

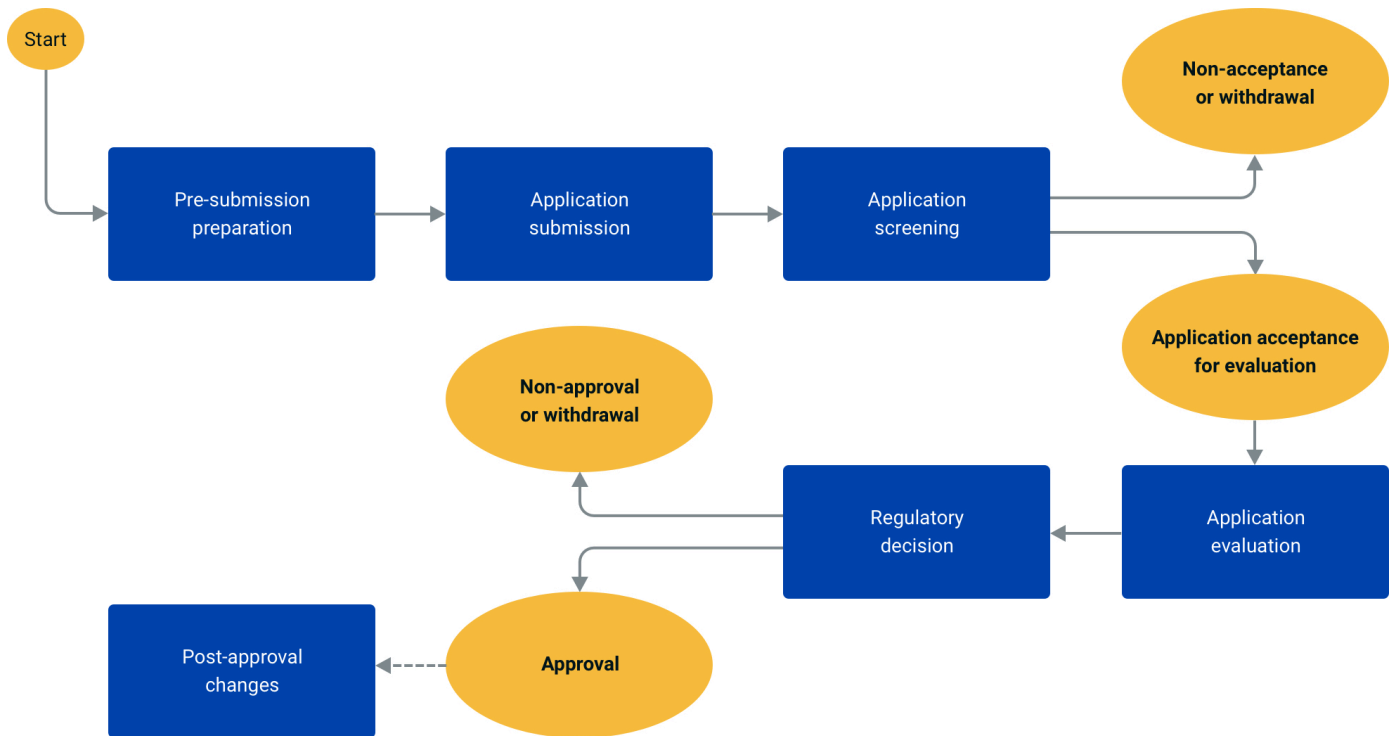
Registration overview of therapeutic products

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1. Registration overview

Understand the therapeutic product registration process before you register your product.

Registration process



Who can register

You will need to be a local company registered with the Accounting and Corporate Regulatory Authority (ACRA) in order to proceed with a therapeutic product registration.

Pre-submission preparation

The following are important considerations before you register your therapeutic product.

Considerations	Options
Identify which application type to apply for.	<ul style="list-style-type: none"> ● New drug application (NDA-1, NDA-2, NDA-3). ● Generic drug application (GDA-1, GDA-2).
Know which evaluation route to choose. You can decide on this within the registration guides later.	<ul style="list-style-type: none"> ● Full (NDA only). ● Abridged. ● Verification. ● Verification-CECA (GDA only).
Choose an application dossier format. You can decide on this within the registration guides later.	<p>You may choose to submit your application dossiers in one of the following formats:</p> <ul style="list-style-type: none"> ● International Council for Harmonisation Common Technical Document (ICH CTD). ● ASEAN Common Technical Document (ACTD).

Note: Different formulations, dosage forms, presentations and strengths of the same chemical or biologic entity are considered different products, and will require separate registrations.

Product types

Therapeutic products could contain either chemical or biological entities as the active ingredients.

A chemical entity refers to any chemical element, naturally occurring chemical material or chemical product obtained by chemical change or synthesis. This includes macromolecules produced by chemical synthesis, such as peptides and oligonucleotides, or any metabolites from a micro-organism, such as antibiotics.

A biological entity refers to any macromolecule extracted from an organism, such as proteins, nucleic acids, proteoglycans, cytokines and growth factors. It can also refer to any substance derived from a biological system, including:

- A whole cell or micro-organism, such as a whole virus or bacterium used as a vaccine.
- A part of a micro-organism, such as a sub-unit vaccine.
- A plasma-derived product.
- A biotechnology-derived substance, such as a protein or polypeptide.

Forensic classifications

You may register your therapeutic product under the following forensic classifications, which determine the level of access control:



- **Prescription-Only Medicines (POM):** A therapeutic product that can only be obtained from a doctor or from a pharmacist with a valid prescription.
- **Pharmacy Only Medicines (P):** A therapeutic product that can be obtained from a pharmacist at a retail pharmacy without a prescription.
- **General Sale List (GSL):** A therapeutic product that can be obtained from any retailer.

Refer to section 1.2 of the [Guidance on Therapeutic Drug Registration](#) for more information.


Patent declaration

Under regulation 23 of the Health Products (Therapeutic Products) Regulations (“Regulations”), an applicant seeking to register a therapeutic product is required to make a declaration on whether the therapeutic product is subject to a subsisting restraining patent.

For applicants of product registration, the relevant resources are provided below:

- The form for furnishing a declaration under regulation 23(2) of the Regulations is specified in [Appendix 1-Patent Declaration Form 1](#)  of the Guidance on Therapeutic Product Registration in Singapore.
- The form for serving a notice on the proprietor of a restraining patent under regulation 23(5) of the Regulations is specified in [Appendix 1-Form 2](#)  of the Guidance document.

For proprietors of a restraining patent, the relevant resources are provided below:

- The form for furnishing a declaration under regulation 23(8)(b)(iii) of the Regulations is specified in [Appendix 1-Form 3](#)  of the Guidance document.
- The online [Submission of Written Notice by Proprietor of Restraining Patent on Application for a Court Order / Declaration form](#) to submit the written notice, evidence, and declaration.

For more information on the patent declaration procedure, please refer to Chapter A, Section 3 of the [Guidance document](#).

Overseas manufacturers of therapeutic products

All new overseas manufacturers who intend to register therapeutic products in Singapore after 1 April 2004 will be subjected to a [Good Manufacturing Practice \(GMP\) conformity assessment](#) by us.

How to apply

Submit your application through [PRISM](#). Ensure you have the following before you access the e-service:

- [CRIS](#) company account
- [Corppass](#) or [HSA PIN](#)

If you encounter technical issues, e-mail the [HSA helpdesk](#) or call 6776 0168 (from 7.00 am to midnight daily).

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