About the DRAFT Readability Guideline (November 2006)

Please reconsider!

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

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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.

Nine 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.

For these reasons, please reconsider the implementation of this draft guideline.

In order to provide appropriate guidance, it is necessary to start from the activities that are necessary to develop optimal information, and support each step in this process. Four steps are required:

1. Restructure the contents to follow the activities of intended users of this guidance.
2. Clarify the aims of each activity and clarify the relevant criteria.
3. Provide effective guidance, based on best practice and research.
4. Test the guidance before implementing it. Untested guidance might do more harm than good.

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Introduction

The Draft guideline promises 'to assist applicants and marketing authorisation holders when drawing up the labelling and package leaflet and preparing the specimens or 'mock-ups' of the sales presentations.'
Three additional objectives are mentioned:
1 - 'aid the production of high quality information',
2 - 'meet the legal requirements', and
3 - 'presented in a consistent way'.

In this comment, I'll check whether this Draft guideline fulfills these aims by asking the following questions:
1. What are the deliverables? What exactly needs to be produced?
2. What are the criteria to evaluate these deliverables?
3. Who are the people who can do this?
4. Does this guideline help to decrease some of the problematic issues related with information about medicines?

In the sections five, six and seven, I'll look at the different activities that an applicant or marketing authorisation holder must do in order to develop labelling and package leaflets: writing, designing and testing. In section 8, the general approach of this Draft guideline towards the development of information about medicines is discussed.

There are two appendices. Appendix 1 shows an outline of a Guideline that follows the comments in this paper. The second appendix provides a line-by-line comment of Chapter 1 and annex 1 of the Draft Readability guideline.

In previous papers, I addressed some of the issues related to the use of the template ('Enabling users or Readability?' May 2005), and comment on Chapter 3 of the guideline ('Some comments on the draft 'Guidance concerning "consultations with target patient groups" for the package leaflet'. September 2005). These papers can be downloaded by clicking on their titles.

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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.

The following terms are used to describe the artefacts in the introduction and Chapter 1 of the Draft Readability guideline (in alphabetical order):
- blister foil
- blister pack presentation
- the carton
- content of labelling and package leaflet
- critical information
- a complete summary of product characteristics
- copy of the flat artwork design in full colour
- draft package leaflet
- element of a promotional nature
- face
- foil
- format resulting text
- formats appropriate for the blind and the partially-sighted
- formats suitable for the blind and partially sighted patients
- full colour mock of the package leaflet
- immediate packaging
- immediate packaging units
- immediate packaging information
- inner packaging
- inner packaging components
- information from the summary of product characteristics
- the information
- the information presented
- information on the label and package leaflet
- label text
- labelling
- labelling and packaging components
- labelling particulars
- labelling text
- leaflet
- the medicine
- medicinal products
- medicinal product package
- mock-ups
- mock-up of the outer and immediate packaging
- outer pack
- outer packaging
- outer packaging design
- outer packaging information

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- outer or immediate packaging information (labelling)
- outer/inner labelling text
- the pack
- package leaflet
- packaging
- packaging information
- paper copy
- paper labels
- particulars
- presentation of the content of the labelling and package leaflet
- product
- product information
- replica of both the outer and immediate packaging
- relevant full colour mock up of the packaging
- the required information on labels
- sales presentations
- small containers
- small packs
- small pack sizes
- specimens
- statutory information
- a tear-off portion
- text
- three dimensional presentation.

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.

The terminology is very confusing and often conflicting. Three examples:

Example 1: The word 'specimen' does not appear in the Directive anymore. It was deleted from article 8(j), article 15 and article 61. It is confusing to use 'specimen' in the Draft Readability guideline.

Example 2: The differences between 'text', 'information', 'particulars', 'statutory information', 'product information', 'labelling information', 'packaging information', and so on, is not clear. It is essential to make absolutely clear what is required.

Example 3: The Directive itself is not clear whether a 'package leaflet' (artilce 8.3(j)) or a 'draft package leaflet' (article 61(1)) needs to be submitted. A guideline must clarify this.

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.

2. Criteria: What needs to be achieved?

The guideline provides the following criteria in section 1 and annex 1. This list is in alphabetical order. These are the criteria that - according to the guideline - could be applied to examine the quality of the information.

- Able to be understood
- Accessible
- Accessibility of the information
- Achieving readable text
- Active style
- Aid comprehension of information (graphic elements)
- Aid navigation (graphic elements)
- Appear consistently (headings)
- Avoid repetition of information
- Avoid abbreviations unless they are appropriate
- Being able to act on the information presented
- Clarify certain aspects (graphic element)
- Clarity of the text
- Clarity of the information
- Clear
- Clear demarcation between the languages used (leaflet only)
- Clear line space
- Clearly comprehensible
- Clearly distinguished (characters)
- Clearly legible
- Clearly recognisable (headings, leaflet only)
- Clearly worded (leaflet only)
- Comprehensibility
- Comprehensive
- Consistency in the explanations (technical terms)
- Context makes clear what the pronoun refers to.
- Difficult (reversed-out type, leaflet only)
- Difficult to read (thin paper, leaflet only)
- Doubt about the meaning (pictogram)
- Easily be turned over (leaflet dimensions)
- Easily distinguished (numbers/letters)
- Easily legible, legible
- Easy to use
- Easy to read / harder to read
- Easy to put back into the pack (paper dimensions, leaflet only)
- Enabling the users to act appropriately (leaflet only)
- Ensure consistency across a number of different medicines
- Facilitates navigation / help navigate (column)
- Facilitates access
- Few syllables
- Followed in a user-friendly way (paper dimensions, leaflet only)

