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| **GUIDELINE FOR PATIENT INFORMATION LEAFLET FOR HUMAN MEDICINES** |

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| This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medicines and variations. It represents the Authority’s current thinking on the safety, efficacy and quality of medicines. It is not intended as an exclusive approach. SAHPRA reserves the right to request any additional information to establish the safety, efficacy and quality of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The Authority is committed to ensure that all registered medicines will be of the required safety, efficacy and quality. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.Guidelines and application forms are available from the office of the Chief Executive Officer and the website. |

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**INTRODUCTION**

**Legal Framework**

In terms of Section 35 (1) (ix) of [PRODUCT NAME]s and Related Substances Act, 1965 (Act 101 of 1965, as amended) (hereinafter ‘the Act’), the Minister of Health may, in consultation with the SAHPRA, make regulations prescribing the information that must be furnished regarding the use of any medicine or Scheduled substance.

Regulation 12 of the Act requires that each package of a medicine shall have a Patient Information Leaflet (PIL) and prescribes the information that must be contained therein.

A person dispensing or administering a medicine must ensure that a PIL is made available at the point of such dispensing or administration.

**Purpose of this Guideline**

This guideline is intended to provide information and guidance to applicants on the format and data requirements of the SAHPRA for the preparation and submission of Patient Information Leaflets (PILs) for evaluation. This guideline is also intended to provide information to applicants on the requirements regarding the legibility, format and content of the PIL for use by consumers, once approved.

The primary objective of this guideline is to ensure that the PIL is written in clear and intelligible terms for the patient and is clearly legible. Applicants are requested to follow the format stipulated in this guideline.

**REQUIREMENTS FOR SUBMISSION**

**Format of submission for evaluation**

Patient Information Leaflets for evaluation should be typed using double line spacing. The print quality of the PIL should be clear so as to enable duplication at a later stage for inclusion into various documents, during the evaluation and registration process. The spelling and grammar in the text of the PIL should be checked thoroughly before submission of the application.

**Language**

Although PILs should be submitted in English (United Kingdom) for evaluation purposes, it is currently a regulatory requirement that a PIL should be made available to consumers in English and in at least one other official language. It is the responsibility of the applicant to ensure that a PIL, once approved, has been appropriately translated and the translation validated, prior to being made available to consumers.

**Reference documents to be supplied**

Patient Information Leaflets are evaluated in accordance with the information provided in the proposed/approved scientific Professional Information. An application to evaluate a PIL for a registered medicine would require that the latest approved Professional information also be submitted. For new medicine applications, the proposed PIL must be submitted at the same time as the proposed Professional Information. In this case, the PIL will be evaluated in conjunction with the proposed Professional Information, for final approval by SAHPRA.

Reference to the Professional information for each statement in the PIL should be included in a broad margin provided on the right-hand side of each page for the purpose of evaluation. Reference to the exact page/s in the Professional information should be included. No references should, however, be included in the finalised, printed PIL.

**Changes to approved Patient Information Leaflets**

After registration of [PRODUCT NAME], the PIL may not be altered without the approval of SAHPRA. When a proposed/approved Professional Information is submitted to SAHPRA for variations, a corresponding proposed PIL and previously approved PIL must be submitted simultaneously.

**LEGIBILITY OF THE PIL**

**Print size and type**

The information appearing in the PIL to be provided to the consumer should be printed in English (United Kingdom) and in at least one other official language and in a type size having a minimum legibility.

**Syntax**

Lengthy sentences (i.e. more than 20 words) should be avoided. Where appropriate, bullet points should be used. A group of bullet points should be introduced with a colon and a single full stop should be placed at the end of the group. A list of bullet points should begin with the uncommon and specific case and end with the common or general case, unless this is inappropriate for [PRODUCT NAME].

For example:

**Tell your doctor or pharmacist if you suffer from:**

* Tuberculosis of the lungs
* Any allergies that affect your lungs
* Any chronic lung condition

A minimum number of words should be used in the bullet points and not more than one sentence for each bullet point. There should preferably be no more than nine items where the bullet points are simple and preferably no more than five when these are complex. Abbreviations should be avoided. Pronouns (e.g. ‘it’) should be used in preference to repeating the name of [PRODUCT NAME], provided the context clarifies what the pronoun refers to.

**FORMAT OF THE PIL**

**Headings**

Headings and sub-headings should be made conspicuous. More than two levels of headings may impair legibility.

