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# Guidance for Presenting PIL and Labeling Information of Herbal & Health Products

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Version 2.3

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# Guidance for Presenting PIL and Labeling Information of Herbal and Health Products

Version 2.3

Saudi Food & Drug Authority

Drug Sector

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## **Saudi Food and Drug Authority**

### **Vision and Mission**

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#### **Vision**

To be a leading international science-based regulator to protect and promote public health

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#### **Mission**

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

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## Document Control

Version	Author	Date	Comments
1.0	Drug Sector	24 August 2017	Draft for comments
2	Drug Sector	6 May 2018	Final
2.1	Executive Directorate of Regulatory Affairs	19 January 2021	Update
2.2	Executive Directorate of Regulatory Affairs	05 August 2021	Update
2.3	Executive Directorate of Regulatory Affairs	12 June 2022	Update (Next page shows the updated details)

## What is New in version no. 2.3?

The following table shows the update to the previous version:

Section	Description of change
Appendix 1	<b><u>Delete:</u></b> <b>Appendix 1: Important considerations</b>

## Table of Contents

I.	Introduction .....	7
II.	Labeling.....	8
1.	Particulars to appear on the <outer packaging> <and> <the immediate packaging> .....	8
2.	Minimum particulars to appear on blisters or strips .....	10
3.	Minimum particulars to appear on small immediate packaging units .....	11
III.	Patient Information Leaflet (PIL) .....	13
1.	What {product name} is and what it is used for.....	15
2.	Before you <take> <use> {product name}.....	15
3.	How to <take> <use> {product name}.....	16
4.	Possible side effects.....	17
5.	How to store {product name} .....	17
6.	Further information .....	18
	Appendix 1: Arabic Patient Information Leaflet (PIL) .....	20
	Appendix 2: Recommended labeling statements.....	23
	Appendix 3: Readability of the label and patient information leaflet (PIL).....	25

## I. Introduction

This guideline is intended to guide applicants on how to present the following required information for:

- Labeling
- Patient Information Leaflet (PIL)

This guideline provides advice on the principles of presenting information. Applicants should maintain the integrity of each section of the document by only including information in each section, which is relevant to the section heading. However, some issues may need to be addressed in more than one section and in such situations the individual statements may cross-refer to other sections when these contain relevant additional information.

When submitting a new application for registration, renewal or variation, the information presented by the applicant regarding the PIL and labeling must follow this guidance. Additionally, it should be noted that products with different strengths must have different packaging color codes that differentiate between different strengths.

Following the SFDA's approval of the PIL and labeling contents, such contents cannot be changed except with the approval of the SFDA (*refer to guidelines for variation requirements*).

## II. Labeling

The data should be presented according to the template below, irrespectively of their sequence on the actual labeling and their position and possible repetition on the individual sides/flaps of the packaging (e.g. top flap, front, back etc.).

A separate text for inner (primary packaging) and outer (secondary packaging) labeling should be completed per strength and per pharmaceutical form.

All companies shall disclose all ingredients that may cause allergies, such as Gluten, and/or contraindicated with chronic diseases, like Diabetes and Blood Pressure.

*Bracketing convention:*

*{text}: Information to be filled in.*

*<text>: Text to be selected or deleted as appropriate.*

### 1. Particulars to appear on the <outer packaging> <and> <the immediate packaging>

#### a. Name of the product

*{(Invented) name, strength (optional) and pharmaceutical form}*

*{Active substance(s) and strength}*

*- A standard packaging box has six faces on which information can be displayed. If it is feasible, display a product description on more than three non opposing faces.*

*- Use blank space to emphasize critical information such as the product name, generic name and strength.*

- Note: The invented (trade) name should be Arabized.*

#### b. Statement of active substance(s)

*- Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight for each active substance. Where the active substance is present as a salt, this should be clearly indicated.*

