



## User test

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# User test

## Readability test

### Consultation with target group

## User consultation

- **What is a user test?**
- **Why do we need user tests?**
- **How should a user test be assessed?**
- **Lessons learned since 2005**

# What is a user test?

- **Legislation**

Directive 2001/83/EC as amended Directive 2004/27/EC  
(human)

The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.

# What is a user test?

## A study, collection of data, report to be assessed

- Proper mockup
- Appropriate "users"
  - find, understand, act
  - oral/written questions and discussions
  - ensuring authorities
    - definition of key messages
    - transparency in questionnaire
    - detailed conclusions for amendments
  - Justifications for changes/no changes

# What is a user test?

## Proper mockup

### 1. WHAT X IS AND WHAT IT IS USED FOR

This medicine is used for treatment of sore throat.

### 2. BEFORE YOU TAKE X

#### Do not take X

- if you are allergic (hypersensitive) to Y or any of the other ingredients of X.

#### Take special care with X

- if you have had sore throat for more than 5 days
- when you have headache at the same time as a sore throat
- before you are going to have a surgery

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,

including medicines obtained without a prescription.

#### Taking X with food and drink

Take X together with a light meal, e.g. a sandwich. Alcohol should be avoided during treatment with X. Tiredness is a common side effect of X and you may feel even more tired if you combine the treatment with alcohol.

Appropriate  
"users"



find  
understand  
act

# What is a user test?

## Full user test – Bridging – Focus test

- **Full user test**
  - Testing the whole PL including layout
- **Bridging**
  - Comparing with another user test
  - Including layout or comparing (two bridgings)
- **Focus test**
  - Testing part of a PL

# What is a user test?

## Australian model

- **Pilot phase**
  - 2-3 users
- **Test rounds, 2 or more**
  - 10 users in each round
- **Oral questions**
  - Approx 15 questions including layout/general questions
- **Requirements**
  - 81% should find and understand

# What is a user test?

## What does 81% means?

- **90% should FIND the information**
- **90% should then UNDERSTAND that information**
- **That means that a total of 81% should find and understand the information asked for**
- **Understanding means acting properly**



# What is a user test?

## Translation

- **User test can be performed in any language**
- **Results and report in relevant language**

**Be careful in the translation step.**

**Readability is also achieved in using lay language**

**Good quality, rather than strict literal translations**

# Why do we need user test?

A user test is **a tool** to ensure that a user:

- can find the information
- can understand the information
- can act properly after finding and understanding the information

**A user can be a patient, a carer, a parent...**

**A user test itself does not improve the patient information but can show areas to work with.**

# Why do we need user test?

**The aim is to achieve legible, clear and usable PLs.**

Lay language

Heartburn ~~Reflux esofagitis~~

Active language

Take the tablet ~~The tablet should be taken~~

Short words and sentences  
One message, one sentence  
Bullet point lists

Contact your doctor if you  
- have fever  
- feel tired

Easy to remember?  
Is all information needed?

~~In the event of hyperpyretic episodes,  
fatigue or a deviating result of CRP  
laboratory results a contact with the  
prescribing physician should be taken~~