**Content**

The information contained in the PIL must be in accordance with the Professional information for [PRODUCT NAME] but the text must be phrased so that it is readily intelligible for the patient and address the patient or the caregiver. Where a specialised term is used, a lay terminology explanation should be given or it should be in consumer intelligible language. Repetition of information can sometimes be avoided by cross-referring to information that is under another heading. Information not relevant to the patient should be omitted.

**Style**

An active and direct style should be used, by placing the verb at the beginning of the sentence, for example:

* *‘Take one (1) tablet’ instead of ‘1 tablet should be taken’,*
* *‘You should…’ is better than ‘it is recommended…’*
* *‘Give one (1) medicine measureful...’ where a medicine is clearly indicated for children only*

This principle should be adapted as, for example, in the case of ‘*If ... then*’ instructions, such as: ‘*If you feel ill, tell your doctor or pharmacist*’.

This guidance on style may not be appropriate in all languages, nor for all medicines (e.g. those which are not self-administered).

Pictograms may be used as an additional measure if they make the message clearer to the patient, but be without any element of a promotional nature.

**Product ranges**

There should be a separate PIL for different pharmaceutical forms (e.g. oral and injectable).

In the event of a medicine falling in two different schedules, a separate Professional Information and Patient Information Leaflet should be submitted for each schedule. [Also refer to the Scheduling of Medicines guideline]

**MODEL PIL**

This section contains a model template for developing a Patient Information Leaflet. Applicants are requested to follow the format stipulated in this section.

**Explanatory notes**

An example of a model leaflet is presented in this Section, containing headings and text, which should be used together with examples of text formulated in consumer-intelligible language.

For the purpose of explaining this model leaflet, the following tools are used:

* **Bold type** for the headings
* Normal type for text which is either mandatory or usually relevant and is not a heading
* Possible options which applicants should adapt e.g. for the relevant pharmaceutical dosage form, route of administration or population for which [PRODUCT NAME] is intended (e.g. the mother of a child) are presented with a slash, e.g. take / give / use / are given / receive / administered. The mandatory statement should be adapted to the dosage form.
* Text included [*in italics*]are explanatory notes. When these notes are taken out of the model PIL template, all relevant and mandatory text will remain.

For certain medicines, the headings may not all be relevant. In such instances, the corresponding headings should be omitted. If a heading is omitted, a justification for this should be provided in the cover letter.

Throughout the text, “[PRODUCT NAME]” indicates the (invented) name of [PRODUCT NAME].

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: [SX]**

*[The Scheduling status of [PRODUCT NAME] as it appears in the Professional information]*

**{Invented/PRODUCT NAME strength pharmaceutical form}**

**{Active substance(s)}**

*[The (invented) name of [PRODUCT NAME] (referred to as [PRODUCT NAME] throughout the patient information leaflet, wherever practical) followed by strength and pharmaceutical form (i.e. as it appears in section 1 of the PI) should be stated here in bold. This should be followed by the active substance), which may be written on the line below. In the remainder of the document the [PRODUCT NAME] should appear without bold or underline.*

In the case of a complementary medicine the following shall be included:

* a statement identifying the discipline of [PRODUCT NAME]; and
* if [PRODUCT NAME] has not received registration with SAHPRA the disclaimer “This medicine has not been evaluated by SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.”

*[For* medicines *available* ***only*** *on prescription]*

**Read all of this leaflet carefully before you start taking / using / are given [PRODUCT NAME]**

* Keep this leaflet. You may need to read it again.
* If you have further questions, please ask your doctor or your pharmacist.
* [PRODUCT NAME] has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours. (May be omitted if [PRODUCT NAME] is not self-administered).

*[For* medicines *available* ***without*** *a prescription]*

**Read all of this leaflet carefully because it contains important information for you**

[PRODUCT NAME] is available without a doctor’s prescription, for you to treat a mild illness. Nevertheless, you still need to use [PRODUCT NAME] carefully to get the best results from it.

* Keep this leaflet. You may need to read it again.
* Do not share [PRODUCT NAME] with any other person.
* Ask your pharmacist if you need more information or advice.
* You must see a doctor if your symptoms worsen or do not improve after (number of) days.

