A universal labelling system for communicating the risks of hazardous drugs

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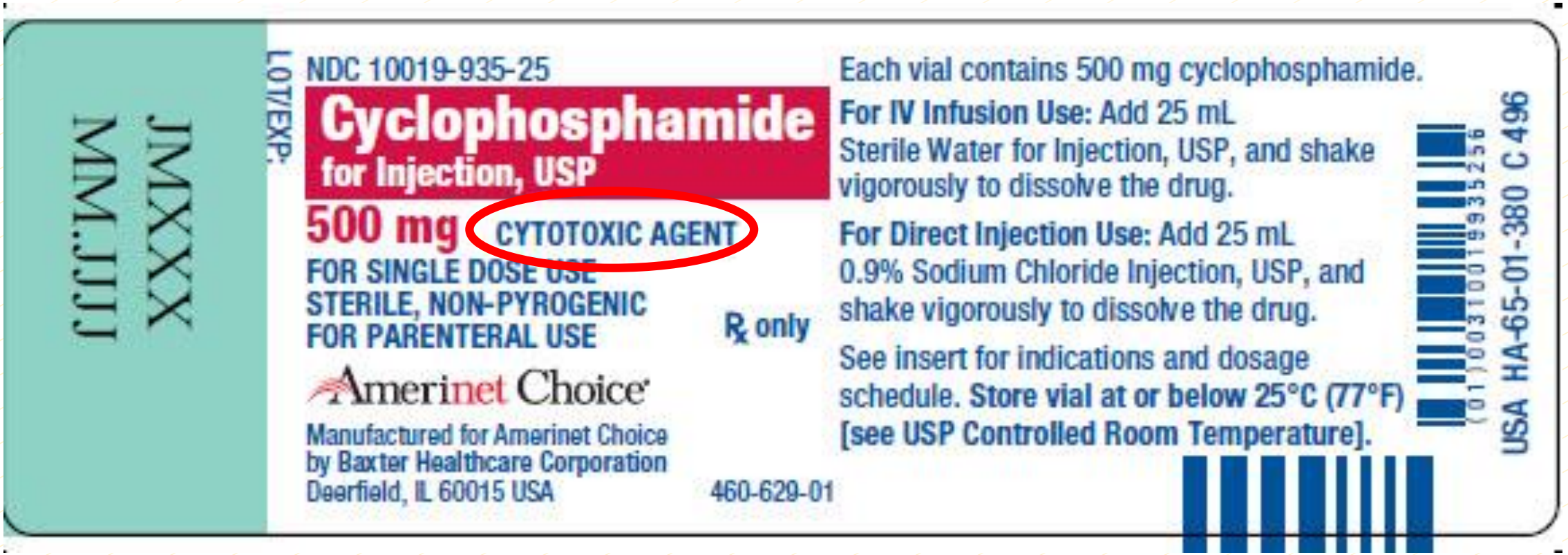
Background

- Danger posed by mishandled drugs often overlooked
  - Used in treatments for cancer, rheumatoid arthritis, lupus, nephritis, multiple sclerosis
- Lapse in handling procedure can be dangerous, not reflected by exterior label
  - Practitioners may overlook due to large number of prescriptions handled
  - Patients may not understand jargon

Cyclophosphamide

- Requires use of impervious gloves when handling packaging
  - IARC Group 1 carcinogen; FDA Pregnancy Category D



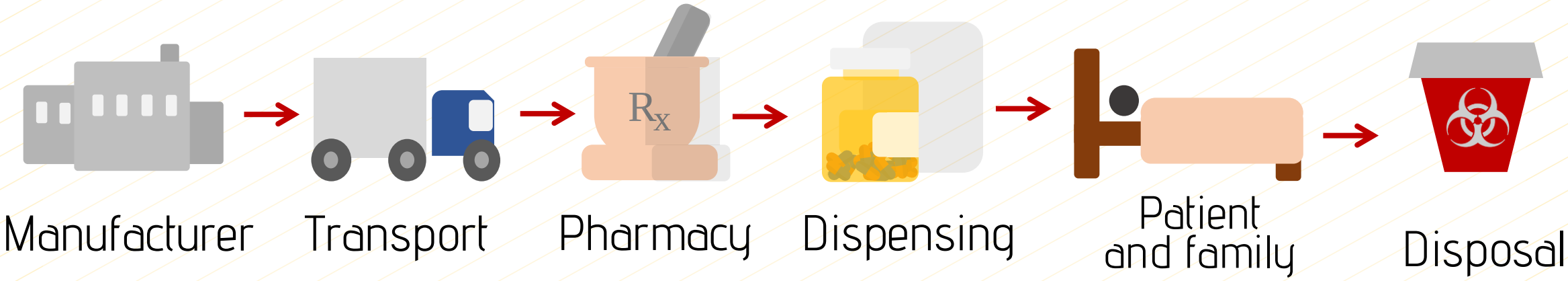
Azathioprine

- Azathioprine tablets – requires precautions when cut or crushed
  - ARC Group 1 carcinogen, FDA Pregnancy Category D

abacavir
alefacept
carbamazepine
apomorphine
azathioprine
cidofovir
cyclosporine
deferiprone
dexrazoxane
divalproex
entecavir
estradiol
fosphenytoin
ganciclovir
lefunomide
lenalidomide
liraglutide
spironolactone
oxcarbazepine
palifermin
paliperidone
phenytoin
pipobroman
progrestrone
raloxifene
risperidone
sirolimus
teriflunomide
thalidomide
tofacitinib
valganciclovir
zidovudine
ambrisentan
bosentan
cetrorelix
clomiphene
clonazepam
colchicine
dronedarone
dutasteride
fluconazole
ganirelix
icatibant
lomitapide
macitentan
mifepristone
misprostol
oxytocin
paroxetine
pasireotide
peginesatide
plerixafor
ribavirin
riociguat
telavancin
temazepan
topiramate
valproate
voriconazole
warfarin
ziprasidone
zonasamide