*- For Herbal substance, Latin name should be provided.*

- *Note: Arabic translation should be added if PIL is not provided.*

**c. List of excipients (must be stated if PIL is not provided)**

*- Express qualitatively those excipients known to have a recognised action or effect. However, if the product is a topical or used for inhalation, all excipients must be stated.*

**d. Pharmaceutical form and contents**

*- Contents by weight, by volume or by number of doses or number of units of administration of the product (e.g. 28 tablets, 100 mL, ...)*

*- For solid dosage form, maximum 180 tablets or capsules are allowed.*

- *Note: Arabic translation should be added.*

**e. Method and route(s) of administration**

*- Method of administration: directions for proper use of the product, use positive statements if possible - use “DO” rather than “DO NOT” e.g. (“Do not swallow”, “Do not chew”(should be deleted) “Shake well before use”). In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the PIL must be made:*

*- Read the patient information leaflet before use (if applicable) .*

- *Note: Arabic translation should be added.*

**f. Purpose of use and dose**

- *Note: Arabic translation should be added.*

**g. Risk information**

*- including cautions, warnings, side effects and contraindications.*

- *Note: Arabic translation should be added.*

**h. Special warning that the product must be stored out of the reach and sight of children.**

*- Keep out of the reach and sight of children.*

- *Note: Arabic translation should be added.*

**i.** Other special warning(s), if necessary

- *Note: Arabic translation should be added.*

**j.** Manufacturing and Expiry dates

- *Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.: 02/2010, Feb 2010.*

- *Where applicable, the shelf life after reconstitution, dilution or after first opening the container should be included.*

**k.** Special storage conditions

*[For recommended labeling statements see Appendix 2]*

- *Note: Arabic translation should be added*

**l.** Manufacturer name

**m.** Marketing company, nationality

**n.** Name and address of the marketing authorisation holder

*{Name and Address}*

*<{tel}>*

*<{fax}>*

*<{e-mail}>*

**o.** Batch number

*<Batch> <Lot> <BN> {number}*

## 2. Minimum particulars to appear on blisters or strips

**a.** Name of the product

*{(Invented) name}*

- *Note: The invented (trade) name should be Arabized*

**b. Manufacturing and Expiry dates**

- Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.: 02/2010, Feb 2010.

**c. Batch number**

<Batch> <Lot> <BN> {number}

- Batch number and Expiry date should be at the end of each blister strip, if technically possible this could be applied to both ends.

**3. Minimum particulars to appear on small immediate packaging units**

Small immediate packaging units are defined as containers sized up to and including 10 ml. On a case-by-case basis the minimum particulars could also be considered for other containers where it is not be feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed upon with the SFDA.

**a. Name of the product and route(s) of administration**

{(Invented) name, strength and pharmaceutical form}

{Active substance(s)}

{Route of administration}

• **Notes:**

- The invented (trade) name should be Arabized.
- Route of administration should be translated into Arabic.

**b. Method of administration**

- Method of administration: directions for proper use of the product, use positive statements if possible - use “DO” rather than “DO NOT”, e.g. “Do not swallow”, “Do not chew”, (should be deleted) “Shake well before use”.

- If full details cannot be included on the immediate packaging itself, a reference to the PIL should be made, e.g. “Read the patient information leaflet before use”.

- Note: Arabic translation should be added.

**c. Manufacturing and Expiry dates**

- Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.: 02/2010, Feb 2010.

- Where applicable, the shelf life after reconstitution, dilution or after first opening the container should be included.

**d. Batch number**

<Batch> <Lot> <BN> {number}.

**e. Contents by weight, by volume or by unit**

**f. Special storage conditions**

*[For recommended labeling statements see Appendix 2]*

- If product requires refrigeration , highlight storage conditions.

- Use positive statements to give directions.

- *Note: Arabic translation should be added.*

**g. Other**

- Space permitting, any other information necessary for the correct use and administration of the product can be included here.

