# ANNOTATED PATIENT INFORMATION LEAFLET (PIL) (OR PACKAGE LEAFLET) TEMPLATE

[Should the product to which a patient information leaflet (PIL) refers be prequalified, the completed PIL will form Part 3 of the WHO Public Assessment Report (WHOPAR) that will be posted on the website of the WHO Prequalification Team: medicines (PQTm).

*A separate PIL should be provided per strength and per pharmaceutical form. During the evaluation process however, applicants may present PILs for different strengths in a single document, but clearly indicating the strength or presentation to which alternative texts refer. If an applicant is also considering marketing a combined PIL, a detailed justification must be included after the PIL text. The justification should take into account the European Medicines Agency’s (EMA) Quality Review of Documents (QRD) guidance as included in its* Compilation of QRD decisions on stylistic matters*. (See also prequalification guidance:* Ensuring consistency Between Product Information Documents for Inclusion in WHO Public Assessment Reports*.) In all other cases, a separate PIL per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned must be provided by the applicant.*

Text which will not appear in the final printed material is to be presented as shaded text.

The following items must appear in the PIL. 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 medicinal products not all items may be relevant, in this case the corresponding heading should not be included.

The leaflet must be readable for the patient. The European Commission’s Guideline on the readability of the label and package leaflet of medicinal products for human use is a useful reference document.

Please also consult prequalification guidance: Ensuring Consistency Between Product Information Documents.

Standard statements are given in the template which must be used whenever they are applicable. If the applicant needs to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case-by-case basis.

Guidance notes in purple cross-refer to the section/information of the Summary of Product Characteristics (SmPC) document which is to be reflected in that particular section of the PIL.

Applicants shall ensure that, on request from patients' organizations, the PIL is made available in formats appropriate for the blind and partially sighted.

<text> signifies text to be selected or deleted as appropriate.

{text} refers to information to be added.]

**PATIENT INFORMATION LEAFLET (PIL) (OR PACKAGE LEAFLET): INFORMATION FOR THE USER**

[Heading to be printed]

# {(Invented) name strength pharmaceutical form}[[1]](#footnote-1)

## {Active substance(s)}

[The (invented) name of the medicinal product (referred to as {INN} throughout this document) followed by the strength and pharmaceutical form (i.e. as it appears in the SmPC 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 medicinal products available only on prescription:]

# <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 health care provider.
* <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 health care provider.>

**In this leaflet**[[2]](#footnote-2):

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
7. **WHAT {PRODUCT NAME} IS AND WHAT IT IS USED FOR**

[Pharmacotherapeutic group.]

[The pharmacotherapeutic group or type of activity should be stated here using language that will be readily understood by patients.]

[Therapeutic indications.]

[The therapeutic indications should be stated here, using language that will be readily understood by patients. If appropriate, specify that:]

## <This medicine is for diagnostic use only.>

1. **BEFORE YOU <TAKE> <USE>** **{PRODUCT NAME}**

[Additional sub-headings within the headings given below may be included if needed to increase readability.]

[List of information necessary before taking the medicinal product.]

[The whole section 2 must take into account the particular condition of certain categories of users, e.g. children, the elderly, special patient populations, e.g. patients with renal or hepatic impairment.]

[Contraindications.]

# Do not <take> <use> {PRODUCT NAME}

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

[include reference to residues, if applicable.]

## - <if...>

[Give information on absolute contraindications here in accordance with the SmPC; this should be in language that will be readily understandable by the patient understandable language and strictly limited to contraindications, including contraindications due to interactions with other medicinal products. Other precautions and special warnings should be made in the next section.

Care must be taken to ensure that complex details are not omitted. It is not acceptable to state only the common or major contraindications. Belief that a patient cannot understand a contraindication is not a reason for omitting it.]

[Appropriate precautions for use; special warnings.]

# Take special care with {PRODUCT NAME}

## <if you ...>

- <when ...>

* < Before treatment with {PRODUCT NAME}, …>

[Information in patient understandable language, special warnings and appropriate precautions for use should be provided here.]

[Interaction with other medicinal products.]

# <Taking> <Using> other medicines

[Describe the effects of other products on the product in question and vice versa. Reference should be made to the intensification/weakening and the extension/shortening of effects.]

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

[Interactions with herbal or alternative therapies should be addressed where necessary.]

