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Statement relating to the

QRD template draft

(status of discussion: 23rd of February 2010)

content

Summary

The Quality Review of Documents (QRD) Working Group published the draft of an updated QRD product information template on 23rd of February 2010 [1]. Most new recommendations affected the package insert.

Some of the template adaptations provided are assessed to be helpful, but others, such as the increase in the volume of text due to more general text modules and the differentiation in the side effect chapter, will significantly impair package inserts. In this statement we endeavour to explain our assessment based on research studies and practical experience gained over ten years as a package insert readability test provider.

Based on the explanations and facts provided below, we recommend a significant compression of the QRD template wording for package inserts so as to retain the focus on the essential need to inform patients about their medicines.

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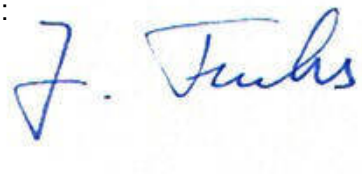
Date: Jena 26th of April 2010

Signature: 

1 Introduction

The QRD product information template has provided, for a long time now, a text frame for the SmPC, label and package insert that is valid in all European Union member states. Whilst acknowledging that some parts of this template could be improved, we assess the QRD template as a very helpful conduit for providing medical information because it:

- harmonizes information order and the texts for different medicines in all European Union member states and their connected countries
- assists patients and healthcare professionals to locate the medical information provided, due to the uniform headings, content and general texts

  If, for example, United Kingdom residents who sometimes use a pain killer at home are required to purchase it while in another European Union Member state, such as Ireland or Spain, they will find identical wording and order in package insert information in each country. In addition, given that this template is used for all medicines sold within the European Union, patients of each member state are already familiar with the text used and the order of the information.
- supports pharmaceutical companies and medical approval agencies developing and assessing the required medical information

Considering the QRD template's special importance, ongoing enhancement is essential. We at PAINT-Consult® embrace the QRD Working Group's publication of the draft of the updated template for discussion and to encourage feedback with the aim of achieving the most appropriate version. We wish to contribute to this process, bringing our experience of over ten years with package inserts - including their readability tests - and our research results gained through multiple studies of this field.

2 QRD template's volume of text

One of our most recently completed surveys, the PAINT2 study, investigated 271 package inserts, representing a random sample selected from all medicines distributed on the German market in the year 2005. We found an average volume of text of 2005 words per package insert and a significant text increase of 63.3% during the last five years ($p<0.001$). Additionally, the QRD and national template texts used in package inserts, also showed a significant rise over this period of 25.1% ($p=0.002$), to an average of 361 words [2].

However, the current QRD template already carries over 500 words [2], a burden on this framework caused mainly by the failure to limit the amount of unspecific information about the medicine.

The PAINT1 study results show that the volume of text exerts a very high influence on a patient's use of package inserts. This study investigated five original package inserts distributed on the German medicine market alongside five model package inserts using the written readability test in a cross-over test design with 1105 participants. The outcomes clearly illustrate that increasing the volume of text significantly decreases patients'

- ability to locate the provided information
- motivation to read the package inserts
- trust in using the medicines after reading the package inserts [4, 5].

The five model package inserts were developed prior to the PAINT1 study using a set of over one hundred quality criteria. They contained the same contents required to sufficiently inform patients as their corresponding original versions, however, using compressed texts with optimized layout and design. Also their template text was compressed to around 200 words. The results indicate that shorter templates are sufficient and lead to significantly better results in the locatability and comprehensibility of the provided information [4, 5].

Our company's most recently completed study, called PAINT3 study, investigated all 271 PAINT2 study package inserts using the written readability test (n = 5091 participants). The results, identical to the PAINT1 study, show that a continuous increase in the volume of text significantly and continually decreases: the motivation to read the information, the trust in using the medicines, the locatability and also the comprehensibility of the provided contents [6].

Furthermore, in the PAINT3 study, we tested eight different model package inserts types, each of three different medicines. The eight different models per medicine contained identical wording, line length and many other identical parameters, with the exception of two which contained the QRD template text (version 1.2 for MRP and DCP procedures) [3] instead of a shorter model text frame of around 200 words (figure 1).

