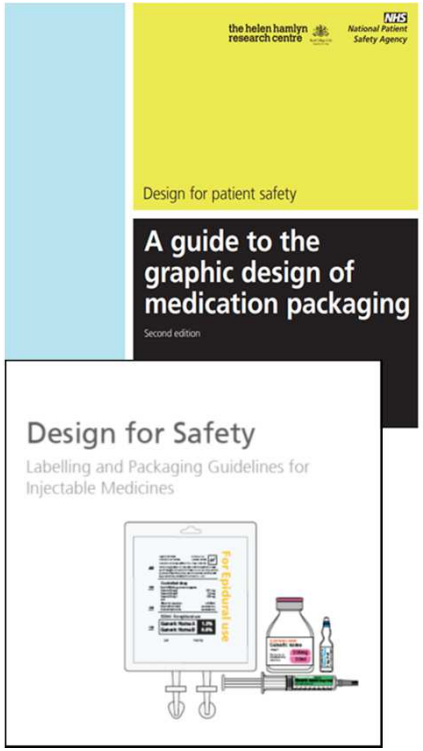
Discussion on producing IMSN guidance on safer labelling and packaging of medicines

Discussion led by David Cousins (UK)

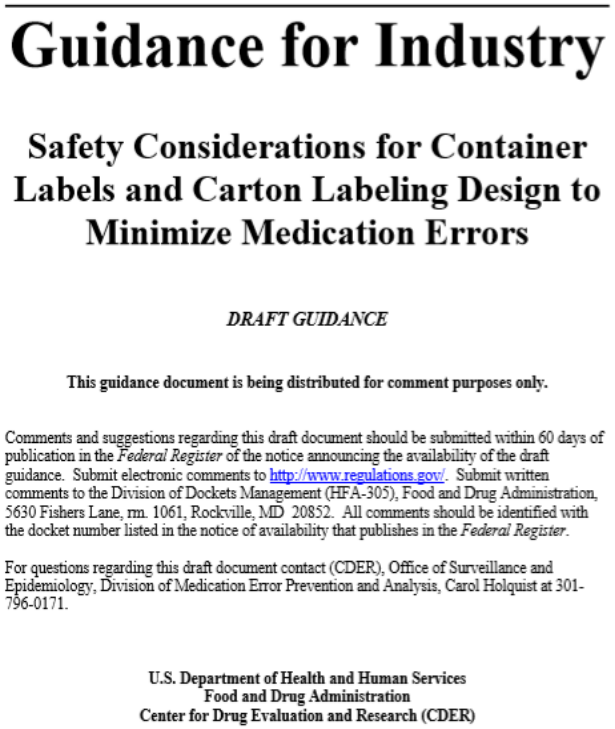
Participants agreed that guidelines are needed regarding the presentation of critical label information to deal with look-alike labels, noting that logos and highly stylized graphics detract from readability of the label. They also suggested review of existing guidelines and consideration of the following best practices related to drug labelling and packaging:

What do we need to produce?
There is a lot of national guidance already



2006

2016



2013

Targeted ***International*** best practice for safe labelling and packaging of prescription medicines

The top 10 practices

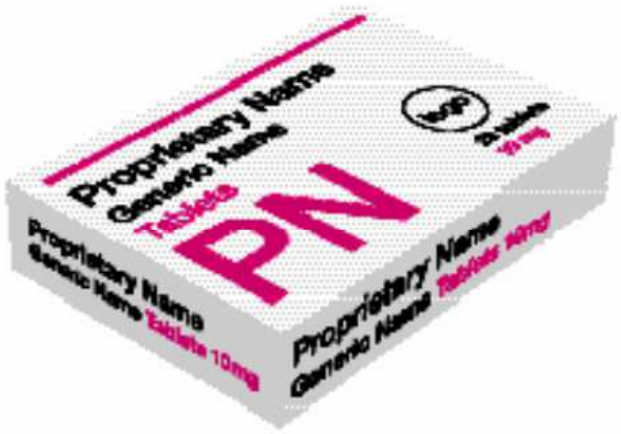
With reference to more comprehensive and detailed national guidance

Missing best practice statements?

