

Testing, Testing...

User Testing And How It Will Revolutionise How We Think About Patient Information Leaflets

By: DK Theo Raynor, Professor of Pharmacy Practice, University of Leeds and Executive Chairman, Luto Research Ltd.

Summary

July 1st 2005 could turn out to be a significant date in the history of patient empowerment and patient safety. In future years, it may seem surprising that we previously placed so little emphasis on ensuring that people taking medicines had usable information on how to take them to best effect. This article looks at the advent of User Testing, its implications and the approach taken by one provider of User Testing services.

This July is when the UK is implementing the requirement resulting from the EU Pharma Review 2001, that all patient leaflets must be tested through "consultations with target patient groups". This is 3 months earlier than for the other member states, and coincides with the UK taking on the EU Presidency. In the UK, "consultation" is being interpreted as formal testing with patients, with the proposed method being User Testing (although this does not rule out other approaches). The MHRA has consulted on these proposals¹, and formal guidance is expected shortly.

What is User Testing?

What does User Testing mean and what are the implications for the Pharmaceutical Industry? Well, it is a form of "performance based" testing, championed by Professor David Sless from the Communications Research Institute of Australia². It was included in an amended form in the EU Guideline on Readability in 1998³. Performance-based testing does what it says

on the tin: it determines how the leaflet performs. In the case of User Testing:

- Can the user easily find key pieces of information?
- Can they express the information in their own words?

It differs from the "content based" approach used in the past, where a checklist is applied to ensure that the correct information is present. Another form of content based testing is the use of readability formulae, usually based on word and sentence length. It is noteworthy that a leaflet written backwards will have the same readability "score" as when written forwards (same words and same sentence length). There is no substitute when testing leaflets for actually involving people who might take the medicine.

Experience in Australia and the US

The Australians have been applying User Testing to manufacturers' leaflets for some



years. This is part of a collaborative approach to improving medicine leaflets, which has involved academics, regulators, industry, the professions and patients. The result is a funded system where pharmacists download and print up-to-date leaflets for the patient. In the US (where there is, as yet, no legal framework) there is only a voluntary process - again based on leaflets generated on-demand in the pharmacy. Here, content based testing is the norm, i.e. assessing whether the leaflet contains the relevant information, rather than whether the information is usable by the medicine-taker. The Drug Information Association has funded a study currently being undertaken in Leeds, where we are critically comparing the patient information leaflet system in the 3 continents.

What is wrong with current UK leaflets?

Our research suggests that all is not well with current leaflets and that most people still don't read package insert leaflets. Only half say they read some of the leaflet and about a third say they have read all of it. Surprisingly, over 10% say they don't remember seeing a leaflet, even when we know it has been supplied⁴.

Focus group research⁵ gave us a further insight, with comments from long-term

medicine users like:

- Too small, folded and in the box
- Things we want to know don't come first
- Priorities are those who wrote it, not patients
- People who suffer should help write leaflets

User Testing effective but not simple

At first glance, User Testing sounds simple - to check whether people can find and understand key points in a leaflet. In fact, there is much more to it than that. First, you need to find your participants, who must be in the target group for the medicine, but not actually taking it. This means that most participants will be older people, who need to be interviewed sensitively – by suitably trained people. This is not market testing, where you need only a clip board and smile. You need to be able to undertake a 30-40 minute interview in an appropriate setting, maybe an older persons' day centre.

The pass standard that has been set for User Testing is: that 90% of users can find the information and then 90% of those can understand it. This is a tough target, and simply going out and testing without prior expert input into leaflet design and content is likely to result in the target not being achieved.

Luto Research Ltd, our Leeds University spin-off company, takes account of this in the process with the inclusion of an "Audience Design Step" at the outset; where we, as experts in effective medicines information provision, address the design and wording of the leaflet to maximise usability.

Which leaflets need User Testing?

This one is easy – all leaflets; whether for branded products, generics, parallel imports and herbals are covered by the legislation. It also includes those products where the information is confined to the pack. This exempts you from the need for a leaflet, but not from having a successful User Test.

Initially, only new Marketing Authorisations submitted after July 1st 2005 will need to include a successful documented User Test; but the process will have to be applied to all existing leaflets within a 3 year timeframe, i.e. before July 2008. For many companies that may mean hundreds of tests. However, it is unlikely that every single one will require a test, with companies being able to apply to have leaflets approved on the back of a successful test with a similar leaflet - but just how similar remains to be seen. What is certain is that



new chemical entities, drugs with significant safety issues and switches will always be required to have an individual User Test completed.

Is it worth it?

Applying the new User Testing regulations across all products over the next 3 years is a mammoth task which will be expensive and need effective project management. However, the gains are considerable: helping to ensure that leaflets will help people to get the best from their medicines and hence allow companies to gain maximum value from their products.

References

1. Consultation Letter: MLX 309. Implementation of Revised EU Medicines Legislation (<http://medicines.mhra.gov.uk/inforesources/publications/mlx309.pdf>)
2. Sless D, Wiseman R. Writing About Medicines For People. 2nd Edition. 1997
3. Guideline on the Readability of the Label and Package Leaflet of Medicinal products for Human Use. (<http://pharmacos.eudra.org/F2/eudralex/vol-2/C/gl981002.pdf>)
4. Raynor DK, Knapp PR. Do Patients See Read And Retain The New Mandatory Medicines Information Leaflets? *Pharmaceutical Journal* 2000; 264: 268-270
5. Raynor DK, Savage I, Knapp PR, Henley J. We Are The Experts: People With Asthma Talk About Their Medicine Information Needs Patient Education And Counselling 2004; 53:167-174.

Theo Raynor is Professor of Pharmacy Practice at the University of Leeds and Executive Chairman of "Luto Research Ltd", a university spin-off company, which provides user testing services to Industry (www.luto.co.uk). He has followed the development of User Testing since its inception in the 1990s and has strong academic and policy links with the US and Australia and is a member of the MHRA Working Group on Patient Information.