

Readability testing of patient leaflets – where to now?



Professor DK Theo Raynor

Testing readability should be just one of a number of steps that companies and regulators should take when improving patient leaflets, argues Professor DK Theo Raynor.

It is difficult to understand why the provision of high quality medicines leaflets for patients has been such a low priority for industry. Leaflets are a key link between the “maker” of the medicine and the “taker”. They are one of the few direct links that

manufacturers have with their true end-users, enabling them to show their level of quality and commitment. A good leaflet can reflect very well on a company, but equally a poor leaflet can reflect very badly.

We know that in the past leaflets were of poor quality (sometimes very poor). A recent review of relevant research showed that most people do not value the leaflets they have been given¹. We have all known this, but not acted. The European Commission’s move to make readability testing mandatory is therefore a major step forward in increasing patient access to information about the safe, effective and appropriate use of medicines – something that should never have been optional. But there are a number of problems related to user testing as currently carried out in the EU:

- Some regulatory authorities are not insisting on full mock-ups being used. Layout and format are crucial – if people cannot find the information, it does not matter how well it is expressed. This means something as close to the final leaflet as possible must be tested.
- Faithful translation is possibly the Achilles heel of current legislation. The importance of format and layout has already been emphasised, and faithful translation of a tested leaflet into different languages focuses solely on the content and not on the format or layout.
- 70% of prescriptions are filled with generics in the UK, and many (but not all) generics companies have left testing to the last minute. It is essential that the leaflets for generics be of the highest quality, as these are the medicines that most people take – they must not be based on bridging to low-quality leaflets that have scraped through a test.
- There is too much reliance on templates. While the consistency of six headings can aid patient navigation, in general, templates tend to stifle innovation. Testing houses should progressively revise the layout and wording they use, as they learn from successive tests. Hence their practice evolves. Such evolution is impossible with rigid application of a legislated template.
- Some assessors have a good understanding of the testing process, but others have more limited expertise. Deficiency letters show that improved understanding is necessary for some assessors to be able to appropriately judge testing reports.

It is also becoming apparent that too much weight is being given to the testing process in isolation. Testing cannot

improve leaflets on its own, but is a highly effective process for identifying whether a leaflet has problems, and how they might be remedied. Passing the test should not be the goal. The testing should be regarded as the catalyst, but the laboratory needs to be a testing house with an understanding of information design and research relevant to consumer medicines information.

Unfortunately, the problem is that some leaflets have passed a test divorced from a context informed by such information design and research expertise. But regulators have little option but to approve such leaflets which have “passed”.

However, the MHRA, for example, makes it clear that it first looks at various aspects of the quality of the leaflet, with the test report forming part of the evidence, rather than the only criterion.

The overall picture for improving patient leaflets is nonetheless positive. Since the introduction of mandatory readability testing, the bar has been raised in terms of the quality level of leaflets patients will receive.

Many good leaflets are coming on stream and general awareness of the importance of good leaflets is now apparent to, and accepted by, most stakeholders. This is particularly the case with pharma personnel (sometimes initially sceptical), who become converts after collaborating in the testing process, and particularly if they sit in on testing interviews.

We need to start focusing more on specific improvements to leaflets such as including a headline section, increasing benefit information and a better description of the likelihood of benefit and harm (as described in “Always read the leaflet”²). Additionally, we should consider whether it is time to test other forms of medicines information given to people, eg, clinical trial patient information. You could argue that it is even more important that people understand this information than that for licensed medicines. The same can apply to the patient information that comes with medical devices.

Finally, what about the wider picture? Patients in Australia have benefited from readability testing for a decade now. It is now coming on stream in Europe. But in the US, patient leaflets lag behind.

Our recent comparative evaluation³ put US leaflets firmly at the bottom of the league – scoring poorly for legibility and comprehensibility. The US Institute of Medicine said in a recent report that: “There needs to be a concerted effort to improve the quality and the accessibility of information about medications provided to consumers⁴.” It is time that all patients saw the benefits of improved medicine leaflets.

Dr DK Theo Raynor is professor of pharmacy practice at the University of Leeds, UK, and executive chairman of the university spin-out firm, LUTO Research, which provides leaflet testing services.

¹Raynor et al (2007). <http://www.hta.nhsweb.nhs.uk/execsumm/>. ²MHRA. www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2018041.pdf. ³Raynor et al. *J Am Pharm Assoc.* 2007; 47: 717-724. ⁴Institute of Medicine. 2006. www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf.