

STANDARD ASSESSMENT GUIDELINE FOR PATIENT INFORMATION LEAFLET (PACKAGE INSERT)

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PIL STANDARD ASSESSMENT GUIDELINE İRD-KLVZ-09

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Standard assessment procedure for the Patient Information Leaflet:

Objective: The purpose of this document is to ensure the standardised assessment of the Patient Information Leaflet (PIL) and to enable PILs prepared in different ways to be presented in a standardised manner to the patient using the medicinal product.

Assessment criteria:

1. Assessment in terms of format: Patient Information Leaflets shall be prepared in accordance with the guideline published on 26/02/2008.

PILs not prepared in accordance with this guideline shall not be accepted for assessment; the PIL shall be requested to be rewritten by means of a Ministry letter.

The PIL shall be requested to be written as described below:

After "PATIENT INFORMATION LEAFLET" is written in bold, 12 point, Times New Roman font at the top centre of the first page;

a) All main headings shall be numbered, written in bold colour, with the first letter capitalised and the remaining letters in lower case. Only the licensed trade name, unit dose and pharmaceutical form of the medicinal product should be stated in the main heading. The trade name should be in capital letters and the dose and form in lower case. In the explanations within paragraphs, only the trade name of the product should be given. The trade name should be written in capital letters in a light colour within the PIL. b) If there are subheadings under a main heading, the subheadings shall be written in bold colour, with the first letter capitalised and the remaining letters in lower case. c) Subheadings and main headings that are not applicable or relevant should not be included in the patient information leaflet. For example, in paediatric forms, headings such as breastfeeding, pregnancy, and driving and using machines.

In all writing, 12 point, Times New Roman font shall be used.

In the case of imported/licensed products, the Original Patient Information Leaflet of the product shall be submitted during the assessment; if the product is a generic, the original patient information leaflet of the original molecule (if available) shall be submitted. If the original PIL is not in English, it shall be translated into Turkish and submitted to the Ministry.

When writing the sections specified below, care should be taken to use the explanations provided in the guidelines..

2. Assessment in terms of content: It should be borne in mind that the PIL is an important tool for conveying information to the patient about the use of the medicinal product. Sentences should be short and understandable, and the use of foreign words should be avoided. However, while doing this, foreign words whose Turkish equivalents are unknown may be given in the text in parentheses (Example: Low blood sugar (hypoglycaemia)). Scientific explanations should be rendered into Turkish in a way that patients can understand when writing the PIL. It should be ensured that the headings specified below in the Patient Information Leaflet Guideline, and in particular the information intended to be emphasised, are complete.

At the beginning of the PIL:

- The trade name of the medicinal product for human use (in capital letters), its dose and pharmaceutical form (in lower case) should be written. (bold)
- The route of administration should be specified. (bold)

Then:

- Active substance: The heading in bold colour (italic), and the active substance(s) should be written in normal type, qualitatively and quantitatively.
- Excipient(s): The heading in bold colour (italic), and the excipient(s) should be written in normal type, qualitatively. For medicinal products available on prescription only: Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- Keep this patient information leaflet. You may need to read it again later.
- If you have any further questions, please consult your doctor or pharmacist.
- This medicine has been prescribed personally for you; do not give it to others.
- While using this medicine, when you go to a doctor or hospital, tell your doctor that you are using this medicine.
- Follow exactly what is written in this leaflet. Do not use a higher or lower dose than the dose recommended for you regarding this medicine.

For medicinal products available without prescription: Read this PATIENT INFORMATION LEAFLET carefully, because it contains important information for you.

This medicine is for you to obtain without a prescription and to treat a mild illness with the advice of your pharmacist, without the assistance of a doctor. Nevertheless, you still need to use it carefully in order to obtain the best results from X.

- Keep this patient information leaflet. You may need to read it again later.
- If you have any further questions, please consult your doctor or pharmacist.
- This medicine has been prescribed personally for you; do not give it to others.
- While using this medicine, when you go to a doctor or hospital, tell your doctor that you are using this medicine.
- Follow exactly what is written in this leaflet. Do not use a higher or lower dose than the dose recommended for you regarding this medicine.

This Patient Information Leaflet contains:

1. What is X and what is it used for?
2. What you need to know before you use X
3. How to use X
4. What are the possible side effects?
5. Storage of X

The following headings are included. The writing, colour and format of all headings and information contained under the headings in this patient information leaflet should be in the format described above.

1. What is X and what is it used for?

X: The trade name of the medicinal product is given without specifying the dose, etc.

In a language understandable to the patient using the medicinal product:

- Pharmaceutical form, contents and pharmacotherapeutic group or type of activity
- Contents in terms of weight, volume, number of doses and pack size
- Therapeutic indications should be written.

2. Things to consider before using X If required, particularly important safety-related information should be placed in a box, in bold, under the main heading.

The following subheadings must be included in full. The descriptions here must be in language that patients can understand.

DO NOT USE X in the following situations It is recommended that the sentence begins with "If". However, cases where the word "If" cannot be used are also acceptable. Contraindications, including contraindications due to interactions with other medicinal products, should be stated here in language that the patient can understand.

USE X WITH CAUTION in the following situations It is recommended that the sentence begins with "If". However, cases where the word "If" cannot be used are also acceptable. Precautions, special warnings, and interactions with other medicinal products should be stated here in language that the patient can understand.

This section must end with the following sentence: "If any of these warnings apply to you, even if they applied only in the past, please consult your doctor." (normal text)

Use of X with food and drink

Pregnancy This section begins with the following standard sentence:

Consult your doctor or pharmacist before using the medicine. (italic)

Information regarding use during pregnancy must be written in a clarity understandable by the user and in accordance with the SmPC. However, in cases where it is not applicable or relevant, this heading should not be included.

This section ends with the following standard sentence:

If you realize you are pregnant during your treatment, consult your doctor or pharmacist immediately. (italic)

Breast-feeding

This section begins with the following standard sentence:

Consult your doctor or pharmacist before using the medicine. (italic)

Information regarding use during breast-feeding must be written in a clarity understandable by the user and in accordance with the SmPC. However, in cases where it is not applicable or relevant, this heading should not be included.

Driving and using machines

Warnings related to the characteristics of the medicine stated in the SmPC must be written in an understandable manner and the section must necessarily end with a concluding sentence. However, in cases where it is not applicable or relevant, this heading should not be included.

Important information about some of the excipients contained in X

Information on which of the excipients are important should be provided here. In providing this information, the Guideline on Excipients in the Packaging and Patient Information Leaflet of Human Medicinal Products should be consulted. Even if the substance is included in the Guideline but is outside the specified threshold values, the substance should be stated in this section with the necessary explanation (e.g., no warning is required due to the route of administration, no warning is required due to the dose).

Use with other medicines

This section is completed with the following sentence:

If you are currently using any prescription or non-prescription medicine, or if you have used any recently, please inform your doctor or pharmacist about them. (italic)

If the product is a vaccine, this section is completed with the following sentence:

If you are currently using any prescription or non-prescription medicine, or if you have used any recently, or if you have recently received any vaccination other than this vaccine, please inform your doctor or pharmacist about them. (italic)

3. How is X used?

First:

- Instructions for appropriate use and dose/frequency of administration: • Route and method of administration: • Different age groups: Use in children: Use in the elderly: • Special use conditions: (renal impairment, hepatic impairment, etc.) This section should contain the subheadings specified above. If there is no special use condition, a statement such as "no special use" should be included. The subheadings for renal and hepatic impairment may be given separately or under a single heading.

When writing these sections, care should be taken to use the descriptions provided in the guidelines.

If the product cannot be self-administered by the patient (e.g., IV infusion), it will be sufficient to include only the following standard sentence under the subheading "Instructions for appropriate use and dose/frequency of administration":

"Your doctor will determine the dose of your medicine depending on your condition and administer it to you." (normal text)

If visual descriptions that may be helpful in the use and preparation of the product are also needed, these figures should be placed under the subheading "Route and method of

administration".

