Naming, labelling and packaging of medicines put patients at risk.
Experiences from SPAIN

Dra. María José Otero
Instituto para el Uso Seguro de los Medicamentos (ISMP-Spain)

*IMSN Paris Conference on Safer Naming, Labelling and Packaging of Medicines*
*Paris, 10 October 2013*
Objective: “Learning effectively from failures”

Supported by the Spanish Ministry of Health through its Patient Safety Strategy.

Collaborate with the Spanish Medication Agency

Reporting ways:
- Web-based reporting form
- Electronic reporting from local organizations through a computer application
- Other systems: E-mail, telephone
Since 2001. Collaboration agreement between AEMPS and ISMP-Spain:

Send medication error reports (without & with harm) filtered and analyzed, with proposals for solutions, about errors related to:

- **Labelling and packaging**, naming, product information, administration devices, shortages, etc.
Major Naming, Labelling and Packaging Problems

- **Look-alike sound-alike drug names**
  - Brand names
  - INN names
  - Brand names and INN names

- **Similarities in packaging and labelling appearance**
  - Different drugs
  - Different dosage strengths of the same product

- **Unclear, ambiguous or incomplete labelling**
  - Unclear strength designation
    - Use of percentages, use of concentration, etc.
  - Poor readability of label information
    - Cluttered labelling, small font, lack of adequate background contrast, etc.
Examples of naming problems

► **Look-alike sound-alike drug names**

- **Confusion between brand names**
  - Aricept- Azilect
  - Luminal- Sumial
  - Humalog- Humalog basal- Humalog mix
  - Oxynorm-Oxycontin

- **Confusion between generic names**
  - doxorubicina- epirubicina
  - hidroxicarbamida- hidroxocobalamina
  - metamizol- metronidazol
  - metotrexa- metronidazol

- **Confusion between brand and generic names**
  - Rohipnol-ropirinol
  - Sandostatin- somatostatina
Feedback: LASA drug names list, TML list, name finder and recommendations
Examples of labelling and packaging problems

► Similarities in packaging and labelling (different drugs)/inadequate prominence of manufacturer name:
Examples of labelling and packaging problems

- Similarities in packaging and labelling (different drugs) /
  poor readability:
Examples of labelling and packaging problems

► Similarities in packaging and labelling (different dosage strengths)
Examples of labelling and packaging problems

► Unclear strength designation: use of percentages
Examples of labelling and packaging problems

- Unclear strength designation: use of concentration
Examples of labelling and packaging problems

► Unclear strength designation: use of concentration
Examples of labelling and packaging problems

Unclear strength designation: use of concentration

**TINZAPARIN LABEL CHANGES IN RESPONSE TO MEDICATION INCIDENT REPORTS**

Two cases from the database of the Institute for Safe Medication Practices Canada (ISMP Canada) outlined problems with labelling for tinzaparin.

*Figure 3.* The manufacturer’s new label for the prefilled syringe now includes the generic drug name (tinzaparin sodium).

*CJHP – Vol. 58, No. 5 – November 2005*
6.5 Nature and contents of container

One pack contains one vial of concentrate and one vial of solvent:
- Concentrate: 1.5 ml of concentrate in a 15 ml clear glass vial (type I) closed with a grey chlorobutyl rubber closure sealed by an aluminium flip-off cap.
- Solvent: 4.5 ml of solvent in a 15 ml clear glass vial (type I) closed with a grey chlorobutyl rubber closure sealed by a gold colour aluminium cap.
Examples of labelling and packaging problems

► Initial labelling in USA:
A closing thought

Medicine labelling & packaging should speak a universal language, however there are international variations which may have important implications for patient safety.

► It is essential to establish international standards for labelling & packaging, and to promote and reinforce international cooperation and information sharing.
Thank you

ISMP-España

www.ismp-espana.org