- Give sufficient detail on how to recognise possible side effects
- Give sufficient detail to understand any action which may be necessary
- More difficult to understand
- Helpful to patients (landscape layout, leaflet only)
- Helpful as a navigational tool (leaflet only)
- Highlight (certain graphic elements)
- Inapproriate (pictogram)
- Inappropriate for the product (sequence of bulleted list)
- Indelible
- Language which patients can understand (technical terms)
- Legibility / impairs legibility
- Length of the leaflet
- Long paragraphs (leaflet only)
- Long leaflets (paper)
- Maximises the number of people who can use the information (leaflet only)
- Meaning is clear (pictogram)
- Meaning is generally understood (all symbols)
- Not be contrary to the standards of decency (Pictograms, symbols, graphics)
- Not be contrary to the standards of good taste (Pictograms, symbols, graphics)
- Not be confusing (Pictograms, symbols, graphics)
- Not be misleading (Pictograms, symbols, graphics)
- Not be promotional (Pictograms, symbols, graphics)
- Open approach
- Place verb at the beginning (style)
- Promotional nature
- Quality of the print
- Recognise word shapes (words, leaflet only)
- Short lists of bullet points
- Simple punctuation
- Simple words
- Size of the graphic
- Spell out meaning in full (abbreviations)
- Sufficient detail
- Transparant (paper weight, leaflet only)
- Twenty word sentence (leaflet only)
- Understandable
- Use the most appropriate term (Lay or medical) (technical terms).
- Useful (symbols and pictograms)
- Useful (reference to other pharmaceutical forms)
- Well designed (leaflet only)

The fundamental problem with these criteria is that only very few of these can be evaluated. The large majority of these criteria is subjective and is open for discussion. Most of the criteria cannot be quantified. It is not possible to establish or check if these criteria have been met.

> **These are simply the wrong kinds of criteria: they cannot be used in practice. Adding more unquantifiable criteria does not resolve this issue.**

Furthermore, many of these criteria are in direct conflict with the requirement to test information. A usability test is the appropriate way to evaluate the quality of information. Many criteria, for example 'the twenty word sentence', might be overruled by the results of a usability test. This conflict between 'providing advice' and the 'obligation to test' needs to be addressed. It should be made clear in which situations the guideline prevails, and in which situations the results of the usability tests must be followed.

Quantifiable criteria

Fortunately, the EU-directives do mention unambiguous and quantifiable criteria. Directive 2001/83/EC states in point 40: 'The provisions governing the information supplied to users should provide a *high degree of consumer protection*, in order that medicinal products may be used correctly on the basis of *full and comprehensible* information.' This phrase provides criteria for all information about medicines.

For package leaflets, the criterion is even more specific. Directive 2004/27/EC, article 63(b)2 states 'The package leaflet must be written and designed to be clear and understandable, *enabling the users to act appropriately*, when necessary with the help of health professionals.' Directive 2004/27/EC therefore provides quantifiable criteria for the provision of information about medicines. Information must not only be 'comprehensible', but it must 'enable users to act appropriately'.

These phrases necessitate the involvement of people who handle medicines in the document development process. Only people who actually handle medicines (patients, nurses, pharmacists, doctors, ...) can judge if information 'protects', 'is comprehensible', is 'full', and is 'enabling to act appropriately'. Nobody else can do this.

Concluding

Criteria need to be clearly defined, unequivocal and measurable. Adding more criteria that cannot be used in practice does not help.

In view of the phrase 'enabling users to act appropriately' in Directive 2004/27/EC, it is necessary to make sure that information is usable. Section 8 outlines an approach that makes this possible.

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3. People: users, patients, consumers?

The Draft guidance and the EU-Directives about the provision of information about medicines do not clearly identify the recipient of this information. The draft guidance uses the following descriptors. In alphabetical order:

- adolescents
- blind
- by those who receive it
- different types of people (test participants)
- health professionals
- him
- hospital staff
- the least able
- literate adults
- new users (test participants)
- older children
- older readers
- older people (test participants)
- partially-sighted
- partially sighted patients
- participants
- patients
- patients' organisations
- patients with visual impairment
- people
- people with poor reading skills
- people who have poor health literacy
- people who can use the information
- people who have or have had the illness (test participants, rare illness)
- people who have previously taken or are currently taking the medicine
- people who do not normally use medicines (test participants)
- people who do not use written information in their working life (test participants)
- people who find written information difficult (test participants)
- population for whom the medicine is intended
- reader
- target patient groups
- those with poor literacy skills
- those with some degree of sight loss
- users
- visually impaired patients
- young people (test participants).