The following sentence should appear at the end of this section:

If you have the impression that the effect of X is too strong or too weak, talk to your doctor or pharmacist. (italic)

Also in this section:

If you have used more X than you should:

In addition to the information required to be written according to the guidelines, if any, the following standard sentence should be used: If you have used more X than you should have, talk to a doctor or pharmacist. (italic)

If you forget to use X

Do not take a double dose to make up for a forgotten dose. (italic)

Possible effects when treatment with X is discontinued

Descriptions should be made with subheadings. An explanation should be provided, including the case where there is no effect.

4. What are the possible side effects? This section begins with the following standard sentence:

Like all medicines, side effects may occur in people who are sensitive to the substances contained in X. (normal text)

Side effects are presented to the patient in full, in accordance with the SmPC, under the necessary subheadings. • Important information regarding side effects may be written in dark-colored letters so as to draw the patient's attention. • Possible side effects should be written, in accordance with the SmPC, in subgroups ordered from the most serious to the mildest according to their importance for users.

The main headings specified below must appear in the PIL exactly (except where the omission of any of the main headings cannot be justified). In some cases, depending on the characteristics of the product, the information to be provided under these main headings may also be given in the form of subheadings such as common/very common/rare.

If any of the following occur, stop using X and REPORT TO YOUR DOCTOR IMMEDIATELY or go to the emergency department of the nearest hospital:

After these adverse effects have been written, this section should be completed as follows.

"These are all very serious side effects." (normal text)

-If you experience any of these, it means that you have a serious allergy to X. You may need emergency medical treatment or hospitalisation'. (normal text)

However, apart from certain allergic side effects, if there are conditions requiring discontinuation of the medicinal product and emergency intervention: -If you experience any of these, you may need emergency medical treatment or hospitalisation'. (normal text) This statement must be written.

'All of these very serious side effects are very rare'. (normal text) -This statement must be written where deemed necessary.

However, apart from certain allergic side effects, if there are conditions requiring discontinuation of the medicinal product and emergency intervention, this section: If you experience any of these, you may need emergency medical treatment or hospitalisation'. (normal text) This statement must be written.

If you notice any of the following, tell your doctor immediately or go to the emergency department of the nearest hospital:

After these side effects are written, this section must be completed as follows. All of these are serious side effects. Emergency medical treatment may be required'. (normal text) 'Serious side effects are very rare'. (normal text) -This statement must be written where deemed necessary.

If you notice any of the following, tell your doctor:

After these side effects are written, this section must be completed as follows.

'These are mild side effects of X'. (normal text)

The possible side effects section is completed with the following standard sentence:

If you experience any side effects not mentioned in this patient information leaflet, inform your doctor or pharmacist. (italics)

5. Storage of X It begins with the following standard sentence:

Keep X out of the sight and reach of children and in its original packaging.

Use in accordance with the expiry date.

Do not use X after the expiry date on the carton/bottle/packaging / use before the expiry date.

Where necessary, there must be a warning regarding signs of deterioration of the product.

'If you notice, do not use X' If the product is of biological origin, the following statement must be included. In order to protect the environment, do not dispose of unused X in the water supply or in household waste. Ask your pharmacist how to dispose of medicines no longer required. (italics) The PIL is concluded with the following information:

Marketing Authorisation Holder: Name and full address The heading in bold, italics, with punctuation marks; name and full address in normal text, Manufacturer: Name and full address The heading in bold, italics, with punctuation marks; name and full address in normal text,

This patient information leaflet was approved on
(day month and year)

-Since the product must be administered by healthcare professionals, if additional information needs to be provided, the necessary information must be presented at the end of the PIL under the heading THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS WHO WILL ADMINISTER THIS MEDICINAL PRODUCT. It must be consistent with the information in section 6.6 of the SmPC.

OTHER SOURCES TO BE PREPARED BY THE MINISTRY

The sources to be used to ensure consistency of terminology in the Turkish translation will be announced by the Ministry in due course.

Entry into force : This Guideline enters into force upon approval by the President of the Agency. Execution : The provisions of this Guideline are executed by the President of the Agency.

REVISION HISTORY Revision No Date of Revision Rationale and Explanations 01 18.11.2022
An update to the format of the Guideline has been carried out.