Over 200 different drugs are considered hazardous

Problem


Rx
Manufacturer
Transport
Pharmacy
Dispensing
Patient and family
Disposal

As many as

8 million healthcare workers

have the opportunity for hazardous drug exposure in the workplace

-NIOSH/CDC, 2016

Proposed solution

- Clear display of whether a drug is hazardous
- Two labelled categories
  - Infant icon = pregnancy risk
  - Exclamation mark = general risk (all individuals)
- Intentionally simplistic – conveys presence of danger
- Encourages careful handling, deference to appropriate safety procedure

100 Tablets NDC 65483-590-10

IMURAN®

(AZATHIOPRINE)

Each scored tablet contains

50 mg

R_x Only

PROMETHEUS LABORATORIES INC.

Manufactured by Pharmaceutics International, Inc.,
Hunt Valley, MD 21031 for Prometheus Laboratories Inc.,
San Diego, CA 92121

LOT

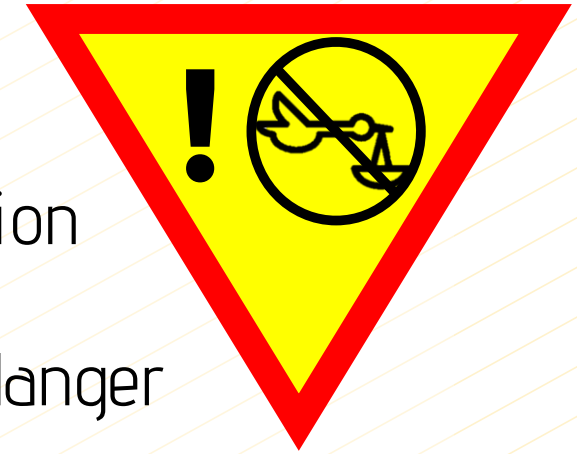
EXP

For indications, dosage, precautions, etc., see accompanying package insert. Store at 20° to 25°C (USP Controlled Room Temperature) (68° to 77°F) in a dry place and protect from light. Dispense in tight, light-resistant container as defined in the USP.

Made in U.S.A. IM001D Rev. 01/14

N 65483590104

Rationale



- Attention getting, universally understandable
  - Healthcare background not required for comprehension
- Inverted triangle was found to best convey a sense of danger
  - Activates amygdala
  - Unconsciously interpreted as danger, attracts attention to label
- Red and yellow chosen due to natural association with danger
- Presence of label makes danger more concrete than a description does

Sources

- OSHA on hazardous drugs

https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html

- Risk of exposure to hazardous drugs

http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume92004/No3Sept04/HazardousDrugs.aspx#USCommerce

https://www.cdc.gov/niosh/topics/hazdrug/default.html

- Cyclophosphamide package insert

http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/012141s090,012142s112lbl.pdf

- Handling of antineoplastic drugs

http://hemaonco.tmu.edu.tw/teachingbank/safe_handling/data/proper_technique.html

- Shapes that capture attention

http://www.mitpressjournals.org/doi/abs/10.1162/jocn.2009.21111

http://psycnet.apa.org/journals/emo/7/3/526/

http://www.sciencedirect.com/science/article/pii/S0031938414003953

adjusted in accord with evidence of antitumor activity and/or leukopenia. The total leukocyte count is a good, objective guide for regulating dosage.

When cyclophosphamide is included in combined cytotoxic regimens, it may be necessary to reduce the dose of cyclophosphamide as well as that of the other drugs.

2.2 Dosing for Minimal Change Nephrotic Syndrome in Pediatric Patients

An oral dose of 2 mg per kg daily for 8 to 12 weeks (maximum cumulative dose 168 mg per kg) is recommended. Treatment beyond 90 days increases the probability of sterility in males *[see Use in Specific Populations (8.4)]*.

2.3 Preparation, Handling and Administration

Handle and dispose of cyclophosphamide in a manner consistent with other cytotoxic drugs.[1] Caution should be exercised when handling and preparing Cyclophosphamide for Injection, USP (lyophilized powder), or bottles containing cyclophosphamide tablets. To minimize the risk of dermal exposure, always wear gloves when handling vials containing Cyclophosphamide for Injection, USP (lyophilized powder), or bottles containing cyclophosphamide tablets. The coating of the cyclophosphamide tablets prevents direct contact of persons handling the tablets with the active substance. However, to prevent inadvertent exposure to the active substance, the cyclophosphamide tablets should not be cut, chewed, or crushed. Personnel should avoid exposure to broken tablets. If contact with broken tablets occurs, wash hands immediately and thoroughly.

Cyclophosphamide for Injection, USP

Intravenous Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use cyclophosphamide vials if there are signs of melting. Melted cyclophosphamide is a clear or yellowish viscous liquid usually found as a connected phase or in droplets in the affected vials.

Cyclophosphamide does not contain any antimicrobial preservative and thus care must be taken to assure the sterility of prepared solutions. Use aseptic technique.

For Direct Intravenous Injection

Reconstitute Cyclophosphamide with 0.9% Sodium Chloride Injection, USP only, using the volumes listed below in Table 1. Gently swirl the vial to dissolve the drug completely. Do not use Sterile Water for Injection, USP because it results in a hypotonic solution and should not be injected directly.

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Cyclophosphamide injection package insert