The use of different terms to indicate recipients of information about medicines has a longer history. Directives 92/27/EC, 2001/83/EC and 2004/27/EC also use several descriptors which are not clearly defined. Three examples are:

Example 1: The definition of a package leaflet (2001/83/EC, point 26) states: 'A leaflet containing information for the user which accompanies the medicinal

product.' In this article, the word 'user' can refer to patients, but equally well to nurses, pharmacists, hospital pharmacists or medical doctors. Directive 2001/83/EC, point 40 states: 'The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.' In this phrase, a 'user' is seen as a 'consumer'. This is an appropriate term for Over-the-counter medicines, where people can make a commercial decision themselves, but it is not suitable for Prescription-only-medicines. Furthermore, if healthcare providers are 'users' (point 26), than this article labels these professionals as 'consumers' too. That seems incorrect to me.

Example 2: Article 59(c) of Directive 2001/83/EC provides examples of users as 'children, pregnant or breast-feeding women, the elderly, persons with specific pathological conditions', while in article 67 of the same Directive the word user means health professional.

Example 3: Phrases like 'consultation with target patient groups ('user consultation')' indicate that 'patient' and 'user' are synonymous. For many medicinal products that might be the case, but for medicines administered by a healthcare professional, these two words have a clearly different meaning.

In order to develop guidance on the information about medicines, it is essential to make very clear for whom the information is intended. The different descriptions are confusing.

Concluding

The Draft guideline does 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 it makes it very difficult to determine valid criteria to evaluate the effectiveness of the provision of information about medicines.

Together with the descriptions of the deliverables (section 1) and the criteria (section 2), it is unlikely that the description of the people who interpret information about medicines (section 3) will lead to guidelines that are helpful for applicants or marketing authorisation holders. It is not clear what needs to be developed, it is not clear for whom this needs te be developed, and it is not clear which criteria could be used to evaluate the quality.

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4. Scope and aims: What are the fundamental problems?

The Draft guideline mentions three aims for the development of information about medicines. The guideline states that the first aim of the provision of information is to 'ensure that information is accessible and understood by those who receive it, so that they can use their medicines safely and appropriately'. This differs from the aim that is mentioned in the Directives. The Directive states: 'The provisions governing the information supplied to users should provide a high degree of consumer protection in order that medicinal products may be used correctly on the basis of full and comprehensible information' (EU Directive 2001/83/EC). There is a difference between 'safely and appropriately' and 'consumer protection and used correctly'. It is not clear why the 'high degree of consumer protection' is not mentioned in the Draft Guideline.

A second aim is the 'harmonisation of product information across all Member states'. Although this is not specifically highlighted, it is one of the main arguments to use standardised templates in different languages. This important argument deserves some more prominence.

A third aim is to minimise confusion and the number of errors. It is strange that this is only mentioned in the section about 'labelling' and therefore does not seem to apply to the information in the package leaflet.

The influence of information on the use of medicines is much wider than this guideline suggests. The provision of information about medicines has at least two other aims. These aims are:

- Consider cost-benefits and risk-benefits. It is likely that the costs of medicines in European countries will continue to increase. It is likely that information about medicines directly influences cost-benefit and risk-benefit decisions.
- Consider compliance (concordance). It is likely that information is directly related to the correct use of medicines. Substantial non-compliance rates could be reduced if appropriate information is provided.

There are therefore at least seven aims:

- 'avoid confusion'.
- 'enhance compliance and effective use'
- 'consumer protection'
- 'cost-benefits and risk-benefits considerations'
- 'error reduction'
- 'harmonisation of information across Europe'
- 'safe and appropriate use'

These aims can ony be considered in the longer term and include a number of factors that fall outside the area of labelling and package leaflets. However, not considering these issues is not an option: they are an integral part of the provision of information to people in Europe.

Concluding: The ultimate aim of the guideline is not considered sufficiently. It is likely that the scope of the guideline is too narrow to be effective. All effects of the provision of information about medicines must be considered.

5. Guidance: Writing

The Readability guideline provides some advice about the writing of information about medicines. It is remarkable that the guideline suggests to 'seek advice from specialists in information design' for the design, and to suggest that tests must be carried out by 'an experienced interviewer with good interview, observational and listening skills'. The guideline does not suggest to ask the advice from a 'medical writer' or 'technical writer' for the development of the text of information about medicines.

It would be very useful to have an explanation in the Readability guideline about the use of the EMEA-QRD templates. Especially the standard texts and phrases cause severe problems. An example is the sentence: 'If any of the side effects gets serious, ...'. This sentence is grammatically correct, but every English reader finds the word 'gets' after the plural 'side effects' an awkward construction. The Guideline should make it clear if 'standard statements' could be modified, or if they have to be used exactly as they appear in the template.

Some of the advice in the Draft guideline is in direct conflict with the EMEA-QRD templates. Three examples are:

Example 1: The example provided in section 6 'Style' states: 'take 1 tablet' instead of '1 tablet should be taken'. The second part of this example - '1 tablet should be taken' - is in conflict with EMEA guidance (Compilation of QRD decisions on stylistic matters in product information. Version 9, December 2005). In this guidance it states: 'it is advisable that the word "should" is avoided wherever possible in the English original itself.'

Example 2: The sentence 'If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist' consists of 26 words. It does contain new information, so this sentence must - according to the guidance in section 5 second bullet - be improved by using a couple of sentences. Unfortunately, the EMEA-QRD template prevents this: 'Standard statements must be used whenever they are applicable.'

Example 3: The guideline suggests to 'Give reasons when telling patients what actions to take. Instructions should come first, followed by the reasoning.' The EMEA/QRD template contains the following obligatory text: 'Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.' In these obligatory sentences, the instruction does not come first. Furthermore, the first sentence is not in the required 'active style by placing the verb at the beginning of the sentence'.

