

## User testing



one way of complying with the legal requirement is by performing a “user testing” of the pil:

user testing was first proposed in the early 1990s in australia. it is performance based and relies on outcomes which will identify barriers to people’s ability to use the information presented. user testing is a development tool which is flexible and aims to identify whether or not the information as presented, conveys the correct messages to those who read it. testing itself does not improve the quality of the information but it will indicate where there are problem areas which should be rectified.

for medicinal products granted after 30 october 2005 the requirements of articles 59(3) and 61(1) of directive 2001/83/ec apply. marketing authorisation holders for all kinds of medicinal products including generic medicines will need to ensure that user tests, or other forms of user consultation, have been undertaken to ensure that all leaflets provided with their medicines comply with the requirements in articles 59(3) and 61(1) of the directive 2001/83/ec.

## Our service:

### pre-testing phase:

- we develop your leaflet on the base of the spc in all european union languages
- or: we check your draft leaflet in a first screening and translate, where necessary
- our working languages are german, english and/or french
- we prepare a questionnaire on the base of the facts given in the pil
- we prepare testing and reporting as required by the authorities

### user testing:

- we include two times 10 volunteers for testing
- we perform the testing in a first run
- we report and discuss the output from this testing with you
- after having proposed a second draft, we test again with 10 volunteers
- if still not yet successful: we repeat a 3rd time

### presentation of results

the results will be presented in an adequate way to be included in module 1.3.4 of the application:

1. product description
2. consultation or test details, such as:
  - method used
  - explanation on the choice of population consulted · language(s) tested
3. questionnaire (including instructions and observation forms)
4. the original and revised package leaflets
5. summary and discussion of results (a.o. subjects’ ½ answers, model answers, problems identified and revisions made to relevant package leaflet section)
6. conclusion