**What is in this leaflet**

[*The content listing would normally reflect the six main sections of the leaflet]*

1. What [PRODUCT NAME] is and what it is used for

2. What you need to know before you <take> <use> [PRODUCT NAME]

3. How to <take> <use> [PRODUCT NAME]

4. Possible side effects

5. How to store [PRODUCT NAME]

6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

*[The pharmacotherapeutic group or type of activity should be stated here using language intelligible to the patient, followed by a brief description of the indications for use of [PRODUCT NAME], as accepted by SAHPRA.]*

1. What you need to know before you <take><use>[PRODUCT NAME]

**Do not <take><use> [PRODUCT NAME]** ><  **[PRODUCT NAME] should not be administered to you <:>**

* if you are hypersensitive (allergic) to (active substance) or any of the other ingredients of [PRODUCT NAME]. *[Include reference to residues, excipients, etc, if applicable]*
* if you…

*[Absolute contraindications]*

*[Information on absolute contraindications, in accordance with the Professional information, should be provided here in patient-intelligible language. This should include chronic accompanying diseases (e.g. kidney insufficiency, liver insufficiency, diabetes and other metabolic diseases), contraindications due to interactions with other medicines, contraindications due to excipients and specified conditions for certain categories of users, e.g. children or the elderly.]*

*[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.]*

**Warnings and precautions**

Tell your doctor or healthcare professional before being given the injection:

Take special care / Special care should be taken with X:

* if you ...
* when ...

*[Information, in patient-understandable language in line with the* ***Special Warnings and Precautions for Use*** *in Professional Information. Care must be taken to ensure that complex details are not omitted and that they are expressed in a way that consumers can understand. It is not acceptable to include only the more common or major special warnings/l precautions.]*

*[A special precaution should be presented as implying the action a patient should take, rather than as factual information that describes a medical condition. The influence of [PRODUCT NAME] on the patient’s behaviour should be described. A differentiation should be made between the influence on cognitive abilities, reactivity and judgment.]*

*[Examples:]*

* If you have asthma (or used to), because [PRODUCT NAME] can bring on an attack
* If you are over 65…
* If [PRODUCT NAME] is given to children…
* [PRODUCT NAME] may make you sleepy

*[Also describe cases (if any) in which the consumer should only use [PRODUCT NAME] after consultation with a medical practitioner. Include (as appropriate and if not mentioned in the previous section) reference to chronic accompanying diseases (renal insufficiency, liver insufficiency diabetes and other metabolic diseases).]*

*[Where applicable, provide information on necessary examinations, which may be carried out by the medical practitioner prior to, or during, the therapy, for example tests carried out in order to exclude* *contraindications. Provide information (if there is any) about important symptoms which may be masked by [PRODUCT NAME] or if [PRODUCT NAME] influences laboratory values. If relevant, reference should be made here to possibilities for intolerance to various materials (e.g. disposable plastic syringes), which must be used as part of [PRODUCT NAME].]*

*[Refer to the need for the avoidance of external influences, such as sunlight after the use of phototoxic medicines. Other warnings concerning for example other diseases and the influence of [PRODUCT NAME] on behaviour should be described. Statements should also include for example, reference to discolorations of underwear as a result of changes in the colour of urine and stool.]*

*[In case of anaesthetic medicines or medicines used for conscious sedation, interference with daily activities may continue for up to 24 hours and no legal/contractual decisions should be entered into for 24 hours after receiving anaesthetic/conscious sedation.]*

[*If relevant, include whether [PRODUCT NAME] may lead to a positive test for a prohibited substance in competitive sport activities.]*

*[Include whether [PRODUCT NAME] may affect the performance of child and adult learning in schools and other institutions of education, learning and training.]*

**Children <and adolescents>**

[*When [PRODUCT NAME] is indicated in children, the warnings and precautions which are specific to this population (and identified as such in section 4.4 of the PI) should be included under this subheading. Where relevant, parents / caregivers should also be alerted in this section of potential children/teenager specific warnings included under “driving and using machines”.]*

*[If there is no indication in some or all subsets of the paediatric population, information should reflect the paediatric subsection of section 4.2 of the PI, e*.g. “Do not give [PRODUCT NAME] to children between the ages of x and y <years> <months> because <of the risk of […]> <it does not work> <the potential benefits are not greater than the risks>, <it is unlikely to be safe>”.]

**Other medicines and [PRODUCT NAME]**

*[The following statement must be included:]*

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

*[Describe the effects of other medicines on [PRODUCT NAME] in question and vice versa. Reference should be made to the intensification/weakening and the prolonging/shortening of effects. This information should be in line with the* ***Interactions*** *as in the Professional information.]*

**[PRODUCT NAME] with< food><and><,><, drink><and><alcohol>**

*[Interactions not related to medicines 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 and other central nervous system depressants.]*

**Pregnancy<and ><,>breastfeeding<and fertility>**

*[Include information given in the Professional information, in patient-understandable language. The following additional statement must be included:]*

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking [PRODUCT NAME].

