APPENDIX 7 POINTS TO CONSIDER FOR SINGAPORE LABELLING

Labelling refers to any printed or graphic information on the immediate container, outer packaging and any other form of material supplied together with the therapeutic product (TP). This includes the outer carton, inner/blister labels and package insert or patient information leaflet.

Each product application must be accompanied by a proposed PI and/or PIL. If multiple manufacturing sites are proposed for registration, information for all sites should be included in the PI and/or PIL. If there are different strengths or dosage forms, a common PI/PIL for all strengths or dosage forms is encouraged. If separate PI/PILs are to be registered for different strengths or dosage forms, the content should be consistent across the PI/PILs, except for strength/dosage form-specific information.

PDF files submitted must be in a format that is searchable, flattened (without layers) and without encryption. Files that are layered, password-protected, or have security restrictions will not be accepted.

All artwork and drafts must be clearly legible in typed / printed format. The draft artwork of the outer carton and inner/blister labels should be consistent with the format, design and colour that are to be printed. Separate labels must be submitted for each different pack size of the drug product.

All product labelling must be in English. If non-English text is included in the labelling, applicants must provide an official statement declaring that the non-English text is complete, accurate, unbiased and consistent with the English text. Information provided in the labels should be consistent with the information submitted in the application dossier.

1 OUTER CARTON AND INNER/BLISTER LABELS

The outer carton refers to the product packaging in which the immediate packaging is placed, e.g. the carton box containing blister strips. The inner label refers to the label that is fixed onto the primary container closure system, e.g. the label affixed to a bottle, vial or ampoule. The blister label refers to the foil backing of a blister strip.

In addition to the legal labelling requirements, the following information shall be present on the labelling of the product:

	Parameters	Outer Carton	Inner Label	Blister Label
1.	Product Name	✓	✓	✓
2.	Dosage Form	✓	✓*	NA
3.	Name of Active Substance(s)**	✓	✓	✓
4.	Strength of Active Substance(s)	✓	✓	✓
5.	Batch Number	✓	✓	✓
6.	Expiry Date	✓	✓	✓
7.	Route of Administration	✓	✓	NA
8.	Storage Condition	✓	✓*	NA
9.	Name & Address of Manufacturer***, Product Owner or Product Registrant	✓	✓*	Name/Logo of Manufacturer/ Product Owner/ Product Registrant
10.	Warnings (if applicable)	✓	✓*	NA
11.	Pack Sizes (unit or volume)	✓	✓	NA
12.	Special Labelling (if applicable)	✓	✓*	NA
13.	Name & Content of preservative(s) (if applicable)	✓	✓*	NA

NA Not applicable

***** Exempted for small labels such as an ampoule or vial with a nominal volume of 10 ml or less. Other factors may be considered such as the amount of information which needs to appear on the label and the font size necessary to achieve legibility of the information.

** When the active substance is present as a salt, this should be clearly indicated, e.g. “each tablet contains 60mg active substance (as citrate) or each tablet contains 10mg active substance hydrochloride” etc. This statement is optional for inner labels and blisters. However, the name and strength of active ingredient must be indicated on the inner label and blister.

*** The words “Batch released by” instead of “Manufactured by” may be used if the site named is responsible for product release.

If the product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner label.

The required information should be printed on the labels. Over-labelling by replacing a new label over the printed label such as the use of stickers is generally not allowed. In circumstances where over-labelling cannot be avoided, the applicant should consult HSA. However, redressing to facilitate product differentiation, such as using colour stickers, is acceptable and the revised product labels should be notified to HSA.

The outer carton and inner labels for products with different strengths, dosage forms, or formulations should be adequately differentiated (e.g. by using different colour schemes) to minimise confusion and medication errors.

Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack. It is important that the particulars remain available to the user up to the point at which the last dose is removed from the blister pack.

The draft artwork, specimen or mock-up of the outer carton and inner/blister labels submitted in the application dossier should be consistent with the format, design and colour that are to be printed.

Email addresses, website addresses and telephone numbers on the product’s labelling are acceptable, as long as the intent of such inclusions is non-promotional. Machine readable codes (QR codes or 2D barcodes) for logistics control or directing

the user to the electronic PI/PIL of the TP (e-labelling) may be included. For more information on e-labelling, please refer to Appendix 7a: Guidance on Electronic labelling for Therapeutic Products.

2 PACKAGE INSERT (PI)

Package inserts are required for products classified as Prescription Only Medicines.

The PI is a document that contains information that will ensure the safe and effective use of the therapeutic product. It should include objective and scientific information of the product's efficacy and safety, as well as any limitations of use based on the data submitted in the application dossier. Information in the PI must be non-promotional in nature.

The PI must contain the following information:

(a) Brand or Product Name

(b) Name and Strength of Active Substance(s) – the non-proprietary name of each active substance.

- When the active substance is present as a salt, this should be clearly indicated, e.g. "each tablet contains 60mg active substance (as citrate) or each tablet contains 10mg active substance hydrochloride".

(c) Product Description – a description of the relevant physical and chemical characteristics of the drug product and its formulation(s).

- A description of the appearance of the product (colour, markings etc.).
- For tablets designed with a score line, information on the purpose of the score-line should be given, e.g. 'the score line only serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses', or 'the tablet can be divided into equal halves'.
- Information on pH and osmolarity, where applicable.
- For products to be reconstituted before use, the appearance before and after reconstitution should be stated. If a diluent/ solvent is part of the

therapeutic product, a physical description of the diluent/solvent should be stated.

- A list of excipients contained in the product, which may include preservatives, pH adjusters, excipient mixture (e.g. list of ingredients of film coating, capsule shell, printing ink, flavouring agent, colourants, diluent/solvent, etc.).

