

A photograph of several capsules and a thermometer. One capsule is white with a green band, another is red with a green band, and a third is white with a green band. A thermometer is visible in the background with the number 6 and 37 marked.

Therapeutic Products

Therapeutic Products

The Therapeutic Products Branch of the Health Sciences Authority administers regulatory control of therapeutic products in Singapore. More information on the HSA is available at www.hsa.gov.sg

As the "Authority" under the Health Products Act, the HPA empowers the HSA to register health products, and to grant, renew, vary, suspend and revoke licences.

Under the HPA, all therapeutic products must be registered before they can be supplied in Singapore. Additional licences such as a Manufacturer's Licence, Importer's Licence and/or Wholesaler's Licence may be required if a company intends to carry out such activities in Singapore.

Product Registration Application

Applications for product registration fall broadly into the following categories:

1. A New Drug Application
 - NDA-1: first strength of a product containing a new chemical or biological entity;
 - NDA-2:
 - first strength of a product;
 - combining a new combination of registered chemical or biological entities;
 - containing registered chemical or biological entity(ies) in a new dosage form (e.g. tablets, capsules, injectables), new presentation (e.g. single-dose vials, multi-dose

Awards

Ranked Band 1 for Life Sciences
[Chambers Global rankings 2014 - 2020](#)

Ranked Band 1 for Intellectual Property
[Chambers Global 2009 - 2020](#)

Medical and Healthcare Law Firm of the Year
[Asian Legal Business Southeast Asia Law Awards 2019](#)

Tier 1 Intellectual Property Firm in Asia
[ALB IP Rankings 2018 - 2019](#)

Asia Pacific IP Firm of the Year
[Managing IP Asia Pacific Awards 2018 - 2019](#)

Ranked Band 1 for Intellectual Property Firm in Singapore
[Chambers Asia Pacific 2010 - 2020](#)

Ranked Tier 1 for Intellectual Property Firm in Singapore
[Legal 500 Asia Pacific 2010 - 2019](#)





- vials, pre-filled syringe) or new formulation (e.g. preservative-free);
 - containing registered chemical or biological entity(ies) for use by a new route of administration;
 - containing registered chemical or biological entity(ies) for new indication(s), dosage recommendation(s) and/or patient population(s); or
 - products that do not fall under the requirements for NDA-1, NDA-3 or GDA; and
 - NDA-3: subsequent strength(s) of a product that has been registered or has been submitted as an NDA-1 or NDA-2. Voluntary recalls may be initiated by the product owner/license holder,
2. A Generic Drug Application (for products that are essentially the same as a current registered product, excluding biologics)
- GDA-1: first strength of a generic chemical product; and
 - GDA-2: subsequent strength(s) of the generic chemical product that has been registered or submitted as GDA-1, provided that the product name and dosage form are identical to that registered for GDA-1.

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Documents Required

Depending on the type of application (as set out above), applicants for product registrations will have to submit either a full, abridged or verification evaluation dossier to the HSA. The type of dossier required generally depends on whether the TP has been approved by any competent drug regulatory agency at the time of the submission of the registration application to the HSA.

Summary of Registration Process

The registration process involves substantive preparatory steps prior to the actual evaluation of the application by the HSA. It is advisable to consult the HSA to ensure that the application dossier is compiled in accordance with the applicable guidelines, as application fees for the HSA's screening of the application dossier (which precedes a substantive evaluation) are non-refundable in the event that the application dossier is rejected for any deficiencies.

Step 1: Pre-Submission Preparations

This involves the compilation of all necessary documents in the application dossier. At this stage, applicants can, and are advised to, seek clarification from the HSA by submitting a pre-submission inquiry or seeking a pre-submission consultation.

Step 2: Application Submission

Upon completion of the pre-submission preparations, the applicant should:

- i. Complete the application form at the HSA's online Pharmaceutical Regulatory and Information System. As a



preliminary matter, a company must have a Company Registration for e-Services account activated to access PRISM; and

- ii. Provide the complete evaluation dossier to the HSA (within 2 working days after the PRISM application above), if not already submitted electronically via PRISM.

Step 3: Application Screening

Thereafter, the application will be screened by the HSA to identify deficiencies (if any) in the application. Requests for information made by the HSA must be furnished by the applicant within 20 working days of the request, failing which the application will be rejected and a new application dossier will have to be submitted for screening.

Step 4: Application Evaluation and Decision

Upon acceptance of the application dossier for evaluation, a regulatory decision will be made based on the outcome of the HSA's evaluation.

Timelines

The target processing timelines from the date of acceptance (i.e. completion of step 3 above) to the HSA's decision are:

- i. 270 working days for full evaluation dossiers;
- ii. 120-240 working days for abridged evaluation dossiers; and
- iii. 60-120 working days for verification evaluation dossiers.

However, the above timelines do not include any time periods during which the HSA may be awaiting a response from the applicant to their input requests. Therefore, depending on the number of input requests and the timelines provided by the applicant to respond to the HSA, the actual evaluation time for product registration applications can be significantly longer than those set out above.

An exception to the above timelines is the priority review route for life-saving drugs which may address local unmet medical needs.

Registration Exclusivity

Under the *Health Products (Therapeutic Products) Regulations 2016*, the efficacy and safety data that has been generated to support the registration of a TP will be granted registration exclusivity for 5 years. During this period, the Authority may not register a subsequent similar TP (Product B) on the basis of the earlier registration (Product A), unless the prior registrant gives consent. In effect, this means that the person who wishes to seek registration of Product B cannot rely on Product A's data within this 5 year period, and will have to generate new safety and efficacy data for Product B to supplement the application.

Patent Linkage

Pursuant to Singapore's obligations under the US-Singapore Free Trade Agreement, the patent linkage scheme has been introduced to assist drug patent owners in policing potential infringement of their patents prior to the launch of generic drugs.



The applicant for registration of a TP needs to declare whether a patent is in force in respect of any TP to which the application relates. Where the therapeutic product in question is covered by a patent, the application may fall under any of the following categories:

- Category A1: where the applicant is the proprietor of the patent, or where the applicant has procured the consent or acquiescence from the proprietor of the patent;
- Category A2: where the applicant seeks the grant of registration upon the expiry of the patent (this application should not be made earlier than 18 months before the expiry of the patent); or
- Category B: where the applicant believes that the patent is invalid or that the drug will not be infringing on the patent in force.

For Category B applications, the HSA will require a notification to be sent to the patent holder to give them an opportunity to take action against the applicant.

Activity Licences Application

Under the HPA, the following licences are required for the corresponding activities:

- i. A ML is required for the manufacture of a TP in Singapore.
- ii. An IL is required for the import of a TP into Singapore.
- iii. A WL is required for the supply of a TP by wholesale in Singapore.

These licences are in addition to the product registration that must be obtained for a TP.

Application Process

- i. Complete the relevant application form via PRISM. Again, as a preliminary matter, a company must have a Company Registration for e-Services account activated to access PRISM; and
- ii. Name a Singapore-registered pharmacist as the Responsible Person in the respective application forms.

The RP will be in charge of ensuring quality control, and that the TP is compliant with Good Distribution Practice standards. More information about the responsibilities of an RP can be found on the HSA's website (see http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Guidance_Documents_for_Industry_and_Applicants.html).

Timelines

The target processing timelines from the date of audit close out for the issuance of a ML, IL or a WL is 10 working days. However, the timeline excludes any "stop-clock" time incurred by the applicant.

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