### III. Patient Information Leaflet (PIL)

A separate PIL should be provided per strength and per pharmaceutical form in cases of different indications for different strengths and/or dosage forms. However, applicants may present PIL for different strengths in one document during the evaluation process, clearly indicating the strength or presentation to which alternative text elements refer. Where applicants consider to also market a combined package leaflet, a detailed justification for such a combined PIL should be provided in the application at submission. E.g. (Different strengths have the same indication).

In exceptional cases, alternative headings may be acceptable, especially for those headings containing <take><use> or where a different wording would be more appropriate for the product concerned e.g. to better reflect the user of the product. This should not in any case impact on the content required for the section concerned. Applicants should justify the use of alternative headings (e.g. by reference to user testing results). For certain products not all items may be relevant, in this case the corresponding heading should not be included.

It is important that the PIL can easily be tracked for updates and review. Each PIL should be given a reference number along with the date the leaflet was issued and a suitable review date. Each PIL should be reviewed when necessary.

The applicant must provide Arabic translation of the PIL in patient understandable language (see appendix 1). The invented name should be Arabized and not translated into Arabic. While the active ingredients should be translated into Arabic language.

The following items must appear on the PIL as required by this guidance. **Unless, the information can be placed on the outer package (secondary packaging).**

*Bracketing convention:*

*{text}: Information to be filled in.*

*<text>: Text to be selected or deleted as appropriate.*

## Patient Information Leaflet (PIL)

**{(Invented) name, strength (optional) and pharmaceutical form}**

{ Active substance(s) and strength }

- *The (invented) name of the product (referred to as X throughout this document) followed by the strength and pharmaceutical form should be stated here in bold. This should be followed by the active substance(s) (as stated on the label section 1), which may be written on the line below.*

- *For Herbal substance, Latin name should be provided.*

**<Read all of this leaflet carefully before you start <taking> <using> this product.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider> <or> <presentspharmacist>.
- < Do not pass the product on to others. It may harm them, even if their symptoms are the same as yours>
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider> <or> <pharmacist>.

### **In this leaflet:**

1. What {product name} is and what it is used for?
2. Before you <take> <use> {product name}
3. How to <take> <use> {product name}
4. Possible side effects
5. How to store {product name}
6. Further information

## 1. What {product name} is and what it is used for

- *Purpose of indication:*

*The purpose of indications should be stated here, using patient understandable language. If appropriate.*

## 2. Before you <take> <use> {product name}

### a. Do not <take> <use> {product name}

- *<if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of {product name}>*
- *<if ...>*

### b. Take special care with {product name}

- *<if you ...>*
- *<when ...>*
- *<Before treatment with {product name}, ...>*

### c. <Taking> <Using> other medicines, herbal or dietary supplements

- *Describe the effects of other products on {product name} and vice versa.*  
*<Please tell your <doctor, health care provider> <or> <pharmacist> if you are taking or have recently taken any other products, including products obtained without a prescription.>*

### d. <Taking> <Using> {product name} with food and drink

- *Interactions not related to products should be mentioned here. Where relevant, guidance should always be included to clarify if the product must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.*

### e. Pregnancy and breast-feeding

- *Where the information is significantly different, pregnancy and breast-feeding information can be presented under separate headings.*

- *Include conclusion summary of the information, in addition to the following optional statement:*

*<Ask your <doctor, health care provider> <or> <pharmacist> for advice before taking any product.>*

f. Driving and using machines

- *<Do not drive <because...>.>*
- *<Do not use any tools or machines.>*

g. Important information about some of the ingredients of {product name}

- *If appropriate, details of those excipients knowledge of which is important for the safe and effective use of the product, including relevant warnings for residues from the manufacturing process.*

### 3. How to <take> <use> {product name}

*<Always <take> <use> {product name} exactly as your doctor or health care provider has told you. You should check with your <doctor, health care provider> <or> <pharmacist> if you are not sure.> <The usual dose is...>*

- *You may include the following sub-headings within the headings given below if needed to increase readability:*

