User test

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QRD member
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**
  

  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
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.
   - 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

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"

What is a user test?

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

Heartburn Reflux esofagitis
Take the tablet The tablet should be taken
Contact your doctor if you
- have fever
- feel tired
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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Taking X with food and drink
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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

- Guidance concerning consultation with target groups for the package leaflet

- 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)