These three examples show that following the EMEA/QRD template unavoidably leads to the rejection of the advice of the Draft guideline.

Terminology

Apart from the terminology about the 'deliverables' (section 1), 'people' (section 2) and 'criteria' (section 3), there are many other terms that need to be clarified and defined. Three examples are:

- font, typeface, print, characters, text

- font size, type size, print size
- elements, particulars, items of information

Spelling

Several words are spelled in different ways in the guideline. Please use a consistent spelling for:

- ‘partially sighted’ or ‘partially-sighted’.
- ‘Package Leaflet’ or ‘package leaflet’.
- ‘word shape’ or ‘word-shape’.
- ‘side effects’ or ‘side-effects’.
- ‘mock up’, ‘mock-up’ or ‘mock’.

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6. Guidance: Designing

The Readability guideline provides some advice about the design of the labelling and package leaflet.

The main aim of the visual presentation of labelling information and the visual presentation of package leaflets is to support the main aim of the supply of information: 'to enable users to act appropriately'. Examples of activities are 'identification', 'locate a starting point', 'keep leaflets and packaging together', 'follow the instructions', 'check the leaflet', 'recognize a package', and so on. These visual actions are known or they can fairly easily be described.

Observing participants during a readability test provides valuable data about the ways in which people look at package leaflets. People rarely look at the detailed level of visual elements, and do not distinguish between 'typeface', 'typesize' or 'the use of columns'. Characteristic ways of looking at a package leaflet are a sequence of scanning, turning, rescanning, focussing on a detail, searching for another detail, and returning to the first detail to confirm the first interpretation. At this point, the participant focusses on a specific sequence of words and interprets these words.

Observing pharmacists while they select the medicines from a large cupboard shows how important visual design is for this activity. 'Visual memory' plays an important role here. It seems that searching for a specific package involves the matching of visual imput of colours and shapes within a limited area with a 'memory image' of a specific package.

The Draft guideline does not provide guidance to optimally support these different visual activities of people. The Draft guideline does not focus on the 'higher level' visual activities.

In stead, the Draft guideline focuses on the description of a limited number of visual elements, such as 'type', 'colour' and 'headings'. There are two fundamental objections to this 'single variable' approach. The first is that it directly conflicts with the obligation to test package leaflets. Three examples:

Example 1: The Draft guideline suggests to use a typesize for the main text of 12 points. A readability test might show that a package leaflet with a substantially smaller typesize passes the 'location and understanding' criteria. Either the results of a readability test are followed, and the textsize is smaller than 12 point, or the Draft guidance is followed, and the textsize is set at 12 points. However, it is likely that this larger typesize increases the dimensions of the package leaflet, which might have severe financial consequences.

Example 2: The Draft guideline suggests that 'a serif typeface is preferred, since the shape of the characters is easier to read'. If a package leaflet is set in a sans-serif typeface, and it passes a readability test, is it still necessary to follow the advice in the guideline?

Example 3: The Draft guideline suggest that 'reversed-out text is particularly difficult for older readers'. If a readability tests shows that this statement is incorrect, does this advice prevail, or should the guideline be ignored?

A second objection is that the Draft guideline suggests that it is possible to consider graphic variables independently. That is not the case. A graphic designer or information designer needs to consider all factors at the same time and choose the combination that best suits a specific situation. Focussing on a single graphic variable, or on a range of variables does not automatically lead to an appropriate design. Three examples:

Example 1: Headings in colour might interfere with the visual salience of warnings. They need to be considered at the same time to make sure that the contrast is as clear as possible, before a readability is conducted.

Example 2: The relation between 'emphasized texts' and headings need to be balanced in such a way that they do not lead to a confusion about their status.

Example 3: For the design of the information on the packaging, the guideline suggests to 'make best use of the space available'. This is not very helpful, because any design must follow this advice.

Furthermore, the design of the guideline seems to be in conflict with its own advice. Again three examples:

Example 1: It is not clear why section 1 and 2 use bullets and section 3 and 4 do not use bullets. The visual presentation indicates that the text in section 3 and 4 has a different status, or a different type of content than section 1 and 2.

Example 2: The guideline suggests to choose a typeface in which similar letters/numbers such as "i", "l" and "1" can be easily distinguished from eachother. The typeface of the guideline itself makes it impossible to distinguish the "1" and "l".

Example 3: The guideline states that 'same level haings should appear consistently (numbering, bulleting, colour, indentation, font and size) to aid the reader. The design of section heading B and section heading C differ in their space that follows the B and C, and the headings in Chapter 2 do not follow this advice.

Concluding

The Draft guideline seems to describe the visual design of information at the most detailed level only. It would be more beneficial to start from the visual activities of users at an overall level. The advice in the Draft guideline might be in conflict with the results of readability tests. The guideline does not provide any advice if this situation occurs. The Draft might actually prevent the developments of novel solutions. Furthermore, the Draft guideline treats graphic variables as separate elements. That is not a practical approach. Designers must consider the relations between the graphic variables.

7. Guidance: Testing

The Readability guideline provides testing advice in annex 1. Below are some comments related to the participants, criteria, method and validity.