Lesen Sie bitte aufmerksam die Packungsbeilage!

Enal 20 mg Tabletten

1. Wofür wird Enal verwendet?
- gegen hohen Blutdruck
- gegen verringerte Herzleistung kombiniert mit anderen Mitteln
- Fehlfunktion der linken Herzkammer

2. Was müssen Sie vor Einnahme von Enal beachten?

Nicht einnehmen bei
- Überempfindlichkeit gegen einen Bestandteil von Enal
- Schwangerschaft
- Stillzeit
- Kindern unter 18 Jahre
- gestörte Leberfunktion
- Therapie zur Abschwächung einer Allergie gegenüber Insektengiften
- Ausflussbehinderung der linken Herzkammer
- Neigung zu meist schmerzhafter, starker Schwellung tiefer Hautgewebe, oft im Gesicht
- Verengung von Blutgefäßen der Niere
- nach Transplantation einer Niere
- zu viel des Hormons Aldosteron im Blut
- Gebrauch spezieller Membranen zur Dialyse wie AN 69®
- Entfernen von LDL-Cholesterin mit Dextransulfat

Erst nach Arztrücksprache einnehmen bei
- gestörter Nierenfunktion
- Eiweiß im Urin über 1 g pro Tag
- gestörtem Mineralhaushalt
- Dialyse – Siehe auch: „Nicht einnehmen bei"
- gestörter körpereigener Abwehr
- dauerhafter Verhärtung von Hautbereichen
- Mangeldurchblutung im Herz oder Gehirn

Einnahme mit anderen Arzneimitteln

Reden Sie mit Ihrem Arzt oder Apotheker bei Gebrauch anderer Arzneimittel in den letzten 14 Tagen. Dies gilt besonders bei:
- Allopurinol: ein Mittel gegen zu viel Harnsäure
- Blutzucker senkende Mittel
- Blutdruck senkende Mittel
- chemische Schlafmittel
- Cortison zum Verabreichen in den Körper
- die körpereigene Abwehr senkende Mittel
- harntreibende Mittel, die Kalium im Körper zurückhalten
- Heparin: ein Mittel zur Blutverdünnung
- Lithium: ein Mittel gegen seelische Störungen
- kaliumhaltige Mittel
- Mittel zur Betäubung
- Mittel gegen Krebs.
- Mittel gegen Schmerzen, Entzündungen oder Fieber, wie Acetylsalicylsäure, Indometacin
- Procainamid: ein Herzmittel

Nahrungsmittel und Getränke

Verzichten Sie auf das Rauchen, Alkohol und den Verzehr von mehr als 6 g Salz pro Tag.

Verkehrstüchtigkeit und Maschinen

Bedienen Sie Fahrzeuge oder Maschinen erst nach Rücksprache mit Ihrem Arzt.
Eine Therapie mit Enal kann Ihr Reaktionsvermögen beeinträchtigen.

3. Wie ist Enal einzunehmen?

Nehmen Sie Enal immer nach Anweisung Ihres Arztes ein.

Hoher Blutdruck
- Startdosis: ¼ Tablette täglich
- **Übliche Dosis: 1 Tablette täglich**
- Maximale Tagesdosis: 2 mal 1 Tablette

Andere Anwendungsgebiete
- Nur für die Startdosis schwächere Tabletten nutzen!
- **Übliche Dosis: ¼ Tablette täglich**
- Maximale Tagesdosis: 1 Tablette

Nierenkranke und über 65-Jährige
- Startdosis: ist von der Nierenfunktion abhängig
- Maximale Tagesdosis: 1 Tablette

Art der Einnahme
- unabhängig von den Mahlzeiten und immer zur selben Tageszeit, bevorzugt morgens
- sitzend oder stehend mit einem Glas Wasser mit mindestens 100 ml Inhalt
- teilen der Tabletten wie im Bild zu sehen

Dauer der Einnahme
- bestimmt Ihr Arzt

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a) Enalapril package insert using model text template (page 1)

