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 printed material supplied together with the therapeutic product (TP). This includes the outer carton, inner/blister labels and package insert or patient information leaflet.

All product labelling must be in English. If non-English text is included in the labelling, applicants must provide an official statement to declare that the non-English text is complete, accurate and unbiased information and is 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.	Manufacturing Date	✓	✓*	NA
7.	Expiry Date	✓	✓	✓
8.	Route of Administration	✓	✓	NA
9.	Storage Condition	✓	✓*	NA
10.	Name & Address (or Logo) of Product Owner and/or Product Registrant	✓	✓*	Name/Logo of Manufacturer/ Product Owner/Product Registrant
11.	Name & Address of Manufacturer***	✓	✓*	NA

12.	Warnings (if applicable)	✓	✓*	NA
13.	Pack Sizes (unit or volume)	✓	✓	NA
14.	Special Labelling (if applicable)	✓	✓*	NA
15.	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. The name and address of either the manufacturer or the batch releaser should be present.

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.

Information that is required should be printed on the labels and the use of overstickers is generally not allowed. In circumstances where overstickering cannot be avoided, the applicant should consult HSA via the online feedback form. However, redressing (e.g. use of colour stickers) to facilitate product differentiation may be acceptable and the revised product labels should be submitted for registration.

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 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.