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Your sign:	Your message from:	Our sign:	Date
		JF	18 November 2010

QRD template draft

Dear Alexios Skarlatos

Thank you for providing me with the opportunity to participate in the QRD template workshop on 10th November 2010, as well as the interesting talks during and after the workshop.
As I have already told you, we had investigated the current QRD template and a shorter model version in a readability test with 192 participants. The results were part of our statement of 26th April 2010 relating to the QRD template draft and showed significant advantages in time take to locate required information, but also in the locatability and comprehensibility. According to the PAINT1 and PAINT3 readability test studies, which involved 1 105 and 5 091 participants respectively, any reduction in the number of words contained in package inserts significantly increases patients' motivation to read the provided information as well as increasing their trust in using the medicines.
In the interim, we have submitted the template study results in the form of an article to an international journal. This also included the English version of the shorter model template text (see pages 24 and 25 of the submitted article text). As promised during our conversation following the workshop, I have attached five copies of said article with this letter.
I would like to emphasise strongly that it is not our intention to delete information from package inserts which is necessary for patients. However, as the aforementioned studies clearly illustrate, we should take greater heed of the need to reduce the number of words contained in package inserts; particularly given unremitting increase in the volume of text, which is significantly impairing the usability of this important patient information.

As you and your colleague requested at the workshop, we can offer you the opportunity to test the updated QRD template in which the new version can be compared with both the current and a shorter model template. We can also facilitate this in different European Union languages where required.

With reference to the discussion during the workshop concerning the side effect frequency explanation, I would like to take the opportunity to provide you with the study results of the PAINT1 and PAINT3 studies relating to this aspect, as I mentioned on the 10th of November.

In the PAINT1 study we tested 5 package inserts available on the German medicine market and 5 model package inserts, using the written readability test. The model package inserts contained the following side effect frequency explanation, identical to that recommended in the 'Fourth meeting of the EMEA Human Scientific Committees Working Party with patients' and consumers' organisations (PCWP)' of September 2007:

- "very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1 000
- rare: affects 1 to 10 users in 10 000
- very rare: affects less than 1 user in 10 000
- not known: frequency cannot be estimated from the available data"

As you can see in the attached PEC article on page 163, all 5 model package inserts registered significantly higher rates of located and comprehended side effect frequencies (73.6 to 86.3%) in comparison to the package inserts available on the German medicine market (10.6 to 56.7%). In the latter group, some package inserts only provided the side effect frequency in adjective form, without an equivalent numerical explanation. The best result of this group with 56.7% was achieved using explanations which were open on one side, such as 'common, more than 1 per 100 users' - similar to that contained in the QRD template draft of 10th November 2010. However, this version was always significantly worse than that used in the model package inserts and recommended at the meeting of September 2007, mentioned above.

The PAINT3 study - publications in pending - investigated a random selection of all package inserts available on the German medicine market in the year 2005, along with some model package inserts. In total 295 package inserts were tested using the written readability test, involving 5 091 participants. In this study the locatability and comprehensibility of the used side effect frequency explanations was tested in one question.

As illustrated in the figure below and as already known based on other investigations, side effect frequencies should always be provided using both frequency adjectives and numerical explanations as this combination is more appropriate for patients. Also illustrated is the rate of locatability and comprehensibility (measured as the percentage of correct answers), itemised according to the explanation forms used. Here too the side effect frequency explanation recommended at the meeting in 2007 and found to be the most appropriate version in the PAINT1 study, is again proven to be the best explanation form in the PAINT3 study. The results were also significantly better than achieved using the side effect explanation form of the 1998 Readability Guideline (e.g. 'common, less than 1 per 10 but more than 1 per 100') and the explanation form which was open on one side, 'common: more than 1 per 100 users'.

The table below also provides the standard deviations in which the explanation recommended at the meeting of September 2007 had a deviation of less than 10%, additionally illustrating its advantage over other versions.

We have also used the side effect explanation recommended at the EMEA and PCWP meeting in many of our clients' user tests and did not encounter any problems with this form; regardless of the test languages used, such as English, German and Spanish. This shows that patients living in the United Kingdom experience a similar ease of use with this side effect explanation as those of other European Union countries. Furthermore, using an explanation form which is open on one side does not give patient a clear separation of the different frequency groups, which is assumes added importance if the explanations are not provided in a single table.
Another aspect worthy of mention is that the side effect frequency explanation recommended at EMEA and PCWP meeting has been more frequently used in recent years, a result of its officially recommended status. Switching to a new explanation form from this version which patients are already familiar, is more likely harm patients, even more so given that the explanation recommended in 2007 is, according to our results, the most appropriate version.

