South African Health Products
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GUIDELINE FOR PATIENT INFORMATION LEAFLET FOR HUMAN MEDICINES (CATEGORIES A AND D)

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Human Medicines (categories A and D) containing specified substances. With respect to Category D medicines, the guidance provided herein is related to general content requirements. Any specific technical guidance indicated in Category D medicine guidelines should be applied. In addition to this guideline, SAHPRA reserves the right to request any additional information to establish the safety, quality, and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. SAHPRA is committed to ensure that all registered medicines will be of the required quality, safety, and efficacy.

Guidelines and application forms are available from the office of the Chief Executive Officer and the website.

Document History

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Glossary

The table below the key abbreviations and terminology used in this document, including the reconciliation of related terminology used by SAHPRA and EMA.

Abbreviation/ Term	Meaning
Amendments	Used interchangeably with the term 'variations'
EMA	European Medicines Agency
MAH: Market Authorisation Holder	Equivalent to HCR: Holder of the Certificate of Registration
Package Leaflet	Equivalent to PIL: Patient Information Leaflet
SAHPRA	South African Health Products Regulatory Authority
SmPC: Summary of Product characteristics	Equivalent to PI: Professional Information
The Authority	Relevant regulatory authority, in this case

1. INTRODUCTION

In terms of section 35(1)(ix) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965, as amended) (hereinafter 'the Act'), the Minister of Health may, in consultation with SAHPRA, make regulations prescribing the information that must be furnished regarding the use of any medicine or scheduled substance.

The General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), require a Patient Informational Leaflet (PIL) to accompany each medicine (regulation 12). As such, the PI is required by the Authority to be included in the application for the registration of a medicine (regulation 16(3)(g)).

The PIL sets out the agreed position of the medicine as determined as an outcome of the assessment process. As such, the content cannot be changed except with the approval of the South African Health Products Regulatory Authority (SAHPRA).

1.1 Purpose

This guideline is intended to provide information and guidance to applicants on the format and data requirements of SAHPRA for the preparation and submission of 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.

1.2 Scope

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Human Medicines (categories A and D) containing specified substances. With respect to Category D medicines, the guidance provided herein is related to general content requirements. Any specific technical guidance indicated in Category D medicine guidelines should be applied. In addition to this guideline, SAHPRA reserves the right to request any additional information to establish the safety, quality, and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. SAHPRA is committed to ensure that all registered medicines will be of the required quality, safety and efficacy.

2. GENERAL NOTES

The PIL is regarded as the document that ensures the safe and effective use of the medicine under most circumstances. It presents a scientific, objective account of the medicine's use and limitation as established by the supporting evidence.

2.1 Format of submission for evaluation

PILs 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.

2.2 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.

2.3 Reference document to be supplied

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

2.4 Changes to approved PILs

After registration of a medicine, the PIL may not be altered without the approval of SAHPRA. When a proposed / approved PI is submitted to SAHPRA for variations, a corresponding proposed PIL and previously approved PIL must be submitted simultaneously.

Changes to the PIL should be indicated by single underlining for additions, strike through for deletions and broken underlining for re-wording or for text that has been moved. Applicants may use the 'Track Changes' functionality in MS Word to make these changes, provided that they comply with the formatting requirements in the previous sentence above.

2.5 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, as defined in the General Regulations made in terms of the Act.

2.6 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 the medicine.

For example:

Tell your doctor or pharmacist if you suffer from:

- Tuberculosis of the lungs;
- any allergies that affect your lungs; or
- 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 the medicine, provided the context clarifies what the pronoun refers to.

3. FORMAT OF THE PIL

3.1 Headings

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

3.2 Content

The information contained in the PIL must be in accordance with the PI for the medicine, 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.

3.3 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 measure...' 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, then 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 should be without any element of a promotional nature.

3.4 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 PI and PIL should be submitted for each schedule (also refer to the 2.36 Scheduling of Medicines Guideline).

4. MODEL PIL

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

Explanatory notes

The template contains headings and text, which should be used together with examples of text formulated in consumer-intelligible language.
For the purpose of applying this model PIL template, the following conventions 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 the medicine is intended;
- 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; and
- {text} refers to information which must be filled in.

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 the medicine.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: [SX]

[The Scheduling status of the medicine as it appears in the PI]

{[PRODUCT NAME] strength pharmaceutical form}

{Active substance(s)}

{Sugar / sweetener status}

[The (invented) name of the medicine (referred to as [PRODUCT NAME] throughout the PIL, 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 (invented) name should appear without bold or underline.]

[For oral and parenteral administration of a medicine which contains sugar, provide the status as per Regulation 12 of the General Regulations made in terms of the Act (i.e. "Contains sugar" and the name and quantity of the sugar or "Sugar free"). For oral administration of a medicine which contains sweetener, provide the name and quantity of sweetener other than sugar, along with the statement "contains sweetener".]