Test participants: criteria for inclusion

The example method in Annex 1 suggests that it is necessary to select the test participants according to the following criteria.

- population for whom the medicine is intended.
- a range of different types of people who are able to imagine needing to use the medicine
- (rare illness only): people who actually have or have had the illness. It might be necessary to exclude people who have previously taken or are currently taking the medicine
- the least able
- new users
- people who do not normally use medicines
- people who do not use written documents in their working life
- people who find written information difficult
- literate adults

There is no motivation why these critiria need to be applied. There might be an expectation that these criteria have an influence on the results of a readability test, but this assumption is not supported by any evidence. The list leaves many questions open. Three examples:

Example 1: 'people who do not normally use medicines'. This implies that there are people who 'normally use medicines'. That is a very odd phrase because it makes 'people needing treatment' the standard, and it classifies 'healthy people who do not use medicines' as 'abnormal'.

Example 2: 'people who do not use written documents in their working life.' I'm not sure if there are any documents that are not 'written'. Is there any reason to assume that 'literate adults' must be subdivided into 'people who do not use written documents in their *working life*' (= manual labourer?), 'people *who do use* written documents in their working life' (= desk worker?), or 'people who do not use written documents *in any other life*' (= retired? housewife?). Every individual in our society has to deal with 'written documents'. Tax forms, bank statements, insurance letters and invoices are fairly common. The classification 'literate adults' varies between 'barely able to read' to 'fully competent'. I'm not sure why 'people who do not use written documents in their working life' need to be singled out in this guideline.

Example 3: 'people who find written information difficult.' This statement confuses cause and result. 'Finding information difficult' is not a classification of people, but an indication of the quality of information. I can easily read a Unix manual, but have severe problems with a tax form or a financial report.

If the guideline wants to suggest which participants should be approached, it needs to make this advice clear.

Test participants: illnesses and medicines.

The guideline states that for medicines for rare illnesses, it would be advised to approach people who have or have had this rare illness. However, in order to find out if a person has a rare disease, or has used certain medicines before, it is necessary ask this directly. 'Have you got Y?' and 'Have you ever used X before?'. Other ways to find the answers to these questions are not allowed due to privacy-legislation, and the strict codes of professional conduct of doctors and pharmacists. Asking these questions could be interpreted as a personal critique on the professional decision of a medical doctor. The following answers are possible:

1. 'yes'. The patients tells the interviewer that they have rare illness Y and that their doctor has prescribed medicine X. The implication is that this decision is questioned: 'That is an uncommon/strange decision of your doctor'.
2. 'no'. The patients tells the interviewer that they have rare illness Y and that their doctor has not prescribed medicine X. The implication is that this decision is questioned: 'That is an uncommon/strange decision of your doctor'.

Both answers are undesirable because they imply a judgement on the professional decision of a medical doctor.

The Draft guideline makes a difference between 'people with a rare illness' and 'people without a rare illness'. It is assumed that this difference will influence the test results of a readability test. I'm not sure if there is any evidence that people with a rare illness locate and interpret information in any other way if this group is compared to people without a rare illness.

The situation is likely to be different for 'experienced patients' and 'recently diagnosed patients'. The knowledge about a particular situation Y and medicines X of experienced patients certainly differs from 'novices'. However, it is not sure if experienced patients 'locate' and 'comprehend' information in a fundamentally different way, nor if this has any influence on the scores of a readability test.

Criteria: 90%?

The criteria of the Readability test need careful consideration. The following comments highlight some of the issues.

1. The Draft guideline suggests that it is possible to calculate 'quantitative results' from a 'qualitative test method'. The most useful results of the interviews are the remarks of participants, and not the number of correctly located answers or the number of correctly answered questions. The guideline should make clear that the verbal responses of participants are the main result of a Readability test. The calculated percentages are only a secondary result.
2. The aim of the readability test is not defined well. The first line in section 3 of the Annex states that 'the aim is to meet the success criteria in a total of 20 participants'. This is not correct. The main aim of the Readability test is to improve the text and design of the information in such a way that it optimally 'enables users to act appropriately'. With the rephrasing of the aim, the Draft guideline applies criteria that do not relate to a aim of the provision of information stated in the European Directive.

3. The success criterion relates percentages (90%) and the number of participants (20). Ninety per cent of 20 participants is 18 participants. Ninety per cent of 18 participants is 16.2 participants. This last number – 16.2 – makes it impossible to apply the 90% criteria to readability test results. Does this mean that a package leaflet fails the test if 16 people out of 20 can locate and understand the information?
4. Furthermore, it is not clear if this 90% level must be calculated per question, as it was mentioned in the previous version of the guideline. It might also be possible to achieve the 90% level calculated over all questions in a test (20 people times 15 questions = 300 questions. 90% =270 correctly located answers and 243 correctly understood)?
5. The '90% of 90%' makes different levels of understanding acceptable. If 100% of the participants can find the information, and 90% of this information is understood correctly, than 90% of the 'literate adults' might be 'enabled to use a medicine appropriately'. If 90% of the participants can find the information, and 90% of this information is understood correctly, than 81% of the 'literate adults' might be 'enabled to use a medicine appropriately'. The difference between 90% and 81% is very substantial. It means that between 1 out of 10 patients and 1 out of 5 patients is not able to understand information about medicines. That is a very low threshold if it is related to vital safety information. It seems necessary to vary the importance of questions according to their relevance and safety.