**Driving and using machines**

[*Include whether [PRODUCT NAME] may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment]*

It is not always possible to predict to what extent [PRODUCT NAME] may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which [PRODUCT NAME] affects them.

**< [PRODUCT NAME] contains {name the excipients(s)}>**

*[If appropriate, warnings of those excipients knowledge of which is important for the safe and effective use of [PRODUCT NAME]. Information on intolerances to excipients (e.g. lactose monohydrate), including alcohol should be provided. Indicate “sugar free” if applicable.]*

**How to <take><use>[PRODUCT NAME]**

Do not share medicines prescribed for you with any other person.

*[The following statements should be included, where applicable:]*

 *[For medicines available on prescription only:]*

<Always <take> <use> [PRODUCT NAME] exactly as your doctor <or pharmacist> has told you. Check with your <doctor> <or> <pharmacist> if you are not sure.>

*[For medicines available without prescription:]*

<Always <take> <use> [PRODUCT NAME] exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you. Check with your <doctor> <or> <,> <pharmacist> <or nurse> if you are not sure.>

The usual dose is...

*[For medicines available* ***only*** *with a prescription, a statement such as the following should be included on the usual duration of the therapy:]*

Your doctor will tell you how long your treatment with [PRODUCT NAME] will last. Do not stop treatment early because … If you have the impression that the effect of [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.

*[For medicines available* ***without*** *prescription:*

*In particular, and if at all possible, for medicines available without a prescription, precise statements should be included on the usual duration of the therapy, the maximum duration of the therapy and intervals with no treatment, together with clear guidance on when to consult a doctor.*]

*[The instructions for proper use and the intended dosage ranges (individual and daily doses separately), as well as the maximum daily dose, the frequency, method, route of administration and the duration of treatment, should be stated if relevant. In addition, it may be necessary to explain the route of administration in consumer-intelligible language.]*

*[Instructions should:*

* *be used to tell consumers what to do. They should not be used to justify or explain an action.*
* *be described in a practical manner.*
* *tell consumers how to use [PRODUCT NAME] properly.*
* *be positive rather than negative, whenever possible. Negative instructions should only be used when the consumer should avoid specific actions.*
* *be given as separate instructions when the consumer is to carry out two separate actions. Separate actions should not be compressed into a single sentence.*
* *be numbered and put into the exact order that the consumer should follow.*
* *usually be intelligible without explanations, so as not to overburden consumers with information.]*

*[Explanations should be used to expand on the reasons for instructions and not to give further information. Instructions may be presented in italics or other type with explanations in plain type, so as to give consumers a guide as to the significance of the information.]*

*[When applicable, there should be descriptions (if useful with illustrations) of opening techniques for child-resistant containers and other containers to be opened in an unusual manner.]*

*[Some examples of statements that may be included here:]*

* *Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)*
* *…one or two tablets (500 to 1 000 mg of paracetamol) three times a day, this means a daily maximum of six tablets (3 000 mg of paracetamol)’*
* *…in the morning, at lunchtime, immediately before meals, with food, after food’*
* *Do not swallow*
* *Do not chew*
* *Shake well before use*
* *Dissolve the effervescent tablet in one glass of water. Then drink the contents of the whole glass'*
* *Take [PRODUCT NAME] once a day, every day, at about the same time each day*
* *Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets*
* *Allow to reach room temperature before using (e.g. insulins)*

*[For medicines not self-administered]*

*[The route of administration should be included] [Include]*

You will not be expected to give yourself [PRODUCT NAME]. It will be given to you by a person who is qualified to do so.

**<If you<take>more [PRODUCT NAME] than you should>**

*[Description of signs and symptoms of overdosage that the patient is able to recognise and actions to be taken]*

*[The following statement must be included:]*

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

*[For medicines not self-administered] [The following may be acceptable:*]

Since a healthcare professional will administer [PRODUCT NAME], he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**<If you forget to<take><use>[PRODUCT NAME]>**

*[Provide clear explanations of what should be done following irregular use of [PRODUCT NAME], e.g.:]*

Do not take / receive a double dose to make up for forgotten individual doses.

*[For medicines not self-administered] [The following may be acceptable:*]

Since a healthcare professional will administer [PRODUCT NAME], it is unlikely that the dose will be missed.

**<If you stop<taking>using>[PRODUCT NAME]>**

*[Indicate any effects of interruption or ending treatment early, if applicable. Indicate withdrawal effects when the treatment ends, if applicable]*

1. Possible side effects

*[A description of the side effects should be provided. Begin this section with:]*

[PRODUCT NAME] can have side effects.

