CPC-076

INTERNAL AUDIT ON THE LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS (IMP)

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Background

The purpose of labelling is to protect persons who take part to clinical trials. It must permit to identify product, research and to make safe the use of the drugs. The decree of May 24th, 2006 [1] sets out informations to be included on the labelling of investigational medicinal products (IMP).

Objective

Assess regulatory conformity of IMP labelling's.

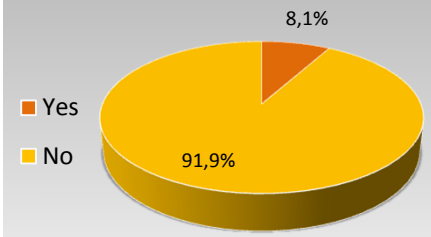
Materials and Methods

An assessment grid was established from the decree of May 24th, 2006.
This audit investigates the labelling of the primary or secondary packaging, according to the presentation, of **135 IMPs** corresponding to 75 clinical trials.

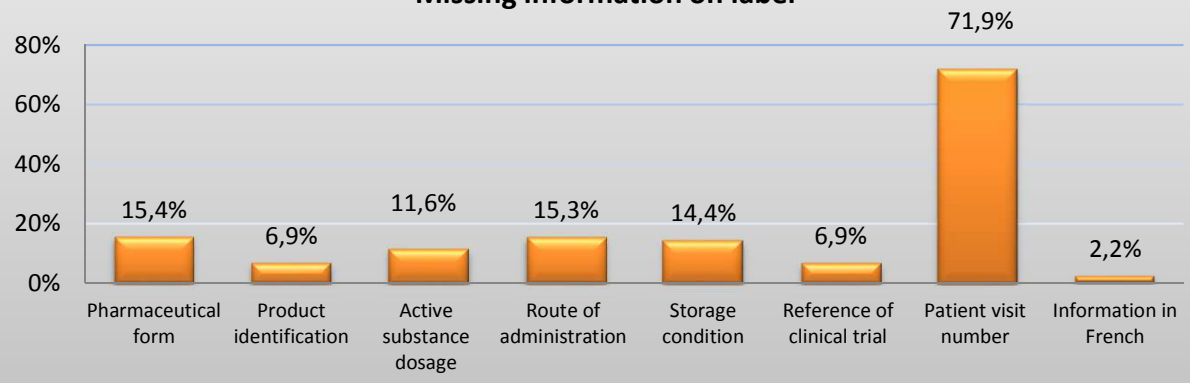
List of regulatory mentions

- Pharmaceutical form
- Route of administration
- Active substance dosage
- Batch number
- Expiry date
- Instructions
- Pickup unit number
- Storage condition
- Product identification
- Reference of clinical trial
- Sponsor address
- Sponsor phone number
- Investigator name
- Patient identification number
- Treatment number
- Patient visit number
- Presence of information in French
- Mention "Only for clinical trial use"

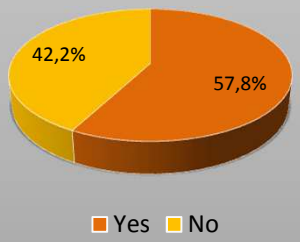
All regulatory mentions presence



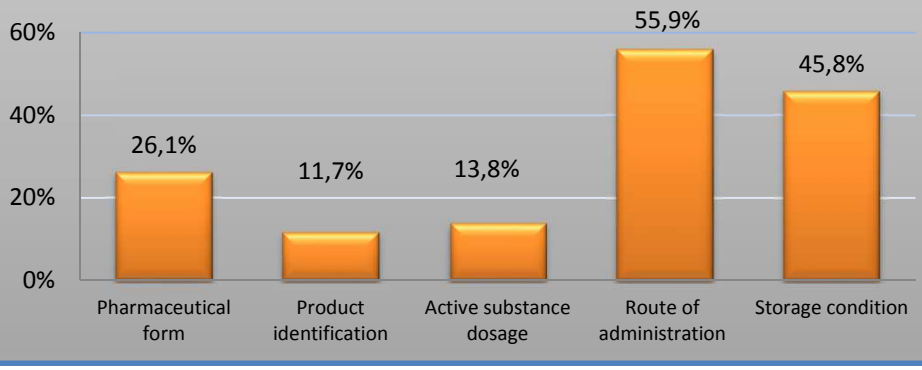
Missing information on label



Layer presence



Missing basic information on the first layer



Discussions and Conclusion

In spite of an important and rigorous regulation, we note non conformities on labelling with sometimes important omissions. A lot of informations have to appear on the label that's why sponsors reduce font size and present the labels with layers. This audit highlights that the large number informations present on the label make it difficult to read and can induce medication errors, especially in elderly patients.

[1] Order of May 24th, 2006 fixing the content of the labelling of investigational medicinal products published in France's official journal on May 30th, 2006