[Interactions with food and drink.]

# <Taking> <Using> {PRODUCT NAME} with food and drink

[Interactions not related to medicinal products should be mentioned here. For example, patients should not consume milk in combination with tetracyclines and no alcohol should be consumed during treatment with benzodiazepines. Where relevant, guidance should always be included to clarify if the medicine must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.]

[Use by pregnant or breast-feeding women.]

# Pregnancy and breast-feeding

[Where the information is differs significantly, pregnancy and breast-feeding information can be presented under separate headings.]

[Include conclusion summary of the information given in the SmPC, in addition to the following optional statement:]

## <Ask your health care provider for advice before taking any medicine.>

[Information on teratogenicity in language that will be readily understood by the patient should be included in the leaflet when the product is contra-indicated during pregnancy.]

[Effects on the ability to drive or to use machines.]

# Driving and using machines

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

<Do not use any tools or machines.>

[Excipients warnings.]

# Important information about some of the ingredients of {PRODUCT NAME}

[If appropriate, include details of those excipients, knowledge of which is important for the safe and effective use of the medicinal product. See the European Commission guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use, including relevant warnings for residues from the manufacturing process.]

1. **HOW TO <TAKE> <USE> {PRODUCT NAME}**

[Additional sub-headings within the headings given below may be included if needed to increase readability.]

[Instructions for proper use.]

[The following 4 items can be combined as one paragraph.]

[Dosage.]

## <Always <take> <use> {PRODUCT NAME} exactly as your health care provider has told you. You should check with your health care provider if you are not sure.> <The usual dose is...>

[Method and/or route(s) of administration.]

[Method of administration: directions for a proper use of the medicinal product; e.g. “Do not swallow”, “Do not chew”, “Shake well before use”.

Route(s) of administration according to the Standard Terms Database of the European Directorate for Quality of Medicines and Health care (EDQM). An additional patient-friendly explanation may be given if necessary.

Where applicable, descriptions (with illustrations, if useful) should be provided of opening techniques for child-resistant containers and other containers that are opened in an unusual way.

Where relevant, guidance should always be included to clarify whether the medicine must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.]

[Frequency of administration.]

[Specify if necessary the appropriate time(s) at which the medicinal product may or must be administered.]

[Duration of treatment.]

[If appropriate, especially for products available without prescription, precise statements should be included on:

* *the usual duration of the therapy*
* *the maximum duration of the therapy*
* *the intervals with no treatment*
* *the cases in which the duration of treatment should be limited.]*

[Symptoms in case of overdose and actions to be taken.]

# If you <take> <use> more {PRODUCT NAME} than you should

[Describe how to recognize whether someone has taken an overdose and what to do.]

[Actions to be taken when one or more doses have been missed.]

# If you forget to <take> <use> {PRODUCT NAME}

[Make clear to patients what they should do after irregular use of a product.]

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

[Indication of the risk of withdrawal effects.]

# If you stop <taking> <using> {PRODUCT NAME}

[Indicate any effects of interrupting or ending the treatment early, if applicable.A statement on the potential consequences of stopping the treatment before finishing the course of treatment and the need for a prior discussion with your health care provider should be included as appropriate in language that will be readily understood by the patient. Indicate withdrawal effects when the treatment ends, when necessary.] [As appropriate, close this section with:]

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

1. **POSSIBLE SIDE EFFECTS**

[Description of side effects (frequency according to MedDRA)[[3]](#footnote-3).] [Begin this section with:]

## Like all medicines, X 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

1. **HOW TO STORE {PRODUCT NAME}**

Keep out of the reach and sight of children.

[Expiry date.]

[Where a specific abbreviation for expiry date is used on the labelling, the full term should be mentioned here as well as the abbreviation.]

## 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.>

[Storage conditions.]

[For storage condition statements see prequalification guidance: Section guidance for Part 3 — Patient Information Leaflet — of a WHO Public Assessment Report (WHOPAR).]

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]

[Please refer to EMA’s Note for guidance on Maximum Shelf Life for Sterile Products for Human Use after first opening or following reconstitution.]

[Where appropriate, warning against certain visible signs of deterioration.]

## <Do not use X 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.>

1. **FURTHER INFORMATION**

[Full statement of the active substance(s) and excipient(s).]

