

ISPE Pictogram Task Team

Engagement presentation

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Janssen Clinical Supply Chain

One Team United With a Purpose for Patients



Task Team Members

- Rolf Baumgartner – Roche
- Gary Cunningham – BI
- Andy Dwyer – GSK
- Katrin Foerstner – Novartis
- Jason James – BMS
- Nadia Laouar – Novartis
- Audrey F Menzies – Catalent
- **Christine Milligan – Catalent**
- Katrien Moureau – Janssen
- Robert Smith – Consultant

The ISPE pictogram task team

What is the importance for Janssen

Janssen Project: Just in Time Labeling

Postpone the end customization of the Patient KIT as late as possible in the process : **in the distribution area just before shipping**



Impact on Label

Label /pack design changes are required to prevent opening KITs in the JIT stations

Example vials in a KIT carton



- Replace booklet on the primary pack by a **country agnostic single panel label**
- Roadmap :
 1. Introduce concept of “untranslatable label” **(ISPE) – implementation ongoing**
 2. Introduce concept of “universal label” (ISPE & TransCelerate)

REDESIGN PACKAGING

Co-creation with users



Survey
JANUARY – APRIL 2015

Janssen wants to incorporate users' feedback into a new design of packaging.

The major goal is to make the design more suited to users' needs and to ameliorate the proper and safe use of medicines.

LiCalab defined a detailed scenario for generative co-creation sessions with 4 groups of end users.

- 🌸 Patients
- 🌸 Nurses
- 🌸 Pharmacists
- 🌸 Prescribers

IMPROVE LABEL READABILITY

The sessions were conducted in 5 European countries

- 🌸 Belgium
- 🌸 Denmark
- 🌸 Italy
- 🌸 Slovenia
- 🌸 UK

Objectives:

- 🌸 What should the packaging of a medicine look like for it to be used correctly and safely, according to end users ?
- 🌸 What is the best placement and shape/format of the required information on the package ?
- 🌸 Which information gives added value to the package ?
- 🌸 What suggestions do the participants have to distinguish comparable product names ?
- 🌸 Which features of the package help to avoid mistakes ?
- 🌸 Sub-question (hospital) pharmacists, (home care) nurses, doctors :
 - what are the strong points of the package from various suppliers, especially on choice of material, colour, contrast and font ?

140 participants were involved in the research.

REDESIGN PACKAGING

Co-creation with users



Survey
JANUARY – APRIL 2015

Results:

The use of graphic elements is a good idea, especially to support

- The route of administration (e.g. not to be swallowed)
- Images for indication (e.g. headache, stomach)
- Generics. Patients as well as nurses would like a symbol for generic medicine. Also a difference in look&feel is preferable.
- Warnings (don't drive, keep out of reach of children)
- Storage information (keep in the refrigerator)
- Picture or photograph of the tablet on the front panel of the medicine

Graphic elements can support a proper and safe use, but only when it's in balance with the descriptive information

There is a need for an international convention of symbols to avoid misunderstandings.



PHARMACEUTICAL COMPANIES
OF *Johnson & Johnson*

Pharmaceutical Development & Manufacturing Sciences |

Pictogram Task Team Goals

1. Propose a pictogram classification

- Identify types pictogram in use in clinical supplies
- Identify pictogram databases/websites used by the industry
 - Consider the potential for pictograms on the minimum text label/untranslatable label
 - Consider a standard use of Roman Numerals
 - Look at potential for synergies for the use of pictogram from commercial packaging

2. Submit a questions on pictograms to the ISPE patient surveys

3. Provide output to the IP community

- Feedback the task team initial findings at ISPE annual meetings & other industry group meetings
- Prepare an ISPE knowledge brief to share with the Industry

ISPE Patient Surveys

The Pictogram task team were given access to add a question relating to Pictograms to the UK/EU ISPE Patient Survey.

We started by explaining Pictograms with two very common examples:

Definition: -A pictogram is a picture that explains without words an instruction.

Common examples are



No smoking



departures

The results are expected to be published in first half 2016 from NA, EU, Chinese and maybe Japanese surveys

Now, we'd like to ask the Clinical Supplies Forum to get involved and provide feedback!

Small Primary Label

- Consider the potential for pictograms on the primary packaging of small units with minimum text
- Transform into a small “untranslatable” label = no text to be translated
 - **Introduction of pictograms for route of administration**
- Secondary packaging bearing a label with those particulars shown in text format, combined with pictogram used on the primary label

Pilot Trial

Example untranslatable Label Proofs

Carton Label

Caution: New Drug - Limited by Federal (or United States) law to investigational use.
Protocol No.: VACXXXXX Product X 1×10^{11} vp/ml 1×0.5 ml suspension.

1) Med. No.:
2) Ref. No.: B213008
3)  For intramuscular injection.
Store at or below -60°C (-76°F).
Crucell Holland BV, Archimedesweg 4, 2333 CN Leiden, The Netherlands Tel +31 71 519 91 00
Local contact: see patient alert card.

4) Subject No.: _____
5) Name of investigator: _____
Use as directed by the protocol.
Keep out of reach of children.
Keep together with inner packaging.

