

Special Scheme for Registration of Generic Medicinal Products from India

Pursuant to Chapter 5 of the India-Singapore Comprehensive Economic Cooperation Agreement (hereinafter referred to as “the Agreement”), Singapore hereby agrees to establish the Special Scheme for Registration of Generic Medicinal Products (hereinafter referred to as “the Scheme”) for India to facilitate the process of marketing authorization for the supply in Singapore of generic medicinal products manufactured in India. The details of the Scheme are described below and shall be read in conjunction with the Guidance on Medicinal Product Registration in Singapore issued by the Health Sciences Authority (hereinafter referred to as “HSA”), a Statutory Board that regulates medicinal and healthcare products in Singapore.

2 Scope

2.1 The Scheme shall apply to generic medicinal products that are manufactured by facilities in India provided such products in terms of their compositions, manufacturing sites, manufacturing processes, quality control and specifications have been evaluated and approved by at least one of the regulatory authorities (hereinafter referred to as “reference authority”) listed below:

- i. Food and Drug Administration, USA;
- ii. Medicines and Healthcare Products Regulatory Agency, UK;
- iii. Therapeutic Goods Administration, Australia;
- iv. European Medicines Agency, EU;
- v. Health Canada.

2.2 For the purposes of the Scheme, “biological or biotechnological product”, “generic medicinal product”, and “reference product” are as defined by the HSA in its ‘Guidance on Medicinal Product Registration in Singapore’.

3 Products Excluded from the Scheme

3.1 The Scheme shall not apply to the following products:

- (a) products that infringe valid patents in Singapore;
- (b) products which do not have reference products in Singapore; and
- (c) biological or biotechnological products.

4 Application

4.1 The Application to register a generic medicinal product for marketing and supply in Singapore must be made in a format prescribed by the HSA with all the supporting documents specified in the HSA’s Guidance on Medicinal Product Registration in Singapore, a copy of which is available at the HSA’s website: <http://www.hsa.gov.sg/>. The Application must be made by a company based and registered in Singapore (hereinafter known as the “Applicant”). The Applicant must be duly authorized by the product owner.

4.2 In addition, the Applicant shall be required to submit:

- (a) the complete unedited approval package for the said product as prepared by the relevant reference authority. This shall include the approval letter, details of the licensing conditions imposed, final product labeling, chemistry review, and other relevant documents issued by the reference authority in relation to its approval of the product.
- (b) a Declaration that the product submitted for marketing authorization and the information provided are exactly the same as those submitted to the relevant reference authority.
- (c) a copy of a valid Good Manufacturing Practice (GMP) Certificate issued by the relevant reference authority and the latest inspection report.

5 Processing Timeline

5.1 The HSA shall endeavour to:

- (a) screen and inform the Applicant on the status of the Application within fourteen (14) working days from the date of receipt of the Application with the complete requisite documentation as outlined in paragraph 4 above.
- (b) evaluate and make a regulatory decision on the Application within ninety (90) working days from the date when the Applicant is informed of HSA's acceptance of the Application.

5.2 For the purpose of paragraph 5.1 above, in the event the HSA has any queries regarding the Application including the need for more information, data or documentation during the process of evaluating the Application, the time period for any correspondence and any exchanges between the HSA and the Applicant shall not be included within the respective processing timelines above. Such processing time period shall be deemed to be "suspended" time during which further information or data is pending from the Applicant.

5.3 The ninety (90) working days' timeline for evaluation and regulatory decision on the Application may be extended if necessary, at the discretion of the HSA.

6 Regulatory Decisions

6.1 The HSA's regulatory decision with respect to marketing authorization of the product will be independent of and may differ from the regulatory decisions of other authorities, including those listed as reference authorities.

7 Implementation and Review

7.1 The Scheme shall be reviewed twelve (12) months after the date of its implementation.

7.2 The HSA reserves the right to make modifications to the Scheme by giving sixty (60) working days' written notice to the Ministry of Health and Family Welfare of India for the latter's comments and consultations with the HSA before any such modifications are made.

Any outstanding Applications shall continue to be processed based on the Scheme before the modifications come into effect.

8. Dispute Settlement

8.1. Chapter 15 of the Agreement shall not apply to this Annex.

8.2. The HSA and the Ministry of Health and Family Welfare of India shall settle any dispute arising from any interpretation and/or implementation of this Annex by consultations.