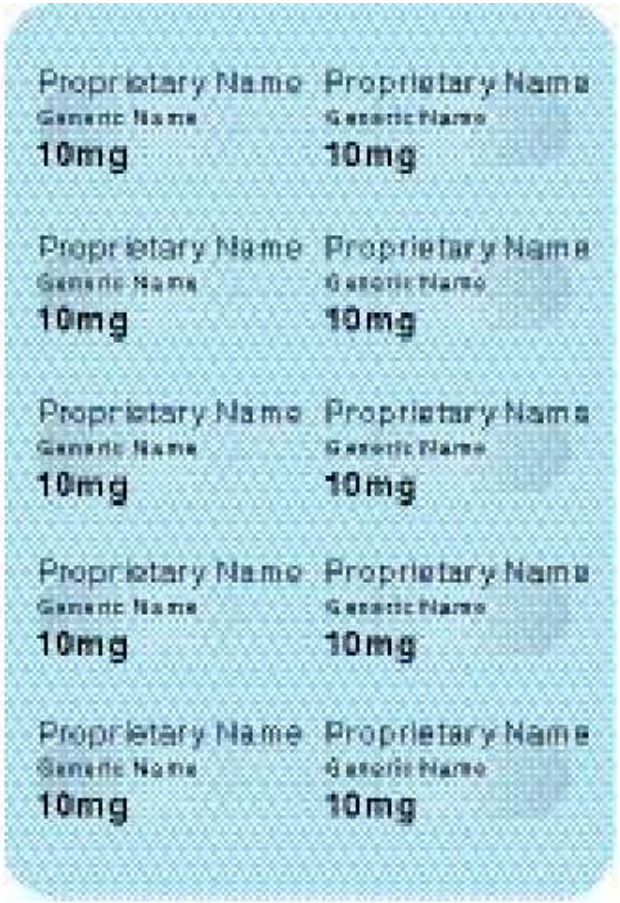
Product differentiation by use of colour and design

Identify critical information, font size and spacing

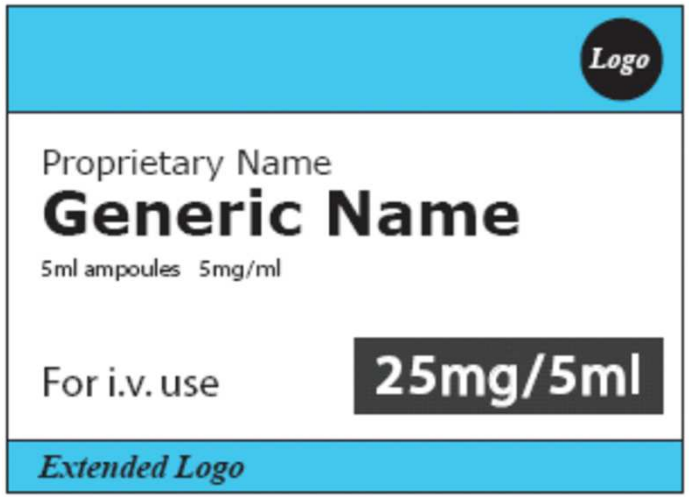
Put critical information in the same field of vision on at least three non opposing faces



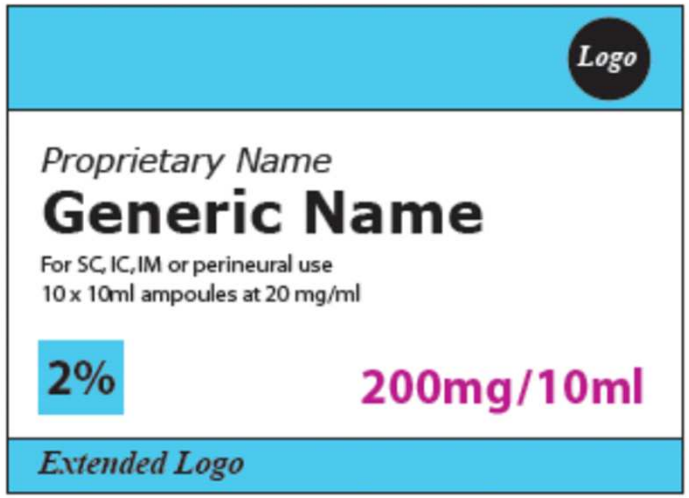
Secondary packaging



1. Include both the per mL and the per container quantity, not the per mL quantity alone, when presenting the concentration for injectables