- *Instructions for proper use*
- *Dosage for different age group*
- *Method and/or route(s) of administration*
- *Frequency of administration*
- *Duration of treatment*

a. If you <take> <use> more {product name} than you should

- *Describe how to recognise if someone has taken an overdose and what to do.*

b. If you forget to <take> <use> {product name}

- *Make clear to patients what they should do after irregular use of a product; e.g. <Do not take a double dose to make up for a forgotten <tablet> <dose> <...>.>*

*<If you have any further questions on the use of this product, ask your <doctor, health care provider> <or> <pharmacist>.>*

#### 4. Possible side effects

- *Begin this section with: "Like all products, {product name} can cause side effects, although not everybody gets them".*
- *Describe, if necessary, the actions to be taken. If the patient needs to seek help urgently, the use of the term <immediately> is recommended; for less urgent conditions, <as soon as possible> can be used.*
- *Close this section with: "If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider> <or> <pharmacist>".*
- *In case of adequate and well-controlled studies have not shown any side effects:*
  - *Delete section the "possible side effects".*
  - *Add the following statements:*
    - *In English leaflet: {product name} has not been shown enough studies to cause side effects.*
    - *In Arabic leaflet:*

حتى الآن لا تتوفر دراسات كافية تبين وجود أعراض جانبية لـ {اسم المستحضر}
  - *It is not acceptable at all to add statements to show the product has not any side effects.*

#### 5. How to store {product name}

- *Keep out of the reach and sight of children.*
- *<Store below °C>, <Store in the original <container><carton>>*

- *Do not use {product name} after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}>. <The expiry date refers to the last day of that month.>*
- *<Do not use {product name} if you notice {description of the visible signs of deterioration}>.>*
- *< products should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of products no longer required. These measures will help to protect the environment.>*

## 6. Further information

### a. What {product name} contains

- *The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified.*
  - *The active substance(s) is (are)...*
  - *The other ingredient(s) is (are)...*
- *For Herbal substance, Latin name should be provided.*

### b. What {product name} looks like and contents of the pack

- *The pharmaceutical form should be stated.*
- *It is recommended to include a physical description e.g. shape, color, texture, imprint.*
- *All pack sizes for this pharmaceutical form and strength should be detailed here; if appropriate indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.*

### c. Marketing Authorisation Holder and Manufacturer

*{Name and address}*

*<{tel}>*

*<{fax}>*

<{e-mail}>

For any information about this product, please contact the local representative of the Marketing Authorisation Holder:

{Name}

<{Address} {City}>

Tel: + {telephone number}

<{e-mail}>

<as appropriate, add additional local representatives to the above table>

d. This leaflet was last approved in {MM/YYYY}; version number { }

e. To report any side effect(s):

- **Saudi Arabia:**

- |   |
|---|
| <ul style="list-style-type: none"><li>– The National Pharmacovigilance and Drug Safety Center (NPC)<ul style="list-style-type: none"><li>○ Fax: +966-11-205-7662</li><li>○ SFDA call center 19999</li><li>○ Toll free phone: 8002490000</li><li>○ E-mail: npc.drug@sfda.gov.sa</li><li>○ Website: www.sfda.gov.sa/npc</li></ul></li></ul> |
|---|

f. This patient information leaflet is approved by the Saudi Food and Drug Authority

## Appendix 1: Arabic Patient Information Leaflet (PIL)

### بيانات النشرة الداخلية للمستحضر (PIL)

معلومات لمستخدم الدواء - النشرة الداخلية للمستحضر:

{الاسم - التركيز (اختياري) - الشكل الصيدلاني للمستحضر}

{المواد الفعالة والتراكيز}

قم بقراءة هذه النشرة جيداً قبل استعمال أو تناول هذا الدواء

- إحتفظ بهذه النشرة، لأنك قد تحتاج إليها لاحقاً.
- في حال كانت لديك أي أسئلة تتعلق بهذا المستحضر قم بإستشارة الطبيب أو الصيدلي.
- يجب عليك عدم إعطاء المنتج لأي شخص حتى وإن كان هذا الشخص يعاني من نفس الأعراض التي سبق وأن عانيت منها.
- قم بالإتصال بطبيبك المعالج أو الصيدلي في حال زيادة حدة الأعراض الجانبية أو الاصابة بعرض جانبي لم يتم ذكره في هذه النشرة.