Method: context

A diagnostic test is a very useful tool to find out exactly where people encounter problems with a document. A diagnostic test is not meant to provide an overall score of the quality of a document. Other types of usability tests are likely to be more appropriate.

The diagnostic test, as it is described by David Sless and Rob Wiseman (1997), investigates the accessibility, comprehensibility or the capacity of the participants to act appropriately on the information (p 79) within an information design process. A diagnostic test does not measure 'readability', 'usefulness', 'legible', 'clear', 'easy to use' nor any of the other criteria mentioned in section 2. Diagnostic tests do not establish if people really act appropriately in practice. It only establishes if participants would be capable to act. In order to find out if people act appropriately, different types of experiments are needed. Before suitable test methods can be chosen, it is necessary to clarify users, criteria and acceptable performance level.

Example 1. Patients need to make a risk-benefit decision before they take prescribed medicines at home. A diagnostic test will not indicate if this decision is made at all, and whether this decision is made correctly.

Example 2. Patients also have to remember the effects (positive and negative) that they might experience after taking a medicine, such as 'feeling dizzy', or it's easier to breath'. A diagnostic test will not show if people will remember these effects when the situations occurs.

If the actions 'making (risk-)decisions' and 'remembering' are relevant to particular medicines, they need to be tested with suitable methods. A diagnostic test seems inappropriate to investigate the use of information for specific actions.

Other methods, such as contextual inquiries, observation studies, and

benchmark studies are more appropriate. The results of the tests in the analysis indicate which criteria are suitable, and which levels could be achieved. These provide a basis for the diagnostic test. Conducting diagnostic tests without those criteria and levels is futile. Diagnostic tests are only useful if they are used appropriately as an integrated part of a larger document development process.

The Guideline assumes that the testing technique proposed for the testing of Consumer medicines information in Australia is also suitable for Package leaflets in Europe. However, these are fundamentally different pieces of information. The source (industry or pharmacists), the delivery method (inside a box or at the local pharmacist), the required languages (multilingual or single language), the legal situation are ignored if the Australian model is copied. It is essential to make sure that this 'example method' is suitable for a European situation before it is implemented in a guideline.

Validity

The internal validity of a diagnostic test is not an issue. The tests clearly show that changes in the design and text of a document influence the test results. The ecological validity is however problematic. The question 'is there a relation between the results of a diagnostic test and the use of information about medicines in practice?' must still be asked and answered. Without some clear evidence, it is not possible to indicate if a test accurately detects information that could lead to dangerous situations or inappropriate use. Suggesting a testing method without any investigation into its ecological validity is very risky.

8. Approach to developing information about medicines.

There are four fundamental problems with this Draft guideline. These are related to:

1. The activities of people. If the aim of the provision of information is to 'enable users to act appropriately', than the starting point must be 'the action of users'. The draft guideline does not do this.
2. The Guideline does not make any reference to other information sources or other modes of communication that 'enable users to act appropriately'.
3. The Guideline does not use a suitable model for an 'information development process'. The division between writing, designing and testing is in practice hardly possible.
4. The judgement of the quality of the information is not integrated into a longer term process. The guideline suggests a 'standard', but does not leave enough room to improve on this.

Each of these problems is described below.

1. Start from the activities of people.

The main reason to provide information about medicines is to support people who handle medicines. The Directive states: 'enabling the user to act appropriately.' In order to comply with the legal requirement of Directive 2004/27/EC to 'enable the users to act appropriately', it is necessary to introduce a development process that leads to the realization of this requirement. Careful consideration must be given to determine which 'people' need to be taken into account, which 'actions' should be evaluated, and what 'appropriate use' exactly entails. These three factors cannot be considered without the involvement of people who have an interest in the provision of information about medicines. A careful analysis of the use of information within a specific context must be used as a starting point.

One specific situation can be used as an example:

> A patient has just arrived home from a visit to a dispensing pharmacist where she has acquired some Prescription only medicines. At her kitchen table, she unpacks a small plastic bag. A first step is that this patient needs to *identify* the products (what is it and what is it for?), to *locate a starting point* (which box and leafl et do I read first?, which information is most relevant for me?), and *keep leaflets, boxes and medicines together* (avoid confusion). As a second step, she needs to *make a decision* (Can I take this medicine?), *consider* if she wants to take it ('Do the benefits outweigh the risks?'), *remember the effects* ('I've got to drive later on today, but this makes me drowsy. I better take it later.') and *learn to understand* how her medicines work. The third step consists of taking the medicines. This consists of *following the instructions* ('Before dinner'), *noticing any effects* ('I feel drowsy'), *check the leaflets again* ('Where did it state that I could get drowsy?'), *react appropriately* ('Do I need to call a doctor?') and *store the medicines* in a safe place ('Roomtemperature?'). After taking the medicines, a patient has to make a *decision whether to stop or continue*, and *decide whether to consult a doctor* again. A final action is to *dispose of any remaining medicines*.

Each of these activities must be supported by relevant information in order to make it possible to use medicines correctly. Each of these activities can be tested when suitable criteria are chosen, and minimally acceptable standards can be discussed.