# Why do we need user test?

## The aim is to achieve legible, clear and usable PLs.

- Do I want to read it?
- Font size
- Space
- Colours

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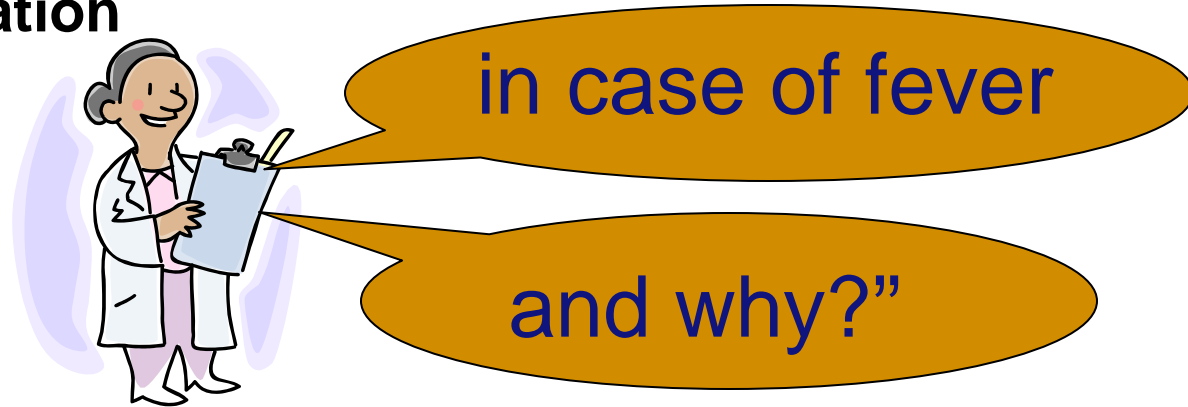
# How should a user test be assessed?

- **Recruitment of respondents**
  - Appropriate number, gender, age, treatment naïves/patients?
- **Questions**
  - Covering key messages?
  - Relevant?
  - Open questions?
  - Expected answer?
  - Layout discussed?
- **Result**
  - Proposals for amendments?

# How should a user test be assessed?

## Be careful with questionnaire

### •Avoid double information



### •Avoid questions with

- yes/no-answers
- talk to your Doctor-answers

# How should a user test be assessed?

## Be careful with questionnaire

- Try to foresee unexpected answers

**”What should you do if you are allergic to any ingredient?”**

- Use other words – not used in the text

**“Side effects such as tiredness may impair your ability to drive and use machines.”**

# How should a user test be assessed?

## Use the respondents!

- **Are the respondents response used?**
  - Spontaneous comments tell a lot
- **How are answers/suggestions used?**
  - Could the comments be applied elsewhere
- **Rational for not taking respondents comments into account**



# How should a user test be assessed?

## Bridging

- Refer to identical text and layout
- Maybe two bridges
  - identical text as a generic product
  - already tested “in-house” layout
- Three or more bridges – hmm?!
  - even if referring to several tested sections – they have to fit together!
- Is it sometimes easier to create a new test rather than bridging?

# How should a user test be assessed?

- **User test template - already in the assessment report template.**
- **Only the Rapporteur (RMS) assessing**
- **Use proposals in your assessment of the PL**
- **Even comments regarding the layout from the user test should be commented upon in a user test assessment, even though we don't see or assess the final layout PL.**

# Lessons learned since 2005

- **Reading the information is not the same as understanding.**
- **Haven't complained is not the same as being satisfied.**

# Lessons learned since 2005

## Obvious justification pitfalls

- **It's according to the template**
  - Of course, that's a basic requirement
  
- **On the market for long time**
  - So bad that people have not even read it?

# Lessons learned since 2005

## Obvious justification pitfalls

- **Prescription, the doctor tells everything**
  - What if the patient forgets
  - What if side effects appear after a while
  - What if the patient becomes pregnant during the medication

# Lessons learned since 2005

## Obvious justification pitfalls

- **OTC, safe product and the patient knows everything**
  - What if there are interactions
  - What if the user gives this “safe” medicine to a child
  - What if the medicine is used too long before contacting a doctor

# Lessons learned since 2005

## Obvious justification pitfalls

- **Hospital product**
  - What if side effects happen afterwards
  - What if relatives want information

# References

- **Guideline on the readability of the labelling and package leaflet of medicinal product for human use**

[http://ec.europa.eu/health/files/eudralex/vol2/c/2009\\_01\\_12\\_readability\\_guideline\\_final\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol2/c/2009_01_12_readability_guideline_final_en.pdf)

- **Guidance concerning consultation with target groups for the package leaflet**

[http://ec.europa.eu/health/files/eudralex/vol-2/c/user\\_consultation\\_200605\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-2/c/user_consultation_200605_en.pdf)

- **CMD: Recommendations for bridging, other methods, Q&A**

<http://www.hma.eu/218.html>

- **QRD template for assessment guidance (within the day 159 AR template)**

[www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500004840](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500004840)