Please, do not hesitate to contact me if you have any questions or if you require further information. I would be more than happy to respond to any comments or questions you may have.

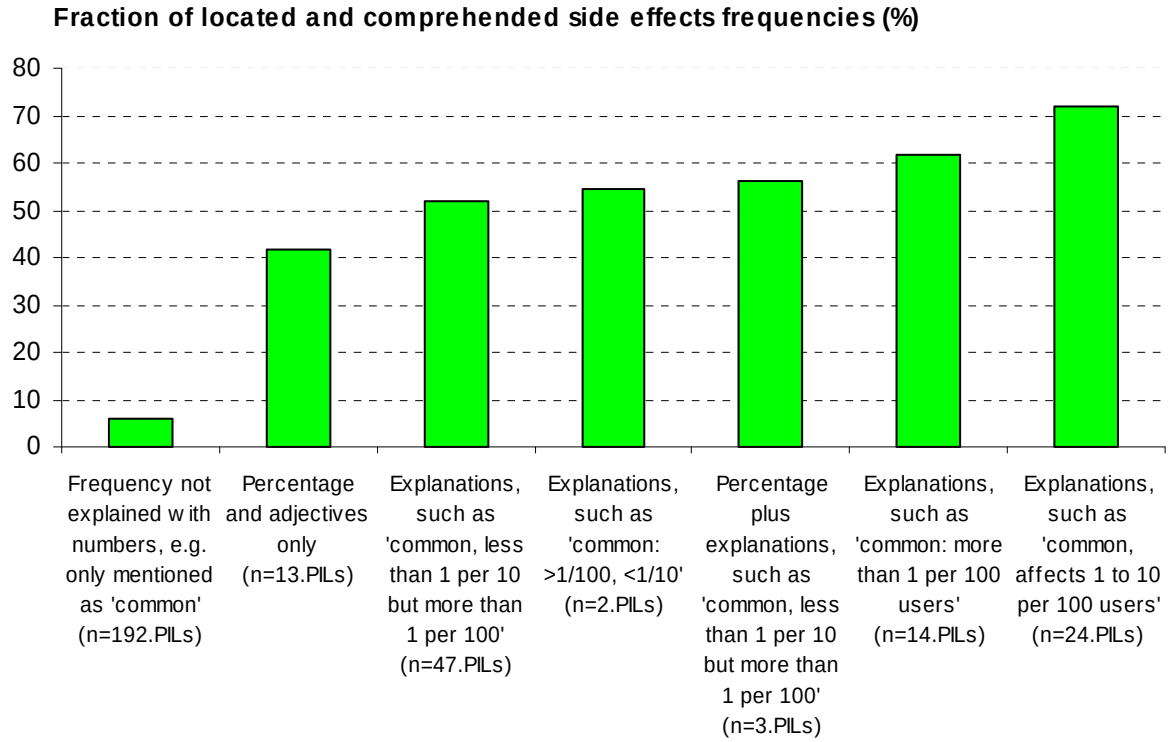
Yours sincerely

Dr. Jörg Fuchs
PAINT-Consult®, Managing director

Attachments

- 5 copies of the QRD template study article
- Patient Education and Counseling article 2007:67;157-168

Figure/table: Fractions of located and comprehended side effect frequencies itemised according to the side effect frequency explanations used



Side effect frequency explanation form	Fraction of located and comprehended side effect frequencies [%]	Number of investigated package inserts	Standard deviation
Frequency not explained with numbers, e.g. only mentioned as 'common'	5.9	192	14.18
Percentage and adjectives only	41.7	13	14.71
Explanations, such as 'common, less than 1 per 10 but more than 1 per 100'	51.8	47	15.33
Explanations, such as 'common: >1/100, <1/10'	54.4	2	6.24
Percentage plus explanations, such as 'common, less than 1 per 10 but more than 1 per 100'	56.2	3	16.54
Explanations, such as 'common: more than 1 per 100 users'	61.7	14	11.69
Explanations, such as 'common, affects 1 to 10 per 100 users'	72.0	24	9.83