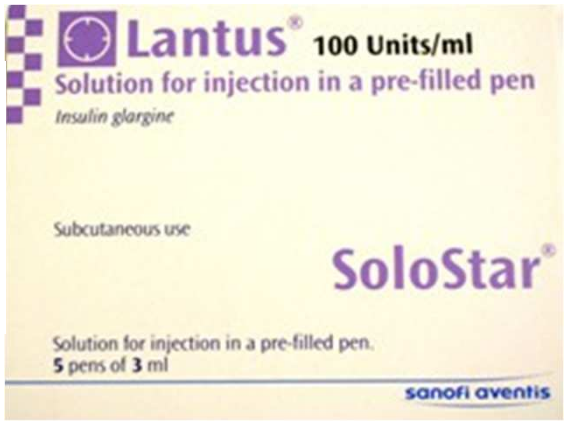
2. Use metric units for products, and eliminate ratio expressions



3. Eliminate potentially error-prone abbreviations and dose designations on labels, such as U for units, IU for international units, or trailing zeros (e.g., 1.0) to express strength

X

Yes



4. Prominently display cautionary statements on carton and immediate container labels of neuromuscular blockers, potassium chloride concentrate injection, methotrexate, and other selected error-prone medications

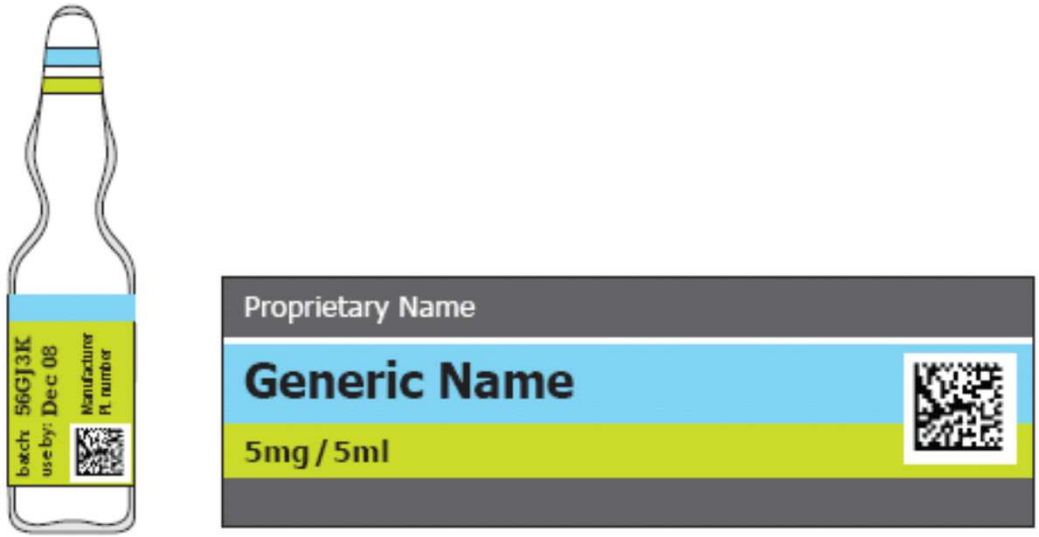
5. Use contrasting label backgrounds for the printing on glass ampules, and recommend font size and label orientation, to improve readability

6. Physically link or integrate diluents with drugs that are powders

7. Increase the adoption of ready-to-use/ready-to-administer syringes, premixed IV solutions, unit-dose packaging, and other more efficient, safer packaging, while considering the overall cost of implementation

8. Develop product-specific world safety standards; for example, standard packaging for non-oncologic methotrexate to prevent accidental daily use and overdoses

9. Include barcodes on packages so they can be scanned at the bedside or other locations where medications are dispensed or administered by healthcare providers



EU – Falsified Medicines Directive

Anti-tampering device

Safety features

Unique Identifier

What information is encoded in the unique identifier?