تحتوي هذه النشرة على:

١. ماهو <إسم المستحضر> وما هي دواعي استعماله
٢. قبل القيام بتناول أو إستعمال < إسم المستحضر >
٣. طريقة إستخدام < إسم المستحضر >
٤. الأعراض الجانبية
٥. ظروف تخزين < إسم المستحضر >
٦. معلومات إضافية

١. ماهو < إسم المستحضر > وما هي دواعي استعماله
٢. قبل القيام بتناول أو إستعمال < إسم المستحضر >
  - أ- موانع استعمال < إسم المستحضر >
  - ب- الاحتياطات عند استعمال < إسم المستحضر >
  - ج- التداخلات الدوائية من أخذ هذا المستحضر مع أي أدوية أخرى أو أعشاب أو مكملات غذائية
  - د- تناول < إسم المستحضر > مع الطعام والشراب
  - هـ- الحمل والرضاعة
  - و- تأثير < إسم المستحضر > على القيادة وإستخدام الآلات
  - ز- معلومات هامة حول بعض مكونات < إسم المستحضر >
٣. طريقة إستخدام < إسم المستحضر >
  - أ- الجرعة الزائدة من < إسم المستحضر >
  - ب- نسيان تناول جرعة < إسم المستحضر >
٤. الأعراض الجانبية
٥. ظروف تخزين < إسم المستحضر >
٦. معلومات إضافية
  - أ- ماهي محتويات < إسم المستحضر >
  - ب- ما هو الشكل الصيدلاني < إسم المستحضر > ووصفه وحجم عبوته
  - ج- اسم وعنوان مالك رخصة التسويق والمصنع
  - د- تم الموافقة على هذه النشرة بتاريخ { شهر / سنة }، { رقم النسخة }

## ٧. الإبلاغ عن الأعراض الجانبية:

### • المملكة العربية السعودية:

– المركز الوطني للتبقيط والسلامة الدوائية
○ فاكس: +966-11-205-7662
○ للاتصال بالمركز الموحد للهيئة العامة للغذاء والدواء ١٩٩٩٩
○ الهاتف المجاني: 8002490000
○ البريد الإلكتروني: npc.drug@sfda.gov.sa
○ الموقع الإلكتروني: <a href="http://www.sfda.gov.sa/npc">www.sfda.gov.sa/npc</a>

### ملاحظة:

يجب أن تكون النشرة الداخلية للمستحضر:

– مترجمة بطريقة احترافية (من حيث استخدام المصطلحات العلمية)،

– مدققة إملانياً ولغوياً،

– مكتوبة بلغة سهلة ومفهومة للمريض.

ولن يتم النظر في أي نشرة داخلية مقدمة ما لم تستوفي الشروط السابقة.

## Appendix 2: Recommended labeling statements

- The statements that should be used if supported by the stability studies for finished pharmaceutical products (FPPs) are listed in Table 1.

**Table 1: Recommended labeling statements for finished pharmaceutical products (FPPs)**

Testing condition under which the stability of the FPP has been demonstrated	Recommended labeling statement
25°C/60% RH (long-term) or 30 °C/65% RH (long-term)	“Store below 25 °C” * (for 25°C/60% RH) <sup>1</sup> “Store below 30 °C” * (for 30°C/65% RH)
40 °C/75% RH (accelerated)	
5 °C ± 3 °C	”Store in a refrigerator (2 °C to 8 °C)”

\* “Protect from moisture” should be added as applicable.

- Additional labeling statements that could be used in cases where the result of the stability testing demonstrates limiting factors are listed in Table 2.

