RWANDA FDA
Rwanda Food and Drugs Authority

GUIDANCE ON FORMAT AND CONTENT OF PATIENT INFORMATION LEAFLET FOR HUMAN PHARMACEUTICAL PRODUCTS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of human pharmaceutical products in order to protect public health by increasing access and availability of essential medicines.

Considering the provisions of the technical regulations governing the registration of human pharmaceutical products, and the guidelines for registration of human pharmaceutical products, the authority has to issue the *Guidance on Format and Content of Patient Information Leaflet for Human Pharmaceutical Products.*

Rwanda FDA adopted the Common Technical Document (CTD) Guidelines on Submission of Documentation for registration of human pharmaceutical products. These guidelines have been developed to provide guidance to the applicants and the Authority in managing applications for registration of human pharmaceutical products. These guidelines were developed in reference to the Compendium of Medicines Evaluation and Registration for Medicines Regulation Harmonization in the East African Community, World Health Organization (WHO) and the International Conference on Harmonization of Technical Requirements for Registration of Medicines for Human Use (ICH) and other available literature.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General



Digitally signed by Rwanda FDA (Director General)
Date: 2024.08.19 21:28:22 +02'00'

GUIDANCE DEVELOPMENT HISTORY

First Issue Date	27/05/2021
Effective date of this version	26/08/2024

DOCUMENT REVISION HISTORY

Version number	Changes made and/or reasons for revision
1	First Issue
2	Adoption of the new Guidance template Adoption of the new document number format Editorial changes

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1. GENERAL REQUIREMENTS

1.1 The Patient Information Leaflet

Particulars in the Patient Information Leaflet shall be easily legible, clearly comprehensible and indelible.

a) Type size and font

The following should be considered while selecting type size and font:

i. The font should be easy to read; stylized fonts which are difficult to read should not be used;

ii. The font should be such that similar letters/numbers such as "I", "l" and "1" can be easily distinguished from each other;

iii. A minimum 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 used;

iv. Widespread use of capitals is discouraged; however, capitals may be used for emphasis.

b) Paper

The quality of insert paper should be taken into consideration in order to ensure proper readability of the Patient Information Leaflet. The following should be considered:

i. The paper weight should be such that the paper is sufficiently thick to reduce transparency which makes reading difficult, particularly where the text size is small.

ii. Uncoated paper is preferred as glossy paper reflects light thus making information difficult to read.

iii. When the leaflet is folded the creases should not interfere with the readability of the information or lead to tearing of the insert.

1.2 Conformity with the Summary of Product Characteristics

The Patient Information Leaflet should be in conformity with the summary of products characteristics.

1.3 Language

The labelling must be presented at least in one of the official languages used in Rwanda. An active style of writing should be used instead of passive.

2. PARTICULARS TO BE INCLUDED ON THE PATIENT INFORMATION LEAFLET

2.1 Content and Format of the Prescribing Information

For prescription only medicines, the Patient Information Leaflet should include prescribing information. The content and format for the prescribing information should follow that of Summary of Product Characteristics (SmPC). Please refer to the *Rwanda FDA Guidance on Format and Content of Summary of Product Characteristics for Human Pharmaceutical* Products

2.2 Content and Format of the Patient Information Leaflet

The patient information leaflet shall include the particulars outlined in the template in the following section.

The applicant should complete the template and delete the parts which are not applicable.

2.2.1 TEMPLATE FOR PATIENT INFORMATION LEAFLET

{(Proprietary) name strength pharmaceutical form}

{Active substance(s)}

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider><or><pharmacist>.
- This medicine has been prescribed for you. Do not pass it 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:

a) What {product name} is and what it is used for

b) Before you <take><use> {product name}

c) How to <take><use> {product name}

d) Possible side effects

e) How to store {product name}

f) Further information

[Delete sections that are not applicable]

a) WHAT {PRODUCT NAME} IS AND WHAT IT IS USED FOR

b) BEFORE YOU <TAKE><USE> {PRODUCT NAME}

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 >

Take special care with {product name}

- <if you ...>

- <when ...>

- <Before treatment with {product name},…>

<Taking><Using> other medicines

<Please tell your <doctor, health care provider><or><pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

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

Pregnancy and breast-feeding

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

Driving and using machines

<Do not drive <because...>.>

<Do not use any tools or machines.>

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

c) 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...>

<Use in children>

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

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

<Do not take a double dose to make up for a forgotten <tablet><dose><…>.>

If you stop <taking><using> {product name}

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

d) POSSIBLE SIDE EFFECTS

Like all medicines, {product name} can cause side effects, although not everybody gets them.

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>.

e) HOW TO STORE {PRODUCT NAME}

Keep out of the reach and sight of children.

<Do not store above ºC>, <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}.

<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.>

f) FURTHER INFORMATION

What {product name} contains

- The active substance(s) is (are)…
- The other ingredient(s) is (are)...

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

It is recommended that the physical description such as shape, colour etc should be stated.

Name and full physical address of Marketing Authorization Holder and Manufacturing site:-

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

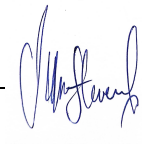
For any information about this pharmaceutical product, please contact the <local representative of the> supplier:

{Country}	**{Country}**
{Name}	{Name}
<{Address}	<{Address}
B-0000 {City}>	B-0000 {City}>
tel: + {telephone number}	tel: + {telephone number}
<{e-mail}>	<{e-mail}>

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

This leaflet was last approved in {MM/YYYY}.

ENDORSEMENT OF THE GUIDENCE

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Date	Date: 2024.08.19 18:08:42 +02'00'	Digitally signed by Vedaste Habyalimana Date: 2024.08.19 19:07:58 +02'00'	Date: 2024.08.19 20:20:07 +02'00'	Digitally signed by Rwanda FDA (Director General) Date: 2024.08.19 21:28:00 +02'00'