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

- *the words* "Complementary Medicine"*;*
- *a statement identifying the discipline or the wording* "Health Supplement"*, as the case may be;*
- *which is not registered by the Authority, the following disclaimer:* "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."*; and*
- *containing at least 5 percent of genetically modified organisms, the identification of the affected ingredients) and the following warning* "contains genetically modified organisms"*.]*

*[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, pharmacist, nurse, or other health care provider.
- [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 the medicine 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><maintain your health>. Nevertheless, you still need to use [PRODUCT NAME] carefully to get the best results from it. *["maintain* your *health" is an example of wording that may ONLY be used for low risk Complementary Medicines, such as health supplements.]*

- Keep this leaflet. You may need to read it again.
- Do not share [PRODUCT NAME] with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after {insert number} days. *[This last bullet may be omitted for low risk Category D medicines where the indication is not related to the treatment of any illness / symptoms.]*

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 the medicine, as accepted by SAHPRA].

2. 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 {insert name of the active substance} or any of the other ingredients of [PRODUCT NAME] (listed in section 6). *[Include reference to residues, excipients,*

etc. if applicable]

- if you…

[Absolute contraindications:

*Information on absolute contraindications, in accordance with the PI, 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 health care provider before being given the injection:

Take special care / Special care should be taken with [PRODUCT NAME]:

- if you ...
- when….

[Information, in patient-understandable language in line with section 4.4 of the PI. 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 and 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 the medicine 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…
- … because [PRODUCT NAME] may make you sleepy

[Also describe cases (if any) in which the consumer should only use the medicine 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 the medicine or if the medicine 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 the medicine.]

*[*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 the medicine 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, include a statement explaining that 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 the medicine may lead to a positive test for a prohibited substance in* competitive *sport activities.]*

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

Children <and adolescents>

[When *the medicine 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 sub-heading. 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 health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

[Describe the effects of other medicines on the medicine 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 PI.]*

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

*[*Interactions *not related to medicines should be mentioned here if reference is made in section 4.5 of the PI. 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. This section should not be used to tell patients whether or not their medicine should be taken before, during or after meals as this should only be addressed in section 3 (below), but a cross-reference to section 3 can be included.]*

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

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

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

[Include whether the medicine 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 excipient(s)}>

[If appropriate, include warnings of those excipients knowledge of which is important for the safe and effective use of the medicine. Information on intolerances to excipients (e.g. lactose monohydrate), including alcohol should be provided].

3. 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 the medicine 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 (with illustrations if useful) 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.

[Where applicable, include a cross-reference to Section 6 for any reconstitution instructions]

<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 health care provider 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 the medicine, 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 health care provider 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]

4. 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 health care provider 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 PI. 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 the medicine 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 PI. Descriptors such as "common", "rare", etc. should not be used.]

[The risk (frequency) of side effects may be presented using the terms very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000) if the information is available in the corresponding PI.

For a MSM PI without its own clinical trial data, ADRs should be categorised according to the frequency classification: 'Frequent' and 'Less frequent' if the information is available in the corresponding PI]

[The following is an example of side effects grouped according to seriousness:]
If any of the following happens, stop taking / using [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:

<u>Common/Frequent side effects:</u>

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

<u>Uncommon/Less frequent side effects:</u>

- 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>. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

[Applicants may opt to include additional, dedicated contact details for the reporting of side effects directly to the HCR]

5. 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 those approved in the PI]

- 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 {provide 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).

6. Contents of the pack and other information

What [PRODUCT NAME] contains:

[Include a 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 PI and in the language of the text: e.g.]

- The active substance is…
- The other ingredients are… *[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 PI*]

[Include any other excipient-related information requirements stipulated by the General Regulations made in terms of the Act.]

[In instances where the patient may need to reconstitute the medicine, include instructions here along with a cross-reference from Section 3.]

[Note: For products where higher concentrations of alcohol are required, (e.g. Complementary medicines, including homeopathic preparations and plant extracts, or where solubility or preservation might be problematic), exemption from ethanol concentration limits will be considered individually, provided that justification and motivation is submitted together with proof that the proposed dosage will not result in blood alcohol levels of 25 mg/dl or higher.]

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 PI.]

[In accordance with information provided in the PI, 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

[Holder of Certificate of Registration: As in the PI, section 7]

This leaflet was last revised in

[As in the PI]

<Registration ><Application number>

[Registration number of the medicine allocated in terms of section 15(5) of the Act or, in the case of unregistered medicines permitted continued rights of sale, the application number allocated by the Authority followed by the expression "Act 101/1965" as may be applicable.]

<Access to the corresponding Professional Information>

[If the corresponding PI will only be available electronically, provide the URL and all contact details (incl. telephone number(s)) of the agent / HCR from which the PI may be obtained. This requirement is stipulated by regulation 12(2)(p).

Note: Where the PI is not contained in the packaging of a medicine, the HCR must include information as to where it may be obtained, regardless of whether or not SAHPRA itself has made the PI publicly available in an electronic format].

5. REFERENCES

Regulations published in Government Notice R.860, GG37032 of 15 Nov 2013.

6. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces a guideline for Patient Information Leaflet for Human Medicines, old document number 2.14. It will be reviewed on this

timeframe or as and when required.