Gebrauchsinformation:
Information für den Anwender

Enal 20 mg Tabletten

Enalaprilhydrochlorid

Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Einnahme dieses Arzneimittels beginnen.
- Heben Sie die Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Wenn Sie weitere Fragen haben, wenden Sie sich an Ihren Arzt oder Apotheker.
- Dieses Arzneimittel wurde Ihnen persönlich verschrieben. Geben Sie es nicht an Dritte weiter. Es kann anderen Menschen schaden, auch wenn diese die gleichen Beschwerden haben wie Sie.
- Wenn eine der aufgeführten Nebenwirkungen Sie erheblich beeinträchtigt oder Sie Nebenwirkungen bemerken, die nicht in dieser Gebrauchsinformation angegeben sind, informieren Sie bitte Ihren Arzt oder Apotheker.

Diese Packungsbeilage beinhaltet:
1. Was ist Enal und wofür wird es angewendet?
2. Was müssen Sie vor der Einnahme von Enal beachten?
3. Wie ist Enal einzunehmen?
4. Welche Nebenwirkungen sind möglich?
5. Wie ist Enal aufzubewahren?
6. Weitere Informationen

1. Was ist Enal und wofür wird es angewendet?
- gegen hohen Blutdruck
- gegen verringerte Herzleistung kombiniert mit anderen Mitteln
- Fehlfunktion der linken Herzkammer
- kaliumhaltige Mittel
- Mittel zur Betäubung
- Mittel gegen Krebs.
- Mittel gegen Schmerzen, Entzündungen oder Fieber, wie Acetylsalicylsäure, Indometacin
- Procainamid: ein Herzmittel

2. Was müssen Sie vor Einnahme von Enal beachten?

Enal darf nicht eingenommen werden,
- wenn Sie überempfindlich (allergisch) gegen Enalaprilhydrochlorid oder einen der sonstigen Bestandteile von Enal sind
- bei Kindern unter 18 Jahren
- wenn Sie eine gestörte Leberfunktion haben
- wenn Sie eine Therapie zur Abschwächung einer Allergie gegenüber Insektengiften erhalten
- wenn Sie eine Ausflussbehinderung der linken Herzkammer haben
- wenn Sie eine Neigung zu meist schmerzhafter, starker Schwellung tiefer Hautgewebe, oft im Gesicht haben
- wenn Sie eine Verengung von Blutgefäßen der Niere haben
- nach Transplantation einer Niere
- wenn Sie zu viel des Hormons Aldosteron im Blut haben
- bei Gebrauch spezieller Membranen zur Dialyse wie AN 69®
- bei Entfernen von LDL-Cholesterin mit Dextransulfat

Besondere Vorsicht bei der Einnahme von Enal ist erforderlich
- wenn Sie eine gestörte Nierenfunktion haben
- falls Sie Eiweiß im Urin von über 1 g pro Tag haben
- wenn Sie einen gestörten Mineralhaushalt haben
- wenn Sie Dialyse erhalten – Siehe auch: „Nicht einnehmen bei"
- wenn Sie eine gestörte körpereigene Abwehr haben
- wenn Sie eine dauerhafte Verhärtung von Hautbereichen haben
- wenn Sie eine Mangeldurchblutung im Herz oder Gehirn haben

In diesen Fällen sollten Sie vorher mit Ihrem Arzt Rücksprache halten.

Bei Einnahme von Enal mit anderen Arzneimitteln

Bitte informieren Sie Ihren Arzt oder Apotheker, wenn Sie andere Arzneimittel einnehmen bzw. vor kurzem eingenommen haben, auch wenn es sich um nicht verschreibungspflichtige Arzneimittel handelt.
- Allopurinol: ein Mittel gegen zu viel Harnsäure
- Blutzucker senkende Mittel
- Blutdruck senkende Mittel
- chemische Schlafmittel
- Cortison zum Verabreichen in den Körper
- die körpereigene Abwehr senkende Mittel
- harntreibende Mittel, die Kalium im Körper zurückhalten
- Heparin: ein Mittel zur Blutverdünnung
- Lithium: ein Mittel gegen seelische Störungen

Bei Einnahme von Enal zusammen mit Nahrungsmitteln und Getränken

Verzichten Sie auf das Rauchen, Alkohol und den Verzehr von mehr als 6 g Salz pro Tag.