The description of the use of a medicine that is used in a hospital is very different. A hospital pharmacist approaches a label and package leaflet in a very different way and sequence. And even identical activities are influenced by the context in which they are executed. For example, the *identification* of an outer package by a pharmacist in a pharmacy differs from the *identification* of the same outer package by a patient in a medicine drawer in a kitchen at home. Not all activities are equally important, not all users are the same, and the context of use must be taken into account.

The guideline starts from the idea that all medicines must be accompanied by information that is structured in the same way ('harmonisation') . This is in direct conflict with the variety of available medicines and the variety of ways in which these are used in practice.

2. Make references to other information sources.

The guideline focuses on the labelling and package leaflet. The separation of the sections in the guideline seems to suggest that they are developed individually. That is not the case: all deliverables need to be considered simultaneously.

The main reason is that people will see the package leaflet, immediate packaging and outer packaging together. People (patients, doctors, nurses, pharmacists, ...) will always see the combination of these artefacts. People do not separate information according to 'labelling and package leaflet' but need answers to their immediate questions. For example 'is this inhaler for daily use, or for asthma attacks only?' At that moment, this information must be very prominent, and it does not matter if it is found on the labelling or in the package leaflet. Focussing on one artefact only - in stead of on the activity of the user - reduces the overall impact. The information must be considered as a whole concept, not as a collection of different details.

Furthermore, the information that must be mentioned on labelling and in package leaflets is not related to other external developments. The developments in digital resources (bar coding, world wide web, e-mail), telephone services (helplines, sms), and patient organisations are not integrated into this guideline.

The guideline starts from the idea that labelling and package leaflets can be developed separately and independently from other information sources. This is incorrect. People search and interpret all information that is available to achieve their goals. If the package leaflet or the packaging does not provide information quickly enough, they will be disregarded.

3. Start from a suitable information development process: Writing, designing and testing cannot be separated.

The Readability guideline provides advice on the development of information about medicines on labelling and in package leaflets. The structure of the guideline suggests that it is possible to separate writing, designing and testing. The guideline mentions first some issues related to the visual design (Part A 1-4). That is followed by some advice about the style (Part A 5-6). The example of a testing method is mentioned in an annex. This division of activities is confusing.

In order to develop information about medicines is essential to describe and analyse the activities of people when they handle and use a specific medicine. These activities are known for each medicine. Every applicant or marketing authorisation holder knows exactly how their medicines are used in practice. The development process of information must start with an observation and an analysis of current practice. 'User experience mapping' and 'contextual enquiries' are examples of techniques to accurately determine the different actions. Observing and recording the current state of affairs needs to be done to find out what is going well, and which activities need additional or a different type of support. Both 'best practice' as well as 'worst cases' need to be recorded with supporting evidence of potentical causes. This observation will reveal the activities that are likely to be problemeatic in relation to safety, benefits, risks, compliance and errors. An added benefit of this description is that information can build upon the expectations and experience of people.

Based on this description of current practice, and the knowledge about a particular medicine, a 'concept for use' can be developed. This concept describes the actions that people need to do to handle a medicine appropriately and indicates which user actions require extra support. All deliverables (package leaflets, packaging, and later websites and telephone helplines) must be developed to support this concept.

From this point of view, it is hard to understand why only the package leaflet must be tested. It would be very helpful to test the labelling too. Many accidents happen due to confusing packaging: these can be avoided if simple tests are conducted.

These are the first steps in a normal 'information development process'. The guideline suggests that the choice of the printsize and type is the most important issue by placing it as the first element to be considered. This conflict between 'good practice' and 'suggested practice in the guideline' is very substantial.

The digital development of information requires a very strict version control of the different documents. This practical issue is not dealt with in the guideline.

The lack of a reference to the Product Information Management (PIM) system is a serious omission too. It would be beneficial if at least a reference to this system is included in the Draft guideline.

The guideline starts from the idea that there is only one type of development process in which writing, designing and testing are separated. The variations in writing, designing and testing are ignored.

4. Judging the quality of information is a continuous process.

The aim of the Readability guideline is to support applicants and marketing authorisation holders to produce 'high quality information' (section 'Purpose'). The judgement about the quality of the information is made by four groups of people:

1 - The applicant or marketing authorisation holder who checks if the information is conform the requirements. Different departments, such as legal, production, marketing, and medical, all have their influence.

2 - Participants in a Readability test, who check if information can be located and understood.

3 - The competent authorities, who check if the legal requirements have been met.

4 - People who handle a medicine after registration.

If 'high quality information' is the real aim, than the Readability guideline must provide a description of a process that relates to these four groups of people. Quality judgement is not a 'single point in time', but a continuous process. Ignoring this process has detrimental effects in a few years time. At the moment it is already very hard to follow the advice in the Draft guideline. In a few years time it is likely to be impossible.

The guideline does not provide guidance about the four different groups who judge the quality of the information about medicines. The guideline does not describe a process of quality improvements.

Concluding

There are four fundamental problems with the Draft guideline and the Directives is that they assume that the information about all medicines can be approached in an identical way. The provision of information about medicines is a lot more complex and requires a variety of approaches. The activities of people, integration with other information sources, information development processes and quality assurance processes are fundamental for a Readability guideline. The Draft guideline does not pay enough attention to these topics.

Conclusions

The comments on the previous pages indicate that the Draft guideline is fundamentally flawed and should not be introduced in this format. The main arguments are:

1. It is not clear what exactly needs to be delivered.
The guideline does not tell what the end results must be. It is not clear what needs to be submitted to the authorities, nor what needs to be developed.

