

## Is user testing fulfilling its goal?

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### Abstract

Although legislation calling for user testing of existing Patient Information Leaflets has been in place since July 2005 in the UK, the deadline later this year may not be met by all companies and quality of testing may suffer in the rush to comply.

### Introduction

At the time of writing this article there remain approximately nine months until the UK Medicines and Healthcare Products Regulatory Agency (MHRA) enforced deadline for user testing existing Patient Information Leaflets (PILs) expires.

The truth is that the likelihood of all existing PILs meeting the MHRA's requirements before the deadline is unrealistic. It should, however, be noted that the relevant legislation has been in place since July 2005, which is likely to be mentioned to all companies that do not meet the deadline.

The main concern of this author is that, due to the fast approaching deadline, the quality

of PILs is now unlikely to be as high as it could and indeed should be.

The reasons for this potential lack of quality are:

- Rushing to meet the deadline leading to a reduction in quality
- Lack of understanding of the legislation and guidance
- A service being provided by unqualified professionals and/ or companies
- Lack of a quality system/ auditing control for this new area of "business".

### Rushing to meet the deadline

It should never be assumed that all personnel involved in the improvement of PILs are from a medical or regulatory background. If we assume, however, that they are, they are more than likely to be aware of the extremely tight deadlines that occur in the regulatory and medical world. They should also be aware of the unfortunate but inevitable negative correlation of reduced timeframe against quality of work.

Sadly, the corresponding inevitable outcome is that outsourcing of required work will often (although not always) fall to the company offering the lowest quote or most reassuring promise of meeting the deadline.

This trap should be avoided at all costs. Time and effort spent upfront in selecting the "correct" company is probably more important than the end result. The reason for this is that there is more to the improvement of PILs than merely selecting the cheapest "user testing company".

Improving a PIL is more involved than merely "meeting the guidance", which, interestingly enough, does not always mean carrying out a user test. PIL improvement should actually be seen as a process to be implemented over time and incorporated into a company's standard operating procedures.

So before panicking over deadlines, remember that an initial early saving may not be as much of a saving in three or five years when further user testing is still required, which could have been avoided.

Do not forget that there is also the opportunity of meeting the MHRA to discuss your strategy and timings, which may or may not fall outside of its deadline.

### Understanding the legislation and guidance

Guidance continues to be released on the area of improving PILs. Companies associated with carrying out a PIL improvement service (hopefully) incorporate this into their processes, allowing themselves to evolve.

As with all new areas of regulation, there is always a learning stage upon implementation. It is extremely important that lessons are learnt and changes and improvements are made by all involved. As such, all parties involved should be provided with the opportunity to input their findings, thus allowing the entire process to move forward efficiently.

The MHRA has recently afforded certain "user testing companies" the opportunity to present some of their findings. The meeting held on February 1, 2007 involved the Commission on Human Medicines Expert Advisory Group on Patient Information (CHM PIEAG) and the minutes of this meeting are eagerly anticipated.

It is always very important to review the actual legislation before commencing any work related to it. The relevant legally binding legislation is taken from Council Directive 2001/83/EC (as amended), which was then transposed into UK law, and states:

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

On its own, this particular "task" has the

potential to be implemented in a number of differing ways. This is why the MHRA and other EU and International agencies have implemented guidance, which should not be ignored. Equally, this guidance should not be treated as a directly binding piece of legislation; hence the use of words such as “should” throughout the documents. As the MHRA correctly mentions, the method it proposes in its guidance is one method of user testing, and other methods for achieving the above task can be used and will be reviewed on a case-by-case basis.

It is not possible to highlight all of the potential methods for carrying out the above “task”. It is, however, worthwhile mentioning how results from certain methods can be construed in vastly differing ways. The tables below show two ways of interpreting the same data from one phase of a user test (using ten “patients”). Table 1.1 lists the results of ten participants being asked fifteen questions relating to a particular leaflet. In this instance a green tick indicates whether a participant could understand the information (ie. whether they provided the correct answer to a question). A red cross shows that they could not answer correctly.

Along the bottom row of Table 1.1, the percentage of participants who could correctly answer each question is shown. In this instance each question achieved a score of 90%. If this was repeated in a second phase of testing on a further ten subjects, then a successful leaflet would be produced, assuming the success criteria were as follows:

*“A leaflet shall be deemed to have passed if all questions are successfully understood by 90% of participants in two subsequent phases of testing”.*

This also assumes that the participants were capable of finding the information, which if they could answer the question is almost certainly guaranteed (unless they answered from memory).