Schwangerschaft und Stillzeit

Sie dürfen Enal nicht anwenden, wenn Sie schwanger sind oder stillen.

Fragen Sie vor der Einnahme von allen Arzneimitteln Ihren Arzt oder Apotheker um Rat.

Verkehrstüchtigkeit und Maschinen

Bedienen Sie Fahrzeuge oder Maschinen erst nach Rücksprache mit Ihrem Arzt.
Eine Therapie mit Enal kann Ihr Reaktionsvermögen beeinträchtigen.

Wichtige Informationen über bestimmte sonstige Bestandteile von Enal

Dieses Arzneimittel enthält Lactose. Bitte nehmen Sie Enal daher erst nach Rücksprache mit Ihrem Arzt ein, wenn Ihnen bekannt ist, dass Sie unter einer Unverträglichkeit gegenüber bestimmten Zuckern leiden.

3. Wie ist Enal einzunehmen?

Nehmen Sie Enal immer genau nach Anweisung des Arztes ein. Bitte fragen Sie bei Ihrem Arzt oder Apotheker nach, wenn Sie sich nicht ganz sicher sind. Falls vom Arzt nicht anders verordnet, ist die übliche Dosis:

Hoher Blutdruck
- Startdosis: ¼ Tablette täglich
- **Übliche Dosis: 1 Tablette täglich**
- Maximale Tagesdosis: 2 mal 1 Tablette

Andere Anwendungsgebiete
- Nur für die Startdosis schwächere Tabletten nutzen!
- **Übliche Dosis: ¼ Tablette täglich**
- Maximale Tagesdosis: 1 Tablette

Nierenkranke und über 65-Jährige
- Startdosis: ist von der Nierenfunktion abhängig
- Maximale Tagesdosis: 1 Tablette

Art der Einnahme
- unabhängig von den Mahlzeiten und immer zur selben Tageszeit, bevorzugt morgens
- sitzend oder stehend mit einem Glas Wasser mit mindestens 100 ml Inhalt
- teilen der Tabletten wie im Bild zu sehen

Dauer der Einnahme
- bestimmt Ihr Arzt

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b) Enalapril package insert using QRD text template (page 1)

Figure 1: Two examples of the model package insert types investigated in the PAINT3 study

The PAINT3 study results do not show that any advantage accrues by using the QRD template in comparison to the shorter model template in:

- locatability of information
- comprehensibility of information
- patients' opinions about the package insert, such as motivation to read the information, user trust in the medicine

Moreover, figure 2 and table 1 clearly show that patients require significantly less time to locate information if using the shorter model text template, in comparison to the QRD. The difference was on average 18 % ($p = 0.01$, Mann-Whitney U test).

Furthermore, table 1 illustrates that the use of the shorter model template reduces the percentage of information incorrectly understood. Even when not significant, the model text frame produced, on average, 29 % better results.