(d) Pharmacodynamics/Pharmacokinetics – the information to be reflected in this section includes:

- The ATC code, if available;
- The pharmacokinetic and pharmacological action(s), particularly in humans, of each drug substance;
- Clinical trial information relating to clinical efficacy and safety; and
- Relevant pharmacogenetic information from clinical studies with data showing a difference in benefit or risk to a particular genotype or phenotype.

(e) Indication – the therapeutic use(s) of the product.

(f) Dosage and Administration – the information to be provided includes the following, as appropriate:

- Dosing regimen (dose and interval);
- Information on dose adjustments in special populations, e.g. elderly, children, renal insufficiency, hepatic insufficiency and concomitant disease;
- Maximum recommended/tolerated daily dose and / or the maximum dose / cycles for the entire course of therapy;
- Relevant information on dosage adjustment from monitoring of clinical symptoms and signs and/or laboratory investigations, where appropriate, with cross-references to other sections, where appropriate;
- Other pertinent information, such as relationship to meals and fluids, as well as compatibility with other drugs.

(g) Mode/Route of Administration – only standard abbreviations should be used. Non-standard or complicated routes of administration should be carefully explained in full to avoid confusion.

(h) Contraindications – where patients should never or generally not be treated with the product, the information must be explicitly stated. Information on the presence of residual quantities of potentially allergenic materials used in the manufacturing of the product must be stated.

(i) Warnings and Precautions – where caution is required to ensure the safe and efficacious use of the product, the information must be highlighted and the risk clearly described.

(j) Interactions with Other Medicines and Other Forms of Interaction – information on clinically relevant drug-drug interactions and other potentially serious interactions based on the pharmacology of the medicine.

(k) Use during Pregnancy/Lactation

(l) Adverse Effects/Undesirable Effects – a description of adverse reactions (MedDRA terminology preferred) reported in clinical trials or post-marketing studies, including frequency, severity and clinical importance.

(m) Overdose – information on signs and symptoms of overdose or accidental poisoning, and management of overdose should be provided, where applicable.

(n) Incompatibilities (for injections only) – information on physical or chemical incompatibilities of the drug with other products with which it is likely to be mixed or co-administered.

(o) Storage Condition – if included in the PI, the storage condition must be consistent with that stated on the product label and/or outer carton.

(p) Shelf Life – if included in the PI, the shelf life must be consistent with that stated on the product label and/or outer carton. Information on in-use shelf-life after dilution or reconstitution or first opening should be provided, where applicable.

(q) Dosage Form or Presentation – this refers to the available dosage form(s), formulation(s), strength(s) and/or pack size(s).

- All pack sizes and the primary container closure system should be stated (e.g. glass vials, PVC/Aluminium blister, Alu/Alu blister, HDPE bottle, ampoule, etc.).

- Any other components should be listed, where applicable (e.g. desiccant, swabs, needles, etc.).
- The primary container closure system of the diluent/solvent provided with the drug product should also be described, where applicable.
- The statement '*Not all presentations may be available locally*', or equivalent, must be stated if this section includes unregistered presentations.

(r) Name and Address of Manufacturer or Product Owner or Product Registrant.

3 PATIENT INFORMATION LEAFLET (PIL)

Patient Information Leaflets (PILs) are required for Pharmacy Only and General Sale List therapeutic products. The PIL must be easily understood and be consistent with the product labels and/or PI, as appropriate. The PIL should contain the following information:

(a) Brand or Product Name

(b) Product Description

- A description of the appearance of the product (colour, markings, etc.).
- For tablets designed with a score line, information should be given on the purpose of the score-line, e.g. 'the score line only serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses', the tablet can be divided into equal halves'.
- A list of excipients contained in the product, which may include preservatives, pH adjusters, excipient mixture (e.g. list of ingredients of film coating, capsule shell, printing ink, flavouring agent, colourants, diluent/ solvent etc.).

(c) Name and strength of active substance(s) – the non-proprietary name of each active substance.

- When the active substance is present as a salt, this should be clearly indicated, e.g. “each tablet contains 60mg active substance (as citrate)” or “each tablet contains 10mg active substance hydrochloride”.

(d) What is this medicine used for?

- The indication(s) for which the medicine is approved.

(e) How much and how often should you take this medicine?

- Dosing instructions including frequency, route and method of administration.
- Duration of treatment and when to seek medical advice.
- What to do if a dose is missed.

(f) When should you not take this medicine?

- Contraindications or situations where the medicine should not be used (e.g. hypersensitivity to active ingredient or excipients), including information for special patient groups (e.g. kidney or liver problems, pregnant or nursing mothers).

(g) Warnings/precautions

- Warnings or precautions, including existing medical conditions, that may require the patient to consult a healthcare professional before taking the medicine.
- Any effects the medicine may have on the patient’s ability to drive or engage in daily activities.

(h) Undesirable effects/side effects

- Adverse effects which may occur and what actions the patient should take if any of these occur.

(i) What other medicine or food should be avoided whilst taking this medicine?

- Medicine or food to avoid due to drug-drug or drug-food interactions, and what actions the patient should take to avoid them.

(j) What to do when you have taken more than the recommended dosage?

- Signs and symptoms of overdose and what to do in the event of an overdose.

(k) How should you keep this medicine?

- Storage condition for the medicine and where applicable, the storage condition after dilution, reconstitution or after first opening. Information should be consistent with that stated on the product label and/ or outer carton.
- Special precautions for storage (e.g. do not freeze, protect from light).

(l) Name/ logo of Manufacturer or Product Owner or Product Registrant

If the product is sold without a PIL, the information that is required in the PIL must be stated on the outer carton.

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