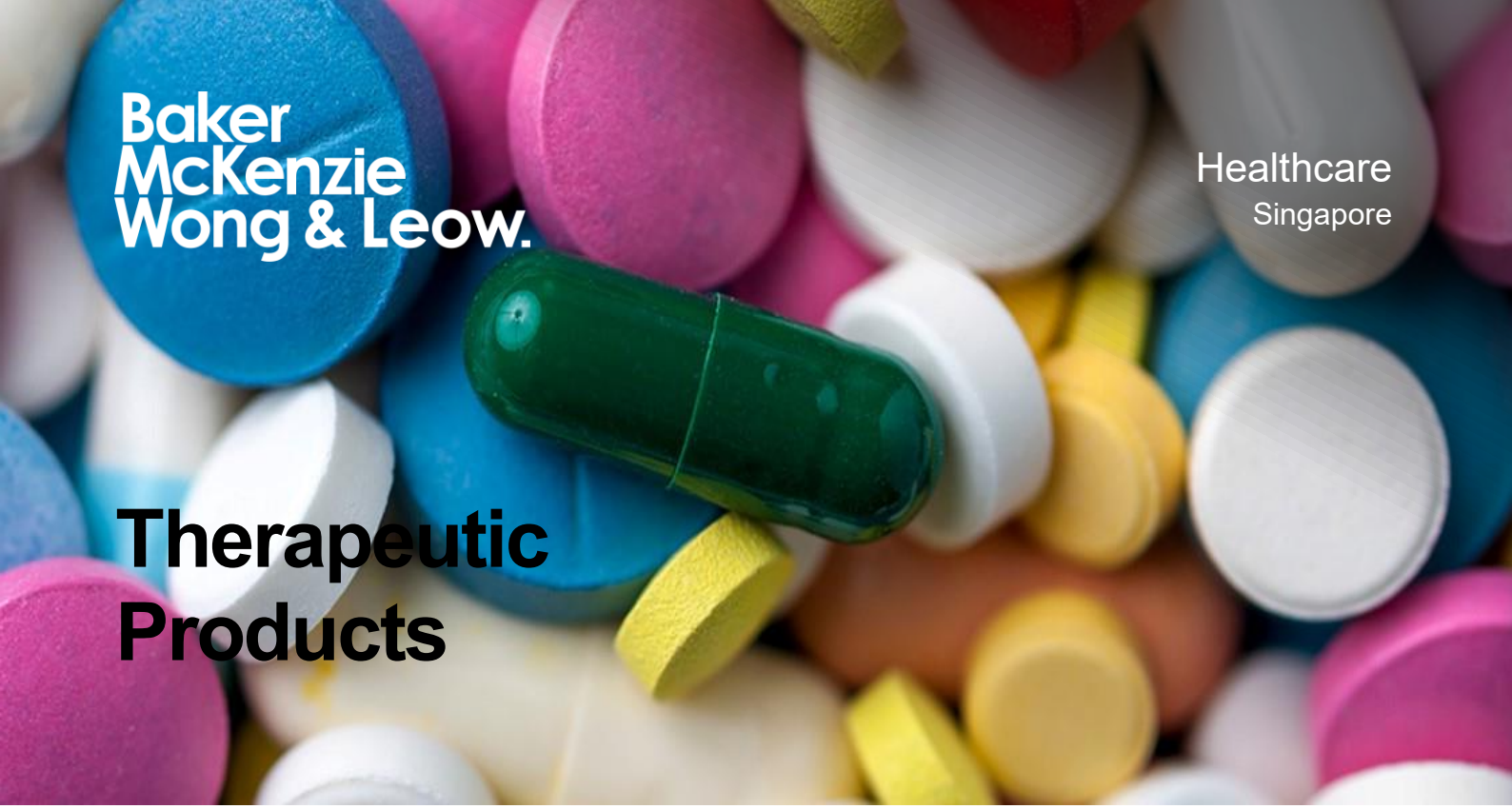

Baker McKenzie Wong & Leow.