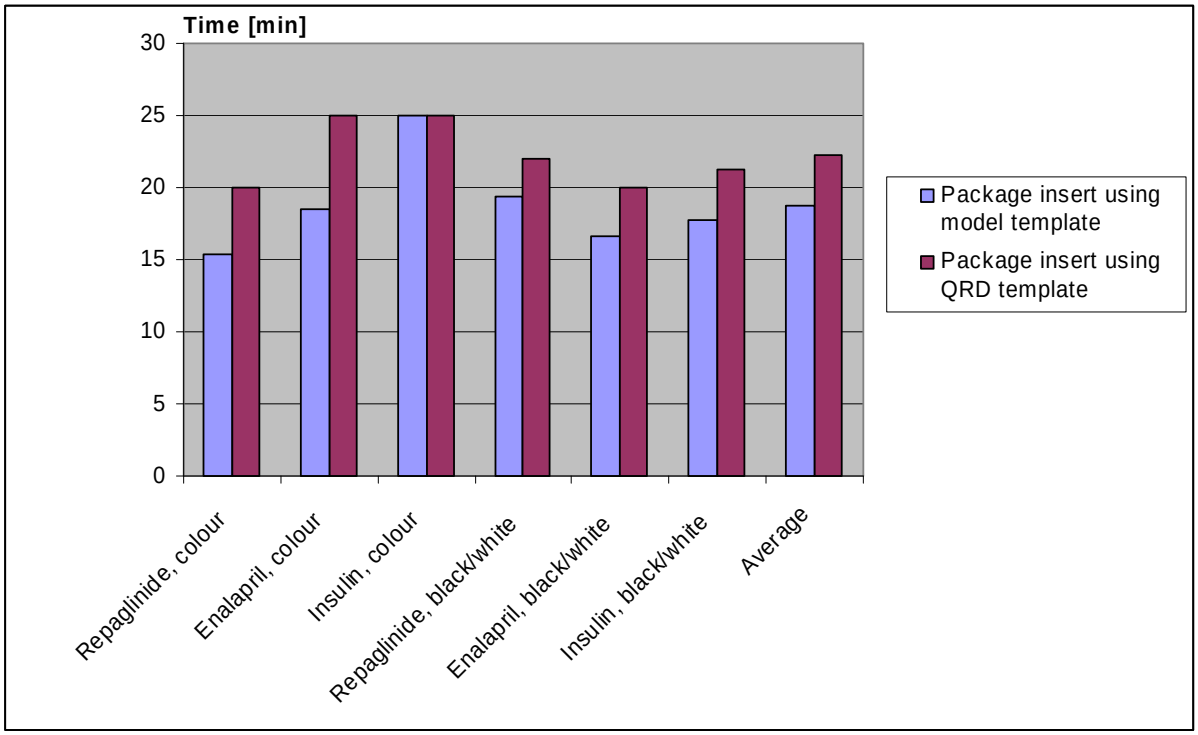

Figure 2: Time needed to locate all 25 tested key messages of different package inserts when using a model text template in comparison to the QRD text template

Table 1: Comparison of the use of the QRD template with a model template for the time taken to answer 25 questions relating to the package insert contents and the percentages of incorrect answers relating to information found, itemized per model package package insert investigated in the PAINT3 study

Model package insert type	**Time to answer 25 questions relating to the package insert content** [min]		**Percentage of incorrect answers relating to the 25 content questions** [average]		**Number of words**		**Number of participants**	
	model text template	QRD text template	model text template	QRD text template	model text template	QRD text template	model text template	QRD text template
Repaglinide, colour	15.4	20.0	7.0	13.4	682	1093	17	15
Enalapril, colour	18.5	25.0	6.6	12.7	849	1333	16	16
Insulin, colour	25.0	25.0	10.2	14.9	835	1265	17	16
Repaglinide, black/white	19.4	22.0	9.3	9.0	682	1093	16	16
Enalapril, black/white	16.7	20.0	10.7	12.4	849	1333	16	16
Insulin, black/white	17.8	21.2	16.4	15.4	835	1265	15	16
Average	**18.8**	**22.2**	**10.1**	**13.0**	**789**	**1230**	**16**	**16**

Considering the findings relating to the volume of text described here, the draft QRD template will impair package inserts in this very important key aspect, as the suggested text frame contains much more than 700 words. Intensive further text increase has to be expected due to the huge amount of additional information recommended in the green highlighted parts of this draft.

The resulting package inserts will continue to move further away from that which patients and healthcare professionals expect: short package inserts limited to the essential points [7, 8]. Significant reductions in the locatability and usability of the provided package insert contents will be the outcome, should this draft come into force without the necessary decrease in the number of words and postulated information contained therein.

Appropriate options for reducing the volume of text contained in the draft and current QRD templates [1, 3], without loss of information that is really necessary for patients include:

- avoid repetitions
- delete the entire information box at the beginning of the package insert, particularly as most of these contents are repetitions
- delete the list of information

  For example, PAINT3 study participants who tested one of the 61 package inserts that contained an index displayed no advantage in locating and understanding the information in comparison to those who used the remaining 210 leaflets without an index [6], even though some patients assessed an index in readability tests as helpful. Special emphasis on the headings and use of a clear layout and design is a very appropriate alternative [4-6].
- avoid long sentences
- avoid unnecessary text modules

Furthermore, no clear evidence-based research is available to prove that the information box is really necessary for patients. Moreover, eliminating the entire text between the medical name and the first chapter as per figure 1a), significantly improves package inserts as shown in both the PAINT1 and PAINT3 studies (figure 2, table, [4-6]).