<sup>1</sup> This requirements is not applicable to products contain chemically synthesized material(s) (e.g.: antiseptic or antilice...etc), recommended labeling statement will be “Store below 30 °C” \* (for 30°C/65% RH)

**Table 2: Additional labeling statements for use where the result of the stability testing demonstrates limiting factors**

<b>Limiting factors</b>	<b>Additional labeling statements, where relevant</b>
FPPs that cannot tolerate refrigeration	"Do not refrigerate or freeze"
FPPs that cannot tolerate freezing	"Do not freeze"
Light-sensitive FPPs	"Protect from light"
FPPs that cannot tolerate excessive heat, e.g. Suppositories	"Store and transport not above 30 °C"
Hygroscopic FPPs	"Store in dry condition"

## Appendix 3: Readability of the label and patient information leaflet (PIL)

### Introduction

The main purpose of this document is to provide guidance on how to ensure that the information on the labelling and patient information leaflet (PIL) is accessible to and can be understood by those who receive it, so that they can use their product safely and appropriately.

This document is written to assist applicants and marketing authorization holders when drawing up the labeling and PIL and preparing the mock-ups or specimens of the sales presentations<sup>2</sup>.

The document is intended to apply to all marketing authorization procedures and to all herbal and health products.

### A. Recommendations for the PIL

#### General

The PIL is intended for the patient/user. If the PIL is well designed and clearly worded, this maximizes the number of people who can use the information, including older children and adolescents, those with poor literacy skills and those with some degree of sight loss. Companies are encouraged to seek advice from specialists in information design when devising their house style for the PIL to ensure that the design facilitates navigation and access to information.

The following guidance sets out recommendations on various aspects related to the preparation of PILs. It is aimed at helping applicants/marketing authorization holders to fully comply with the requirements and is based on experience where it has been shown

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<sup>2</sup> A **mock-up** is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the labelling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A **specimen** is a sample of the actual printed out outer and immediate packaging materials and PIL (i.e. the sales presentation).

that using these techniques optimizes the usability of the PIL.

## **1. Type size and font**

Choose a font which is easy to read. Stylized fonts which are difficult to read should not be used. It is important to choose a font in which similar letters/numbers, such as “i”, “l” and “1” can be easily distinguished from each other.

The type size should be as large as possible to aid readers. A type size of 9 points, as measured in font ‘Times New Roman’, not narrowed, with a space between lines of at least 3 mm, should be considered as a minimum.

Consideration should be given to using different text sizes to enable key information to stand out and to facilitate navigation in the text (e.g., for headings).

The widespread use of capitals should not be used. The brain recognizes words in written documents by the word shape, so choose lower case text for large blocks of text. However, capitals may be useful for emphasis.

Do not use italics and underlining as they make it more difficult for the reader to recognize the word-shape. Italics, however, may be considered when using Latin terms.

## **2. Design and layout of the information**

The use of “justified” text (that is text aligned to both left hand and right hand margins) should in principle not be used.

Line spaces should be kept clear. The space between lines is an important factor influencing the clarity of the text. As a general rule the space between one line and the next should be at least 1.5 times the space between words on a line, where practical.

Contrast between the text and the background is important. Factors like paper weight, color of the paper, size and weight of the type, color of the type and the paper itself should be considered. Too little contrast between the text and the background adversely affects the accessibility of the information. Therefore, background images should in principle not be placed behind the text since they may interfere with the clarity of the information making it harder to read.

A column format for the text can help the reader navigate the information. The margin

between the columns should be large enough to adequately separate the text. If space is limited a vertical line to separate the text may be used. Related information should be kept together so the text flows easily from one column to the next. Consideration should be given to using a landscape layout which can be helpful to patients. Where a multi-lingual PIL is proposed there should be a clear demarcation between the different languages used; all the information provided in each language should be assembled.

### **3. Headings**

Headings are important and can help patients navigate the text if used well. Therefore, bold type face for the heading or a different color, may help make this information stand out. The spacing above and below the headings should be consistently applied throughout the leaflet. Same level headings should appear consistently (numbering, bulleting, color, indentation, font and size) to aid the reader.

