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# Newsletter

Dear Readers!

Over the last few months I attended a number of conferences which focussed on issues regarding making healthcare more effective. And, of course, one of the topics was patient compliance and what can be done to improve it.

I heard about very interesting ideas such as new drug delivery systems and drugs with very slow release so we wouldn't have to take our tablets every day but maybe even only once a week.

Every way to help the patients to adhere to their regimen should be

followed, however the emphasis should be given to those solutions, that have the fastest impact at the lowest cost.

And it is my firm belief that compliance enhancing packaging, whether conventional or using sophisticated technology is the fastest way to serve the patient and to benefit those who pay for the health care system.

We would very much appreciate to have your opinion about how we should pursue our objectives. We therefore have added a forum to our website which will enable you to discuss with us and other parties

who are interested in this topic, the value and the effectiveness of our endeavours. This weblog went live a couple of days ago and I would like to invite all of you to take up the discussion so we can share our ideas.

Thanking you in advance for your support I wish you an excellent summer!

Tassilo Korab  
Executive Director



## Dr. Karel van der Waarde

### Some comments on the 'Draft guideline on the readability of the label and package leaflet of medicinal products for human use'

#### Summary

This paper provides some comments on the assumptions, contents and visual presentation of the 'Draft guideline on the readability of the label and package leaflet of medicinal products for human use'. These comments are based on the practical use of the previous guideline (1998), substantial experience with user testing, and research findings.

#### Eight groups of comments

The Readability guideline aims to support applicants and Marketing Authorization holders to develop labelling and package leaflets. The following pages group the comments in the following categories:

1. The results and deliverables: what are the end results?
2. The description of criteria: how to measure success?
3. The description of people: who could evaluate the results?

4. The aims of providing information: why is it essential?

5. Writing guidance

6. Designing guidance

7. Testing guidance

8. Document development: is this the right approach? Appendix 1 shows an example of an outline for a guideline. Appendix 2 provides a line by line comment of the Draft Readability guideline

#### Conclusion

Following the advice in the Draft guideline should lead to information about medicines that 'enables users to act appropriately'. This Draft guideline is unlikely to achieve this. The terminology, criteria, aims, and activities are poorly described. The activities that must be undertaken to develop appropriate information about medicines - writing, designing, and testing - are not sufficiently supported.

**1. Artefacts: what exactly needs to be developed?**

The Readability guideline provides advice for the development of the text and the visual design of labelling and package leaflet.

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The fundamental problem with all these descriptions is that it is not clear what exactly needs to be developed, and what needs to be submitted to the competent authorities.

#### Concluding:

It is essential to describe what exactly needs to be delivered. The guideline must provide answers to the following questions:

- What are the required results?
- How should these results be submitted to the competent authorities?

The terminology must be reconsidered. Adding more descriptors of 'things that might be required' is not helpful.

Please read the full article under:  
<http://users.pandora.be/waarde/Papers/ReadabilityDraftCommentsWaarde2006.pdf>

## Dr. Karel van der Waarde

### Enabling Users or Readability?

Although the implementation of Directive 2004/27/EC and related EMEA-templates are likely to improve the quality of package leaflets, it might be worth looking at the wider scope of information about medicines. This paper outlines some arguments.

#### Summary

EU-Directive 2004/27/EC significantly changes the motivation for supplying information about medicines to patients. Since 1992 (92/27/EC), the focus was on 'making information readable and understandable'. Directive 2004/27/EC adds that information must be provided in order to: 'enable the users to act appropriately' (article 63 (b)2). Not only should information be provided in such a way that people can understand it, but people must now be able to apply this knowledge and handle medicines in an appropriate manner.

*Information design* has a long tradition in developing information that enables people to achieve their aims. The primary concept is that the only person who can

judge if information really enables actions, is the actual user of information within a specific context. Therefore, it is essential to involve people in information development processes. This can be done by observing people in context when they try to achieve things, and by conducting diagnostic tests to determine if information achieves its aims. Both observations and tests will reveal in which situations information is successful and where information fails. Observations and tests form the basis of 'performance centred information'.

The current approach of the regulatory authorities is to provide templates for package leaflets. This approach, although understandable in its historical context, has several drawbacks. The main problem is that the templates do not differentiate between medicines, users, actions, languages, and contexts. A single template is unlikely to: 'to enable users to act appropriately', because templates cannot incorporate the practical

context and do not relate to actions and criteria that are relevant for users. The template approach article 63(b)2 of Directive 2004/27/EC.

#### Concluding

The EU-Directives do not make it clear for whom information is intended. This confusion causes serious problems, because it makes it very difficult to develop appropriate guidelines and to determine valid criteria to evaluate the effectiveness of the provision of information about medicines.

Please find the full article under:

<http://users.pandora.be/waarde/Papers/WaardeEnablingTemplates.pdf>