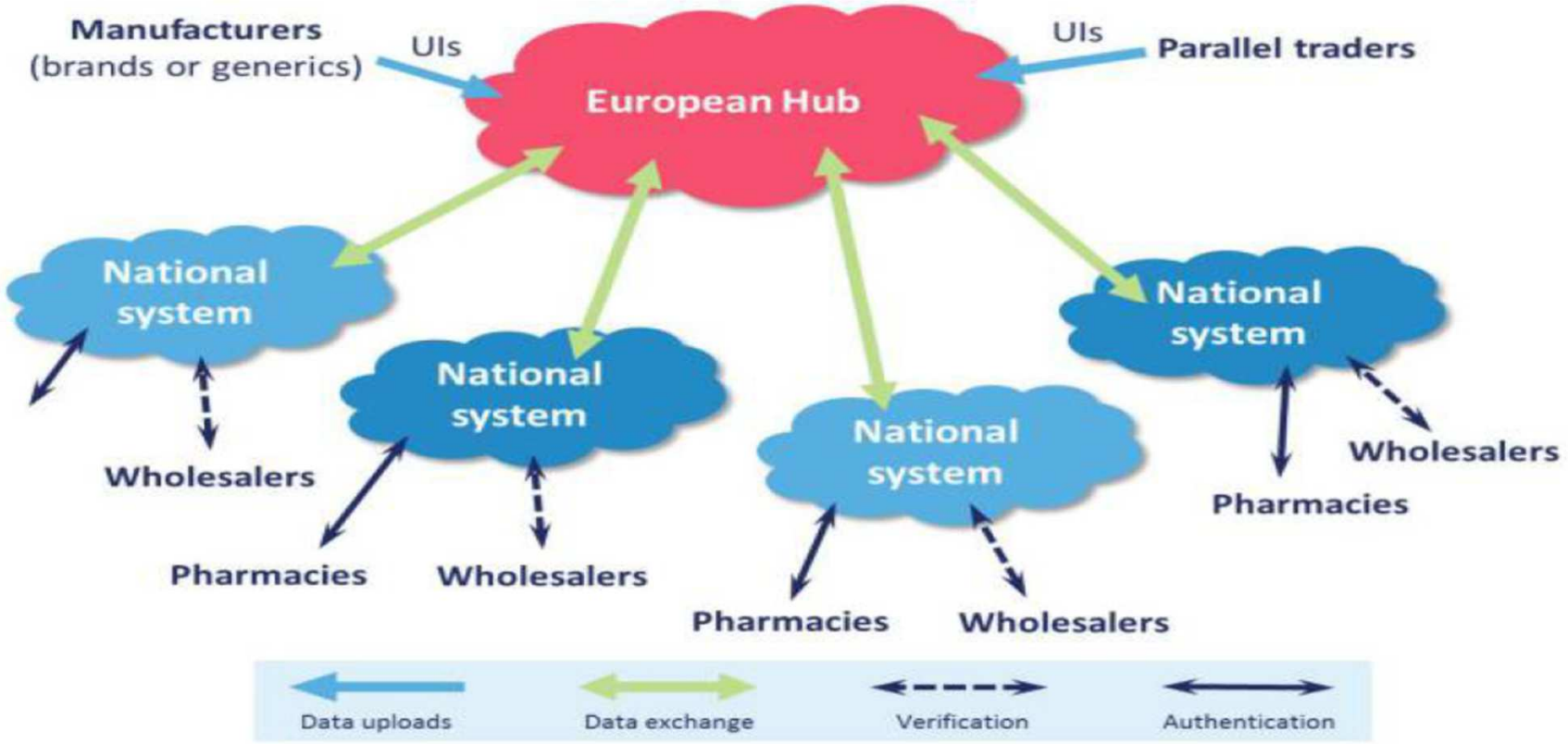
Each individual pack of a prescription medicine will need to carry a **unique identifier** (UI) encoded via a 2D data matrix (barcode). If the pack size permits it, the pack will also carry the same information in human-readable text, printed adjacent to the 2D-code where possible.