The use of multiple levels of headings should be considered carefully, as more than two levels may make it difficult for readers to find their way around the leaflet. However, where complex information has to be communicated multiple levels of headings may be needed.

Using lines to separate the different sections within the text can also be helpful as a navigational tool.

### **4. Print color**

Accessibility is not only determined by print size. Characters may be printed in one or several colors allowing them to be clearly distinguished from the background. A different type size or color is one way of making headings or other important information clearly recognizable.

The relationship between the colors used is as important as the colors themselves. As a general rule dark text should be printed on a light background. But there may be occasions when reverse type (light text on a dark background) could be considered to highlight for instance particular warnings. In such circumstances the quality of the print will need careful consideration and may require the use of a larger type size or bold text. Similar colors should not be used for the text and background as legibility is impaired.

## 5. Syntax

Some people may have poor reading skills, and some may have poor health literacy. Aim to use simple words of few syllables.

Long sentences should not be used. It is better to use a couple of sentences rather than one longer sentence, especially for new information.

Long paragraphs can confuse readers, particularly where lists of side effects are included. The use of bullet points for such lists is considered more appropriate. Where possible, no more than five or six bullet points in a list are recommended.

When setting out the side effects it is particularly important to consider the order in which they are given so the patients/users may maximize the use of the information. In general, setting out the side effects by frequency of occurrence, starting with the highest frequency, is recommended to help communicate the level of risk to individuals. Frequency terms should be explained in a way patients/users can understand – for example “very common” (more than 1 in 10 patients). However, where a serious side effect exists which would require the patient/user to take urgent action this should be afforded greater prominence and appear at the start of the section. Setting side effects by organ/system/class is not recommended since patients/users are in general not familiar with these classifications.

## 6. Style

When writing, an active style should be used, instead of passive. For example:

*-'take 2 tablets'* instead of *'2 tablet should be taken',*

*-'you must....'* is better than *'it is necessary ...'*

When telling patients what action to take, reasons should be provided. Instructions should come first, followed by the reasoning, for example: ‘take care with X if you have asthma – it may bring on an attack’.

“Your product, this product, etc.” should be used rather than repeating the name of the product, as long as the context makes clear what is being referred to.

Abbreviations and acronyms should not usually be used unless these are appropriate. When

first used in the text, the meaning should be spelled out in full. Similarly scientific symbols (e.g. > or <) are not well understood and should not be used.

Medical terms should be translated into language which patients can understand. Consistency should be assured in how translations are explained by giving the lay term with a description first and the detailed medical term immediately after. On a case by case basis the most appropriate term (lay or medical) may then be used thereafter throughout the PIL in order to achieve a readable text. Make sure that the language used alerts the reader to all the information relevant to him/her, and gives sufficient detail on how to recognize possible side effects and understand any action which may be necessary.

## **7. Paper**

The paper weight chosen should be such that the paper is sufficiently thick to reduce transparency which makes reading difficult, particularly where the text size is small. Glossy paper reflects light making the information difficult to read, so the use of uncoated paper should be considered.

Make sure that when the PIL is folded the creases do not interfere with the readability of the information.

## **8. Use of symbols and pictograms**

The images, pictograms and other graphics can be used to aid comprehension of the information, but these exclude any element of a promotional nature. Symbols and pictograms can be useful provided the meaning of the symbol is clear and the size of the graphic makes it easily legible. They should only be used to aid navigation, clarify or highlight certain aspects of the text and should not replace the actual text. Evidence may be required to ensure that their meaning is generally understood and not misleading or confusing. If there is any doubt about the meaning of a particular pictogram it will be considered inappropriate.

## **B. Recommendations for the labeling**

### **General**

Labeling covers both outer packaging and inner packaging. Although inner packaging may

include a lesser set of particulars, many of the principles outlined in relation to outer packaging will apply equally to the labeling of blister packs or other small package units.