Med. No.: VACXXXXX
Ref. No.: B213008

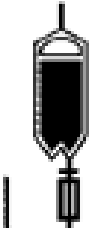
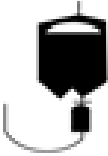
Vial Label

VACXXXXX
Product X 1×10^{11} vp/ml
0.5 ml

1)
2) B213008

3)  IM

Crucell Holland BV

Primary Labelling		
Symbol	Short meaning	Use
		Indicate Route of Administration
  or		Indicate Route of Administration
		Indicate Route of Administration
		Indicate Route of Administration
		Indicate Route of Administration
		Indicate Route of Administration
		Indicate Route of Administration
		Indicate Route of Administration

Meaning?

The pictograms from the ISPE booklet guide

Are these currently being used and if so with or without modification?

4 Good Practice Solutions

4.1 Standard

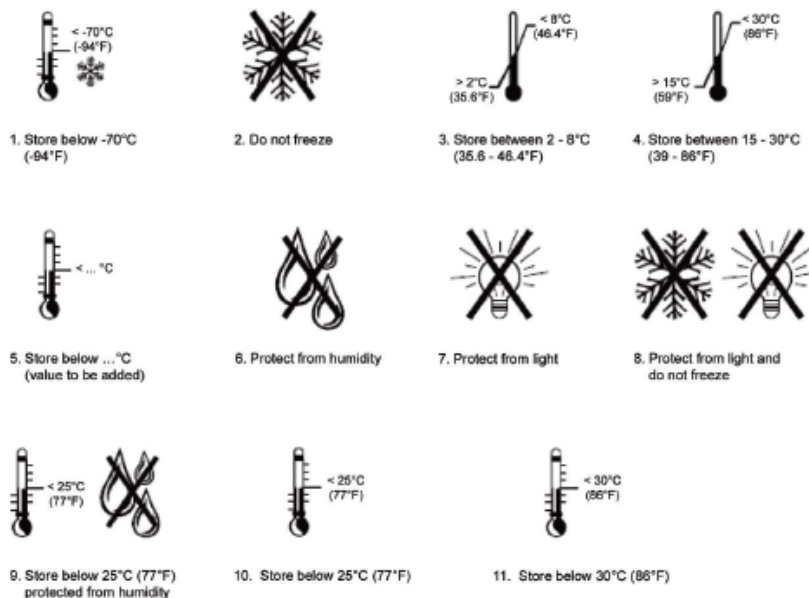
Good practice example, containing all particulars – example of label provided in Section 3 of this Guide.

4.4.1 Usage of Graphical Pictograms/Symbols

Graphical pictograms and/or symbols are recommended, and should be included on the country specific page, (see Table 3.1 and pictures in Section 3.2.2.3 of this Guide). Graphical pictograms and symbols should be placed on the visible part of the base label of a booklet label, as it is visible immediately and affixed to the container. Graphical pictograms and symbols usually do not require translation.

Pictograms should be placed next to the full translated text for the particulars which they represent to help to ensure that the pictograms are comprehensible to subjects.

Figure 4.1: Example Recommended Pictograms



Plus, if applicable:



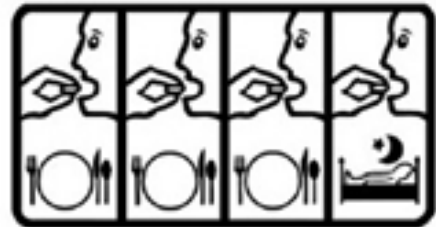
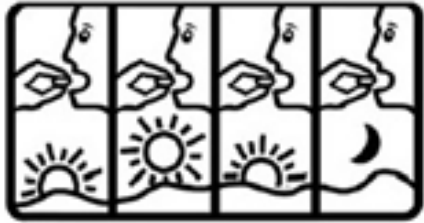
Manufacture Date



Batch no. (if applicable)



Use-by Date



Meaning?

ISPE Pictogram Task Team – Limitations?

- What limitations are there? How far do we take pictograms?
- Which countries would accept pictograms - are there any restriction e.g. – Germany, Korea?
- Cultural or offensive restrictions?

‘If you can’t explain it simply, you don’t understand it well enough’ - Einstein

THANK YOU!



Back-up slide

Annex 13 - Concept of Untranslatable label

Pilot Trial: **ESKETINTRD3001/3002/3003/3004/3005**

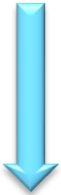
Small label Spray device

ESKETINTRD3001/3002/3003/3004/3005

- (d) ESKETINTRD3001/3002/3003/3004/3005
(b) Esketamine 14%
200 mcl
(e) 1) KIT-567890
(c) 2) 12345678
(b) 3) 
(a) Janssen Research & Development, LLC

Untranslatable
label

In compliance
with Annex 13



30. If the primary packaging takes the form of blister packs or small units such as ampoules on which the particulars required in Paragraph 26 cannot be displayed, secondary packaging should be provided bearing a label with those particulars. The primary packaging should nevertheless contain the following:

- (a) name of sponsor, contract research organisation or investigator;
- (b) route of administration (may be excluded for oral solid dose forms) and in the case of open label trials, the name/identifier and strength/potency;
- (c) batch and/or code number to identify the contents and packaging operation;
- (d) a trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
- (e) the trial subject identification number/treatment number and where relevant, the visit number;

Combined with a Full clinical
(booklet) label on carton level
- translated to the local
language(s)