The unique identifier will consist of [Article 4]:

- **Product code**: the name, common name, pharmaceutical form, strength, pack size and pack type
- **Serial number**: randomised numeric or alphanumeric sequence of up to 20 characters
- **National reimbursement number**: national identifying code, if required by Member State [note: unlikely to be used in UK]
- **Batch number**
- **Expiry date**

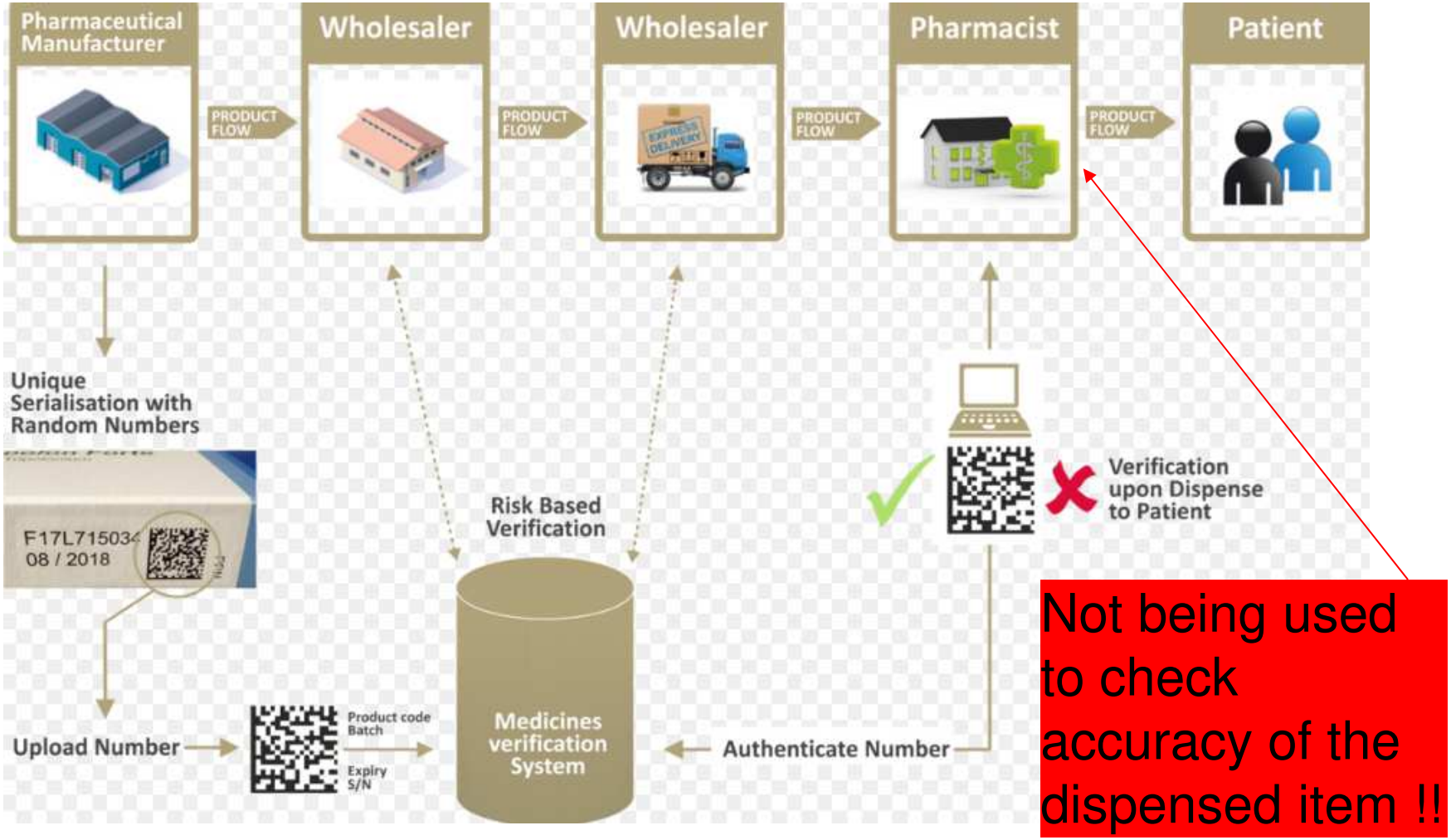
Because this information will be printed and encoded on every pack, it can also be used for some activities in pharmacy, such as stock re-ordering, stock rotation and accuracy checking.

EU Falsified Medicines Directive



Scanning and authentication of packs will come in to effect across Europe from **Saturday 9th February 2019**, following the publication of a Delegated Regulation [2016/161] which set out details for the unique identifiers, the national verification systems and the responsibilities of manufacturers, wholesalers and pharmacies.

The EU Falsified Medicines Directive



New Focus For IMSN

Good Clinical Medication Practice

Health Care Provider Regulators and Accreditation Organisations