If the data from the first table are re-analysed to consider how well a participant understands the leaflet, as opposed to how well a question is understood, the following results are found (see Table 1.2).

**Table 1.1: A method for analysing whether individual questions can be understood by ten participants during a user test**

	Question Number														
Subjects	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
John	✓	x	✓	✓	✓	✓	x	✓	✓	✓	x	✓	x	✓	✓
Jane	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sally	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Gareth	x	✓	x	x	✓	✓	✓	✓	✓	✓	✓	✓	✓	x	✓
Peter	✓	✓	✓	✓	✓	x	✓	✓	x	✓	✓	x	✓	✓	✓
Karon	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Keith	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Simon	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lisa	✓	✓	✓	✓	x	✓	✓	x	✓	x	✓	✓	✓	✓	x
Sarah	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Overall % for Understanding Each Question	90	90	90	90	90	90	90	90	90	90	90	90	90	90	90

As can be seen in Table 1.2, four out of the ten participants, (40%) understood 75% or less of the information. If this were repeated in the second phase of testing, eight out of twenty participants have shown that they do not fully understand the leaflet they are reviewing. This is particularly evident when you consider that a 90% “pass” mark is recommended for understanding each question in the earlier example.

This is just one example of where the methods for analysing data need to be determined precisely before producing accurate and repeatable success criteria. The author suggests that it might be in the interests of pharmaceutical companies and regulatory agencies to suggest an approved method for determining the readability of PILs, particularly when a user test is required.

A “user testing company” could then be audited against their potential to accurately reproduce these user tests in line with an approved protocol. Quality control and auditing of this new area of “business” are discussed in more detail below.

### Services being conducted by unqualified professionals and companies

At present the onus of ensuring quality for user testing has been firmly placed with the pharmaceutical company. Matched with the fact that the legislation is new, there is an understandable opportunity for unqualified companies and professionals to offer a service in what is an expanding business area.

Understandably, it is difficult for a pharmaceutical company to conduct an audit for a process of which it has limited or no knowledge. This is a further argument for “standardising” the method for conducting user tests.

It would still be important for a company offering to provide a service of user testing to be able to prove its competence. This could be shown in its ability to provide a PIL that is more likely to pass a user test, and/or the ability to accurately and repeatedly carry out user testing when it is required.

This is likely to instil greater confidence for pharmaceutical companies when investing large sums of money into improving their PILs. They can be certain that what they are

**Table 1.2: A method for analysing ten participants' ability to understand the information (all questions) from a leaflet**

Subjects	Question Number															Subject's individual % for Understanding the Information
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
John	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓	✗	✓	✗	✓	✓	73
Jane	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Sally	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Gareth	✗	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	73
Peter	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✓	✗	✓	✓	✓	75
Karon	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Keith	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Simon	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Lisa	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓	✗	73
Sarah	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Overall % for Understanding Each Question	90	90	90	90	90	90	90	90	90	90	90	90	90	90	90	

paying for is actually achieving the goal the legislation was originally adopted for:

There seems to be an increasing number of companies appearing with "proven track records" for conducting user testing or readability testing. Unfortunately there is an extremely limited number of companies out there who offer to provide a service to the intended end target (ie, the patients reading the leaflets). It appears that companies are more obsessed with carrying out user testing than improving leaflets; a classic case of too many alligators and not enough people draining the swamp.

When choosing a company to conduct a programme for improving the readability of leaflets it is important to be confident in their ability of achieving this. It is therefore worrying when websites from companies both based in the UK and abroad contain inaccurate information and poorly written English.

There are examples of sentences with over 50 words below statements requesting short sentences in the PILs. Spelling mistakes are commonplace, as are misunderstandings of the legislation. An example includes a company explaining that questions asked towards participants are designed to prompt them to locate the information being asked for. This is just one example showing a clear lack of understanding of the purpose of the legislation.

As PIL improvement is still in its early stages, it is likely to take some time for quality issues to be addressed and ironed out. It does, however, remain vitally important to keep the main goal in mind at all times, which is to improve the readability of information provided to patients.

### Lack of quality system and audit control

It is clear to the author that there is a desperate need to implement a strategy to improve the quality of user testing. Whether this is implemented by the Agencies, pharmaceutical companies or indeed other external bodies/ companies is not yet apparent.

Until a system is implemented to ensure consistency, there is an increased risk that the legislation will not produce its intended goal. At present it appears the various parties involved are pulling in separate directions, hence the seemingly likely outcome that the MHRA's deadline will not be met.

If all involved take a step back and reassess what they are actually trying to achieve, they may be able to work together to reach this target and with better results.