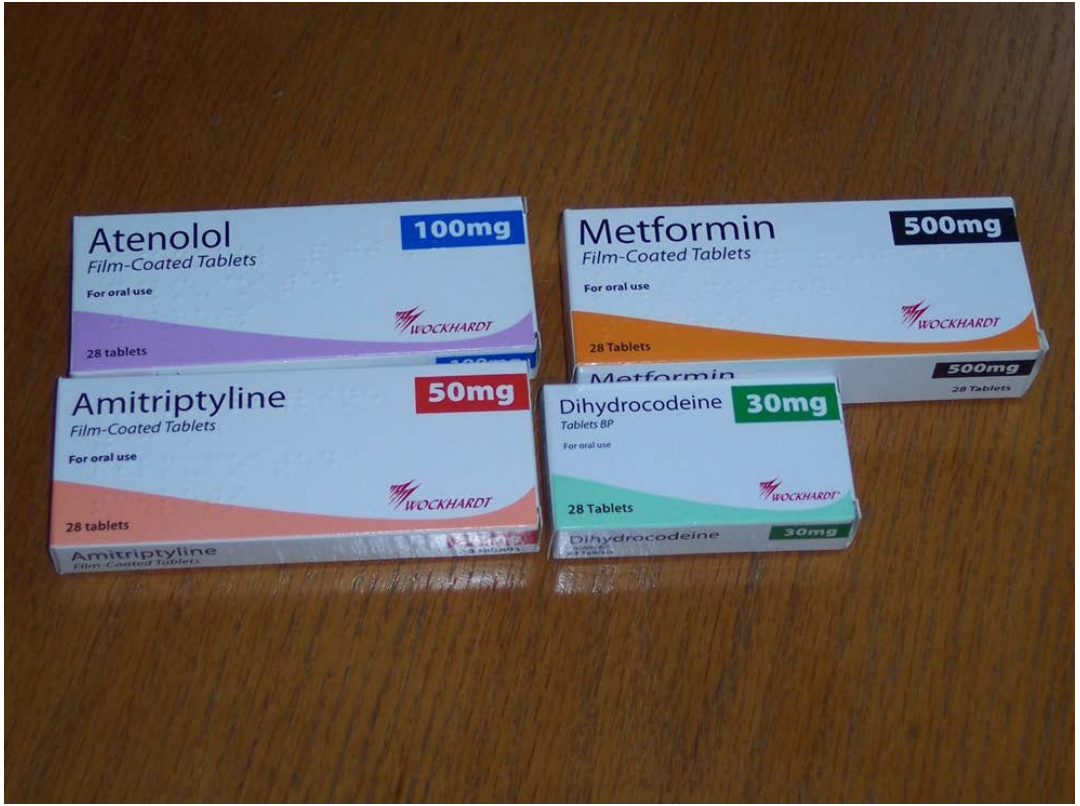
# Back-up slides

# Look- alike packaging - Before


Diamorphine Hydrochloride
5mg
for Injection BP
5 ampoules
Do not store above 25˚C.
Keep container in the outer carton, in order to protect from light.
Keep out of the reach of children.
CP Pharmaceuticals Ltd Wrexham UK
Diamorphine Hydrochloride
10mg
for Injection BP
5 ampoules
Do not store above 25˚C.
Keep container in the outer carton, in order to protect from light.
Keep out of the reach of children.
CP Pharmaceuticals Ltd Wrexham UK
Diamorphine Hydrochloride
30mg
for Injection BP
5 ampoules
Do not store above 25˚C.
Keep container in the outer carton, in order to protect from light.
Keep out of the reach of children.

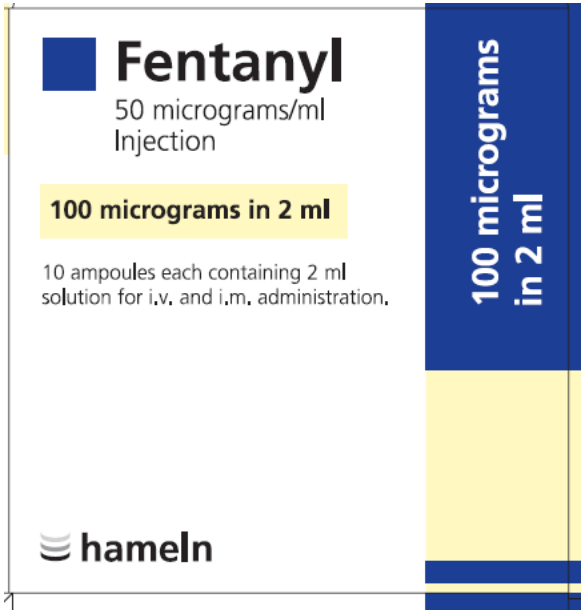
# After

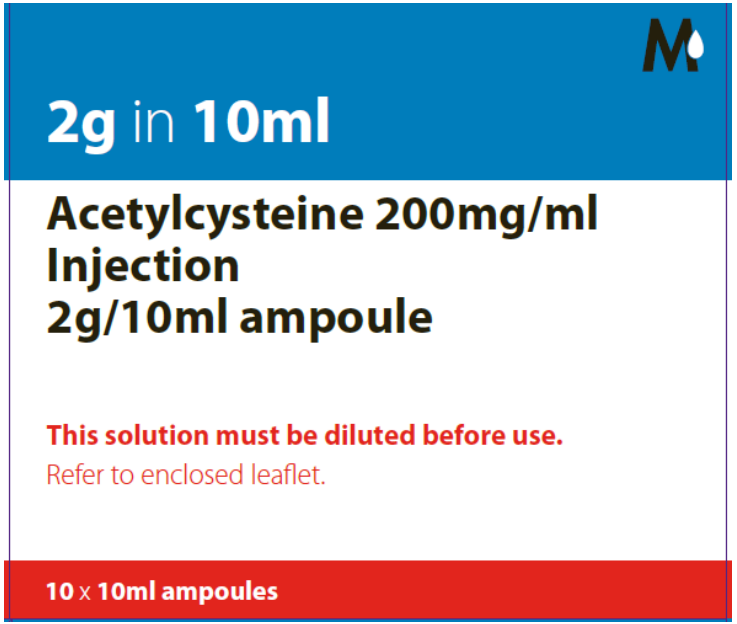

actavis
15 mg
Lansoprazole
Gastro-resistant capsules
28 capsules
For oral use
Lansoprazole
Gastro-resistant capsules
actavis
850 mg
Metformin Tablets
Metformin hydrochloride
56 Film-Coated Tablets
Metformin Tablets
Metformin hydrochloride
850 mg
actavis
3.75 mg
Zopiclone Tablets
28 tablets
For oral use
28 tablets
actavis
Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal.
200 mg
Ferrous Sulphate Tablets
(White sugar-coated)
28 tablets
For oral use
actavis
10
500 mg
Co-dydramol Tablets
(Dihydrocodeine Tartrate and Paracetamol)
Contains paracetamol. Do not take with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.
30 tablets
For oral use
Co-dydramol Tablets
30 tablets


Atenolol
Film-Coated Tablets
100mg
For oral use
28 tablets
WOCKHARDT
Metformin
Film-Coated Tablets
500mg
For oral use
28 Tablets
WOCKHARDT
500mg
28 Tablets
Amitriptyline
Film-Coated Tablets
50mg
For oral use
28 tablets
WOCKHARDT
Amitriptyline
Dihydrocodeine
Tablets BP
30mg
For oral use
28 Tablets
WOCKHARDT
Dihydrocodeine
30mg


Amitriptyline
10 mg Tablets
10 mg
Bendroflumethiazide
2.5 mg Tablets
2.5 mg
Bumetanide
1 mg Tablets
1 mg
Nazdol MR
30 mg Modified-Release Tablets
Gliclazide
30 mg
Simvastatin
40 mg Film-Coated Tablets
For Oral Administration
40 mg
Loratadine
10 mg Tablets
Non-Drowsy
Fast acting
10 mg
Amlodipine
10 mg Tablets
amlodipine maleate
10 mg
Levothyroxine
Tablets BP 50 mcg
For Oral Administration
50 mcg
Lisinopril
20 mg Tablets
For Oral Administration
20 mg
Simvastatin
80 mg Film-Coated Tablets
For Oral Administration
80 mg
Levothyroxine
Tablets BP 100 mcg
For Oral Administration
100 mcg
Clomipramine
10 mg Capsules
For Oral Administration
10 mg

# Total strength in total volume



# Colour-coding – NO!

Judicious use of colour to help differentiate products in a portfolio.

Exception - warfarin


Warfarin
Tablets
28 tablets
1
mg


Warfarin
Tablets
28 tablets
3
mg


Warfarin
Tablets
28 tablets
5
mg