Healthcare
Singapore

Therapeutic Products

Therapeutic Products

The Therapeutic Products Branch of the Health Sciences Authority (HSA) administers regulatory control of therapeutic products (TP) in Singapore. More information on the HSA is available at http://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 (ML), Importer's Licence (IL) and/or Wholesaler's Licence (WL) 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 that is not currently a registered entity in Singapore;
    - NDA-2:
        - First strength of a product containing:
        - New combination of registered chemical or biological entities;

Awards & Accolades

Band 1 for Life Sciences
Chambers Asia Pacific, Asia Pacific Region 2014 - 2025

Medical and Healthcare Law Firm of the Year
Asian Legal Business Southeast Asia Law Awards 2020 and 2021

Band 1 for Intellectual Property
Chambers Global, Asia Pacific Region 2009 - 2025

Band 1 for Intellectual Property, Singapore
Chambers Asia Pacific, Singapore 2010 - 2025

Tier 1 for Intellectual Property, Singapore
Legal 500 Asia Pacific, Singapore 2010 - 2025

Tier 1 for Patents and Copyrights/Trademarks in Singapore
ALB Asia IP Rankings 2018 - 2025

Asia Pacific Patents Firm of the Year
Asia IP Law 2023

Asia Pacific Trademark Firm of the Year
Asia IP Law 2024

Tier 1 for Trademark Contentious and Trademark Prosecution in Singapore
Asia IP Law 2025

Singapore: Copyright & Design; Trade Mark Prosecution Firm of the Year
Asia Pacific: IP Law Firm of the Year (Foreign Firms)
Managing IP Asia Pacific Awards 2024

IP Transactions & Advisory Firm of the Year
Managing IP Asia Pacific Awards 2021 and 2023

Copyright & Design Firm of the Year
Managing IP Asia Pacific Awards 2019 – 2023

Global IP Firm of the Year
Managing IP Asia Pacific Awards 2017, 2018 and 2022

- Registered chemical or biological entities in a new dosage form (e.g., tablets, capsules, injectables), new presentation (e.g., single-dose vials, multi-dose vials, pre-filled syringe) or new formulation (e.g., preservative-free);
- Registered chemical or biological entities for use by a new route of administration;
- Registered chemical or biological entities 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 Biosimilar Product Application, for therapeutic products demonstrated to be similar in physiochemical characteristics, biological activity, safety and efficacy to an existing registered biological product

    - NDA-2: first strength of a biosimilar product with the same dosage form and route of administration as the Singapore reference product; and
    - NDA-3: subsequent strengths of a biosimilar product that has been registered and submitted as an NDA-2. The product name, dosage form, indication, dosing regimen, and patient population should be the same as that for the NDA-2 submission.

3. A Generic Drug Application (for products that are essentially the same as a current registered product, excluding biosimilar or follow-on biologic products)

    - 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.

Documents Required

Depending on the type of application (as set out above), applicants for product registrations will generally have to submit a full, abridged or verification evaluation dossier to the HSA. The type of dossier required generally depends on the type of the TP and whether the TP has been approved by any overseas 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.

Such pre-submission consultations will be based on current information at the time of the consultation, and have no bearing on the eventual outcome of the application.

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

ii. Provide the complete application dossier to the HSA (within 2 working days after the PRISM application above), if not already submitted electronically via PRISM. The date of receipt of the actual technical dossier by the HSA will be taken as the submission date and the start of the application screening timeline.

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 the full evaluation route;

ii. 180-240 working days for the abridged evaluation route; and

iii. 60-120 working days for the verification evaluation route.

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 (e.g., Product B) on the basis of the earlier registration (e.g., 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. A Category A1 declaration will be made where there is no patent in force in respect of the therapeutic product 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 A2: 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 A3: 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.

Post-Approval Variation Application

A variation application of a registered TP needs to be submitted where there is a change to that TP's safety, efficacy, quality, or forensic classification. Variation applications fall broadly into the following categories:

1. Major variation Application (MAV)
    - MAV-1: any variation to the approved indication, dosing regimen or patient group, and/or inclusion of clinical information extending the usage of the product; and
    - MAV-2: reclassification (i.e., change in current approved forensic classification).
2. Minor variation application (MIV)
    - MIV-1: any minor variation specified under the Part A Checklist on Dossier Requirements for MIV-1 Variation of Appendix 13 (Chemicals) or Appendix 14 (Biologics);
    - MIV-2 (Notification): any minor variation specified under the Part B Checklist on Dossier Requirements for MIV-1 Variation of Appendix 13 (Chemicals) or Appendix 14 (Biologics); and
    - MIV-2 (Do-and-Tell): any minor variation specified under the Part C Checklist on Dossier Requirements for MIV-1 Variation of Appendix 13 (Chemicals) or Appendix 14 (Biologics)

Dealer's 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 (RP) in the respective application forms for an IL or WL.

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 https://www.hsa.gov.sg/therapeutic-products/dealers-licence/overview).

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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