Apart from the aspects provided in the five bullet points, the draft QRD template contains many other issues, such as relaying the subdivision of possible side effects in three lists, which will obviously increase package insert' texts. This suggestion should be avoided given that no evidence-based research exists to prove that this recommendation is essential and better options are available which achieve identical aims without further text increases (See chapter 3.4).

3 Package insert chapters

Whilst acknowledging the limitations of some parts of the existing QRD template it remains important not to permanently change the template wording because:

- it takes a long time for patients to become familiar with the current text frame, particularly if they do not use medicines regularly
- it is well-known that such text changes take some years to appear in all medicines already distributed on the market
- it is impossible for the QRD template wording to meet the requirements of every medicine and the opinion of every person
- new guideline requirements usually cause more frequent discussions at the beginning of their implementation between the pharmaceutical companies, consultants and agencies about their correct interpretation

Furthermore, the changes recommended in the draft are not based on evidence-based research. Indeed feedback from user tests and user opinions can be helpful in detecting weaknesses in a package insert and the QRD template, but these cannot supplant systematically acquired results or controlled trials.
Therefore, new texts or text changes should only be made in the template when absolutely necessary, with the exception of condensing the volume of text. Additionally, the updated QRD template instructions should be simple and short as generally recommended. This will best support package inserts and their use by patients, including the case of the implementation of the new requirements.

In the following we will provide further details about selected important aspects of the suggested QRD template changes.

3.1 What X is and what it is used for

The QRD template draft suggests that chapter 1 should, in the future, provide a huge amount of additional information. These are not all compulsory requirements according to Directive 2001/83/EC amended by Directive 2004/27/EC. With the exception of some short beneficial information, every new addition cannot be assessed as sufficiently necessary to recommend its inclusion as part of the QRD template. Furthermore, they will extend the volume of package insert texts prompting the negative results as already described in chapter 2. Therefore, these recommendations should be excluded here.

For example, the recommendation to provide the active substance names at the beginning of chapter 1 cannot be condoned as it is unnecessary here and already contained twice in package inserts – under the name of the medicine at the beginning of package inserts and in chapter 6.
The additional explanations relating to the pharmacotherapeutic group and indication also lend weight to expectations of a further text increase in chapter 1 in the future. Therefore, they too cannot be positively received.
Information relating to the user group, including the relevant age range, is often also required in chapters 2 and/or 3. Further repetitions are frontloaded if this information is to be generally provided here.

3.2 Before you take X

The new heading „What you need to know about X“ is a backward step as it fails to explain to the patient what they will find under this heading. For example, information such as the indication, dosage instructions, possible side effects and storage conditions are also contents which patients need to know about the medicine. Therefore, the previous heading of version 7.2 should be retained as it better explains what subsequent paragraphs might contain.

The new special warning/precautions heading “Warnings and precautions: Talk to your doctor <or pharmacist> before taking X if:” is longer than the previous version. Informing the healthcare professionals represents important information for patients and an improvement on the previous unspecific “Take special care heading”. This is an appropriate optimization.
However the heading should be reduced to the following: “Inform your doctor <or pharmacist> before you take X if”. This measure will bring the heading in line with the consistent form of other headings.

Information relating to children should be limited to mentioning the relevant aspect and the required actions. In some cases, further explanation might be helpful for patients; however, they should only be provided where absolutely necessary and limited to the essential required texts.

Under the heading “Taking other medicines” the draft recommends: “Reference should be made to the intensification/weakening and the extension/shortening of effects.” A general recommendation of this information must be assessed as inappropriate as it once more increases the volume of package insert texts.
The interaction section should be restricted to the essential points: mentioning the medicines that cause interactions and the required actions should interactions apply to patients. Informing patients about the results of interactions should only be done in cases where really necessary as, according to our studies’ results, this information can cause patients to adapt the dosage of their medication themselves. This presents a particular safety risk, as patients are not possessed of the knowledge a doctor or pharmacist has regarding the medical therapy.