# What {PRODUCT NAME} contains

[The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified using their names as given in the Summary of Product Characteristics and in the language of the text, e.g.]

* The active substance(s) is (are)… *[see Section 2 of prequalification guidance:* Annotated Labelling Template*.]*
* The other ingredient(s) is (are)... *[separate the excipients of the different parts of the medicinal product, e.g. tablet core/coating, capsule contents/shell; powder/solvent (e.g. water for injections).]*

[Pharmaceutical form, nature and contents of container in weight, volume or units of dosage.]

# What {PRODUCT NAME} looks like and contents of the pack

[The pharmaceutical form should be stated according to EDQM’s Standard Terms Database, available on EDQM’s website (see above). An additional patient-friendly explanation may be given if considered necessary. Where the short standard term is used on small immediate packaging materials, the short term should be added in brackets. It is recommended that a physical description e.g. shape, colour, texture, imprint, be included.

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.]

[Name and address of the Applicant/Manufacturer responsible for batch release, if different.]

# Applicant/Supplier and Manufacturer

## {Name and address}

<{tel}>

<{fax}>

<{email}>

[State the name and address of the Applicant/Supplier and identify as such e.g. “Applicant: ABC Ltd, etc.” (Full address: name of the country to be stated in the language of the text. Telephone, fax numbers or email addresses may be included (but excluding websites or emails that link to websites).)

State the name and address of the Manufacturer responsible for batch release and identify as such e.g. “Manufacturer: DEF Ltd, etc.” (Full address: name of the country to be stated in the language of the text. Telephone or fax numbers, email addresses or websites are not allowed).

If the Applicant and Manufacturer are the same, the general heading “Applicant/Manufacturer” can be used.

In cases where more than one manufacturer responsible for batch release is designated, all should be listed here. However, the printed PIL of the medicinal product must clearly identify the manufacturer responsible for the release of the concerned batch, or mention only the specific manufacturer responsible for the release of that batch.]

List of local representatives, where applicable.

* *Listing of local representatives is not a requirement, but where used the representatives must be given for all countries. However, a representative may be designated for more than one country and may also be the Applicant/Supplier where no other local representative is indicated. If the same representative is designated for more than one country, the representative’s details may be listed only once below the names of the countries concerned.*
* *Where a local representative is located outside the country concerned, and where an address is given, the country name must be included in the address of the local representative and must be given in the language(s) of the country for which the local representative is designated.*
* *ISO country codes[[4]](#footnote-4) may be used to replace the full name of the country heading. ISO codes together with the respective names of European Union/European Economic Area countries can be found at http://www.iso.org/iso/country\_codes.*
* *In order to save space on the printed PIL, local representatives may be presented sequentially rather than in a tabulated format. In case of multi-lingual leaflets, the list of local representatives can be printed only once, at the end of the printed PIL.*
* *The local representative may be indicated by name, telephone number and electronic email address (optional) only. A postal address may be added, space permitting. Website addresses or emails linking to websites should not be included.*
* *If a representative is outside the relevant country, the name of the country should be indicated.*
* *For Belgium (Brussels) and Finland (Swedish-speaking Finland), addresses may appear in two languages, respectively Dutch/French and Finnish/Swedish.*
* *For Greece and Cyprus, the address must appear in Greek.*

Telephone numbers: international dialling code followed by the area code and telephone number, e.g. EMA: tel: + 44-(0)20 7418 8400.]

## For any information about this medicine, please contact the local representative of the Applicant/Supplier:

## **Country**

{Name}

<{Address}

XXXX {City}>

Tel: + {telephone number}

<{preferably functional, i.e. not personalized, email}>

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

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

[Date of prequalification. Item to be completed by the Applicant at time of printing.]

< Detailed information on this medicinal product is available on PQTm’s website (see: <http://www.who.int/prequal>).>

1. Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility. Throughout a WHOPAR the proprietary name is given as an example only. [↑](#footnote-ref-1)
2. The headers and some of the text elsewhere in this template must be formulated slightly differently for paediatric formulations since they will be read and acted upon by the health care provider rather than the patient. [↑](#footnote-ref-2)
3. MedDRA is specific standardized medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. See https://www.meddra.org/ [↑](#footnote-ref-3)
4. *Except for the United Kingdom, for which UK is recommended (instead of the ISO code GB).* [↑](#footnote-ref-4)