*[The following statement must be included:]*

Not all side effects reported for [PRODUCT NAME] are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking [PRODUCT NAME], please consult your doctor, pharmacist or other healthcare professional for advice.

*[Describe, if necessary, the actions to be taken. If the patient needs to seek help urgently use the term ‘immediately’; for less urgent conditions use the phrase ‘as soon as possible’.]*

*[The information given on side effects should be in accordance with the Professional information. Side effects should be subdivided according to seriousness and frequency, or according to symptom type. Wherever possible, for all side effects the frequency with which they occur must be mentioned to allow patients to know the risk. Irrespective of their frequency, very serious, side effects of [PRODUCT NAME] should be mentioned first or specially emphasised. This applies in particular to side effects where there is an urgent need to take action.]*

*[The risk (frequency) of side effects may be presented using the terms “frequent” or “less frequent” if the information is available in the corresponding Professional information. Descriptors such as “common”, “rare”, etc. should not be used.]*

*[The following is an example of side effects grouped according to seriousness:]*

If any of the following happens, stop taking [PRODUCT NAME] and tell your doctor immediately or go to the casualty department at your nearest hospital:

* ‘swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing’,
* ‘rash or itching’,
* ‘fainting’

These are all very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

* chest pain,
* angina,
* changes in the way your heart beats, for example, if you notice it beating faster,
* difficulty breathing,
* signs of recurrent infections such as fever or sore throat,
* less urine than is normal for you,
* yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

* nausea (feeling sick),
* abdominal cramps or stomach pains,
* headache,
* dizziness,
* tiredness,
* light-headedness,

Less frequent side effects:

* dry cough,
* muscle cramps,
* flatulence or wind,
* diarrhoea,
* loss of appetite.

*[Close this section with:]*

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your <doctor><or><,><pharmacist><or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

1. How to store [PRODUCT NAME]

*[The following statement must be included in this section:]*

Store all medicines out of reach of children.

*[Where applicable, the following statements may be included:]*

*[Storage conditions have to concur with that approved in the Professional information]*

* Store at or below X °C [Explain ideal storage environment]
* Store at or between 2 °C – 8 °C (in a refrigerator)
* Store in a freezer
* Do not refrigerate / freeze [as appropriate]
* Store in the original package / container
* Keep the container in the outer carton
* Keep the container tightly closed
* There are no special storage instructions for [PRODUCT NAME]

*[An additional short explanation of the storage conditions, in patient-friendly terms, should be included when appropriate, e.g.:]*

* Protect from light / moisture
* Do not store in a bathroom
* Do not use after the expiry date stated on the label / carton / bottle

*[Where applicable, shelf life after reconstitution, dilution or after first opening the container should be indicated]*

*[Where appropriate, include a warning against any visible signs of deterioration]* Do not use [PRODUCT NAME] if you notice (*description of the visible signs of deterioration*) *[Information on how to dispose of unused medicine, e.g.:]*

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

1. Contents of the pack and other information

**What [PRODUCT NAME] contains**

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

*[The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified using their names as given in the Professional information and in the language of the text: e.g*.]

* The active substance is…
* The other ingredients are*… [These should be listed alphabetically. This should be in lower case, except at the start of a sentence and when it is a registered invented name e.g. Colourant®. If a preservative or alcohol (2 % or more) is present, the content of each must be indicated as required* *for the Professional information*]

**What [PRODUCT NAME] looks like and contents of the pack**

*[A physical description, e.g. shape, colour, texture, imprint, etc., of the dosage form should be included here in accordance with the Professional Information.]*

[*In accordance with information provided in the Professional information, include the pharmaceutical form, the number, volume or mass per package unit, pack size and a description of the packaging material, e.g. bottle, blister pack, etc*.]

**Holder of Certificate of Registration and Manufacturer**

*[Holder of Certificate of Registration: As in the Professional information, section 7]*

**This leaflet was last revised in**

*[As in the Professional information]*

**UPDATE HISTORY**

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| Sept – Dec 2012 | Amendments to sections: A3; A4; B1; B2; C2; C4; Scheduling Status, Invented name, Strength and pharmaceutical form; What X contains; Before you take/use/are given X; How to take/use/receive X; Possible side-effects;Deletion of text in sections: B2; C1; C4; D; E | v3 December 2012 |
| Dec 2012 | Date of implementation |
| Dec 2013 | Amendment of section 5 in line with Regulations published in Government Notice R.860, GG37032 of 15 Nov 2013 | v4 January 2014 |
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| 02 February 2015 | Implementation for registered products and “Old Medicines” |
| November 2018 |  | V5 January 2019 |