Furthermore, in the interaction section, the draft of the updated QRD template recommends using text brackets for explanation. Already, general recommendation exists to avoid these whenever possible and they are not necessary here for providing explanations relating to the medicines mentioned.

In addition, the general advice to inform healthcare professionals should interactions occur is extended to a sentence containing 44 words. Also here, the draft is in conflict with the readability guideline which explicitly states: “Long sentences should not be used.” [9]. Indeed most patients will not know that products like dietary supplements or minerals can result in interactions with other medicines. In addition, other medicines in everyday use, such as contraceptive pills, are mostly not considered by medical laymen to be medicines which would have interactive potential. However, it does not make sense to provide a general list of all product groups which might be applicable for interactions. Therefore, if vitamins, minerals, herbal medicines or dietary supplements are known to cause interactions with a specific medicine, they must be mentioned in the list of interactions, but not generally in every package insert.

Providing general information relating to “fertility” is another aspect which extends package inserts. Again, where this is important for a specific medicine the appropriate information should be provided in chapter 2 on a case by case basis, but not in all package inserts.

3.3 How to take X

Many adaptations concerning this package insert chapter can be assessed as helpful for patients, such as clarifications relating to the dosage instruction, method and duration of use. However, awareness must be maintained that information provided here should be short and limited to the essential points. Therefore, the general advice at the beginning of the dosage instruction section should be not extended as, for example, is done for medicines available only on prescription. A shorter suggested text is:

“Always use X as described in this leaflet or by your healthcare professional. The recommended dose is:”

3.4 Possible side effects

Providing side effects with their frequencies is a wise recommendation and supports patients in correctly classifying their importance [5, 10]. This applies also to providing information about their severity.

However, general division of the side effect section into three parts a) most serious side effects, b) side effects which should be discussed with healthcare professionals as soon as possible and c) other side effects; and additional further subdivision of those affecting children cannot be assessed as appropriate. This recommendation will lead even more frequently to repetitions and increases in the volume of text. Furthermore, it creates three or more levels of subdivisions which are not recommended according to the readability guideline [9].

A general list of all side effects according to their frequencies is more appropriate. Severe side effects or those which require a patient to immediately contact the doctor should be highlighted in this list. Information about the side effects occurring in children can also be included and emphasized in this list if their importance makes it really necessary. This form of side effect presentation has been repeatedly successfully tested in our readability tests over recent years and is accepted by the agencies. Furthermore, it avoids repetitions and a complicated subdivision system of the side effect chapter 4.

3.5 How to store X and further information

The few changes made in the package insert chapter 5 are acceptable. However, if agreement can be reached between all parties involved in the package insert field, the text provided for chapters 5 and 6 should also be compressed wherever possible.

Also the suggested wording of the chapter 6 heading “What is in the pack and further information” is appropriate as it more clearly informs patients as to what they will find in this chapter.

However, separating excipients, e.g. in tablet core and tablet coating, is not relevant for patients and therefore inappropriate for package inserts. It is irrelevant for patients in which part of the tablet an ingredient is if he/she has an allergy or hypersensitivity to this substance. It is more important for them to know that this substance is in the medicine. Furthermore, the SmPC Guideline from September 2008 states that there is no general onus to provide this separation in the expert information. Why then should it be done in package inserts?

The current and the newly drafted QRD template states: „Listing of local representatives is not a requirement…“. This is an improvement in comparison to the previous templates for centralised approved medicines. However, it would be more appropriate to generally exclude the list of 29 local representatives’ addresses from the template as this is less important information for patients [7]. A reduced number of company addresses – preferably to one per package insert – would very much compress the text and improve package inserts.

4 Conclusion

Continuous further development of package inserts and the related guidelines are important to improve this patient information and bring it in line with the actual requirements. However, many changes provided in the QRD template draft must be assessed as inappropriate, especially as they will seriously extend the volume of package inserts.
According to the studies of results provided in this statement, the QRD template should be reduced to those texts and information which are the essential contents.

We would be very happy if this statement supports an improvement in the QRD template. Gladly, we will provide any further information required, such as study results relating to our model template, to improve the QRD template and by extension, future package inserts.

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