2. The criteria to evaluate and check the results are incorrect.
Adding more immeasurable criteria does not help. It is essential to use relevant and measurable criteria.

3. The people who are involved are inappropriately adressed.
A guideline must make clear who has to do what. The guideline lists many different potential groups, without suggesting how these groups have an influence on the texts in the EMEA-QRD template.

4. The scope of the guideline is too narrow to be effective.
Focussing on details of specific issues is not sufficient. The larger issues (costs, compliance and errors) must be taken into account.

5. The advice on the writing of information about medicines is based on incorrect assumptions.
Writing is not just related to syntax and style. Suggesting that it can reduced to a limited number of factors does not do justice to the writing professions (medical writers, technical writers, document developers, ...).

6. The advice on the designing of information about medicines is based on incorrect assumptions.
Designing is not about 'choosing the details', but to consider all factors simultaniousy to make a prototype of the most promising combination. Suggesting that it can be reduced to a limited number of factors does not do justice to the design professions (graphic designers, information designers, ...).

7. The advice on the testing of information about medicines is based on incorrect assumptions.
Testing is not a solitary activity at the end of the development process. It is an integral part of the process. Suggesting that it can be reduded to a limited number of factors does not do justice to the testing professions (usability professionals, marketing researchers, ...).

8. The approach to developing information about medicines is problematic. The provision of information about medicines is a lot more complex and requires a variety of approaches. The activities of people, integration with other information sources, information development processes and quality assurance processes are fundamental for a Readability guideline. The Draft guideline does not pay enough attention to these topics.

9. The editing, spelling and typography of the guideline itself needs attention. There are many spelling mistakes, poorly edited phrases and paragraphs, poor structuring and poor typography. If this guideline needs to be taken serious as an example of writing, designing and testing, it needs to stick to its own standards.

Based on these nine conclusions, I recommend in the strongest possible terms to reconsider this guideline.

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Appendix 1: Example guideline.

This appendix shows how a guideline could be presented. The guideline is aimed at applicants and marketing authorization holders to make it easier to develop information about medicines. A step by step guideline might be a more appropriate format.

Step 1. Develop a concept based on the activities of people who have to handle your medicine. The concept-document describes the actions, the users, and the acceptable level of achievement for each action. It is essential to investigate the actions and prioritise those that require most attention. After that, it is necessary to decide how each of the different deliverables could support these actions. This concept describes the approach that all information must follow. (* Link to an example of a concept document.)

Step 2. Download the EMEA/QRD templates from the website: www.emea.europa.eu Choose the relevant language(s) and the appropriate registration procedure. (*Link to an explanation of the different procedures.)

Step 3. Modify the template by inserting information about your product. Use the available guidance that can be downloaded from the same EMEA-website. (*Include a list of references and documents here.) Make sure all information of the SMPC is included and that all information conforms to the concept. (Practical issue: Who does the writing? Which software? Version management?) (*Include an example of a time planning here.)

Step 4. Design the leaflet. Start from the available dimensions of paper that are determined by the production facilities. The structure of the headings needs to be most prominent. (Practical issue: who does the design? External, internal, integrated in production? Consider all presentations: paper, sound, Braille, web, multilingual.) (*Include an example of a time planning here. *Include examples of approved leaflets here.)

Step 5. Make a list of the most important issues based on the preliminary research. These are the things that people must know when they handle this medicine. Write these issues in question format. Randomise their order. (*Include an example of a time planning here. *Include an example of a questionnaire.)

Step 6. Pilot test the leaflet. Interview three to five people to find out if the design, the text and the questionnaire do not contain major errors. Three participants are sufficient for a simple leaflet; five participants for a more complex leaflet. The participants of a pilot test do not have to be patients, but people who can imagine that they are in a particular situation. (*Include an example of a time planning here. *Include a list of the individual details of the test participants that must be submitted. *Include requirements in which the original data - comments and recordings - must be archived for future use.)

Description of a single interview:
- Recruitment: where to find people who can provide relevant feedback? (patients or healthy volunteers, How to deal with confidentiallity issues?)
- Location: what is a suitable venue?
- Interview: a step by step description of an interview. (It would be really useful if a video-recording would be made available on the web as an example to show how an interview is conducted.)
- Reporting: a step by step guide how to record, report, analyse and present responses. (*Include an example of a report.)

Step 7. Rewrite and redesign the leaflet and the questionnaire if the pilot test indicates that this is necessary. (*Provide a guide and examples on how to interpret the answers and motivate modifications.)

Step 8. Test 1 + report
Interview 10 people. (*Refer to the guide and examples on how to interpret the answers and motivate modifications. *Provide example of a test report.)

Step 9. Rewrite and redesign. Motivate all modifications. (*Provide examples of correct and incorrect motivations.)

Step 10. Test 2 + report.
Interview 10 people. (*Refer to the guide and examples on how to interpret the answers and motivate modifications. *Provide example of a test report.)

Step 11. Final conclusions + report + final text of the leaflet. (*Provide example of a test report. *Provide a checklist to control if all required files are available.)

Warning: It is absolutely vital to keep track of all versions. Version control of all required files is essential. It would be really useful if an example of all required files for a readability report would be made available on the web.

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