Labeling ensures that the critical information necessary for the safe use of the product is legible, easily accessible and that users of products are assisted in assimilating this information so that confusion and error are minimized.

Those involved in the design of labeling should consider the following sections prior to submission to the authority. The recommendations given in relation to the PIL (section A) may be applicable to labeling and should be borne in mind in designing and laying out the required information on labels. The particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm.

In particular the information presented on small packs will need careful consideration so that the text is presented in as large a type size as possible to reduce the likelihood of medication error.

### **1. Strength and total content**

In some cases the packaging may need to contain information on both the quantity per unit volume and on the total quantity per total volume. The total quantity per total volume can be particularly important for safety reasons products available in solution or suspension.

Different strengths of the same product should be expressed in the same manner: for example 250 mg, 500 mg, 750 mg, 1000 mg and NOT 1 g. Trailing zeros should not appear (2.5 mg and NOT 2.50 mg). The use of decimal points (or comma) should be avoided where these can be removed (i.e. 250 mg is acceptable whereas 0.25 g is not). For safety reasons it is important that micrograms is spelt out in full and not abbreviated. However, in certain instances where this poses a practical problem which cannot be solved by using a smaller type size then abbreviated forms may be used, if justified and if there are no safety concerns.

### **2. Design and layout**

Applicants and marketing authorization holders should make best use of the space available to ensure that the important information is clearly mentioned on prime spaces on the outer

and immediate packaging, presented in a sufficiently large type size. Company logos and pictograms may be presented, where space permits, on the outer packaging and on immediate packaging, provided they do not interfere with the legibility of the mandatory information.

Use of a large type size will be appropriate, although other factors may also be important in making the information legible. Consideration should be given to the line-spacing and use of white space to enhance the legibility of the information provided. For some small packs it may not be possible to present all the critical information in the same field of view. The use of any innovative technique in packaging design to aid in the identification and selection of the product is encouraged. It is also encouraged where space is at a premium.

Colors should be chosen to ensure a good contrast between the text and the background to assure maximum legibility and accessibility of the information. Highly glossy, metallic or reflective packaging should be avoided, as this affects the legibility of the information. Different colors in the name of the product are discouraged since they may negatively impact on the correct identification of the product name. The use of different colors to distinguish different strengths is strongly recommended.

Similarity in packaging which contributes to medication error can be reduced by the judicious use of color on the pack. The number of colors used on packs will need careful consideration as too many colors could confuse. Where color is used on the outer pack it is recommended that it is carried onto primary packaging to aid identification of the product.

Where a multi-lingual outer and/or immediate packaging is proposed there should be a clear demarcation between different languages where space permits.

### **3. Blister pack presentations**

For blister pack presentations it is important that the particulars remain available to the user up to the point at which the last dose is removed. Often it will not be possible to apply all the information over each blister pocket, consequently where a random display of the information is proposed it should frequently appear across the pack. In all cases it will be acceptable to apply the batch number, manufacturing and expiry dates to the end of the

blister strip. If technically possible, applying this information to both ends of each strip should be considered. Where a unit-dose blister presentation is proposed all the information required for blister packs must appear on each unit dose presentation.

In addition, blister foils should be printed to ensure maximum legibility of the information using a sufficiently large font.

Color for the text and the font style, should be chosen carefully as the legibility of the text on the foil is already impaired due to the nature of the material. Where possible, non-reflective material or colored foils should be considered to enhance the readability of the information presented and the correct identification of the product.

### ***Small containers***

Where the labeling particulars cannot be applied in full to the labeling of small containers, the minimum particulars could be considered. Other factors may need to be taken into account such as the amount of information which has to be included and the font size necessary to ensure the legibility of the information.

The criteria for small container status would normally apply to containers of nominal capacity of 10 ml or less.

Innovative pack design is encouraged where space is at a premium (e.g. the use of wrap-around or concertina labels). Paper labels are recommended to increase the legibility of the information applied to, for example, ampoules.