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Extending protection for Pharmaceuticals

Requirements in Australia, China and Singapore

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Our experts across the Asia Pacific provide an overview and comparison of requirements for patent term extensions and data exclusivity in Australia, China and Singapore to assist pharmaceutical innovators in extending protection for their therapeutic products.

A comparison table is also provided, which summarises key requirements and timing considerations for both PTEs and data exclusivity.

Contents

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Australia

Authors: Dr Michael Christie, Principal | Dr Candace Wu, Special Counsel

Patent term extension

Australia's Patents Act provides an extension of up to 5 years beyond the standard 20-year term for certain pharmaceutical patents.
To be eligible for a patent term extension (PTE), the following criteria must be met:

1. one or more pharmaceutical substances per se (or one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology) is in substance disclosed in the patent specification and in substance falls within the scope of the claims,
2. goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods (ARTG),
3. the period beginning on the effective filing date of the patent and ending on the first regulatory approval date of the pharmaceutical substance must be more than five years, and
4. the term of the patent must not have been previously extended.

An important step in applying for a PTE is to correctly define the relevant 'pharmaceutical substance'. Such substance may include:

- a new chemical entity
- a polymorph
- a biological drug
- mRNA therapeutic or vaccine

Patents that only claim medical uses, kits or processes (which do not involve recombinant DNA technology) will not be eligible for a PTE.

Patents that only claim medical uses, kits or processes (which do not involve recombinant DNA technology) will not be eligible for a PTE.

A PTE application must be filed within six months of the date of grant of the patent, or within six months of first inclusion of the pharmaceutical substance on the ARTG, whichever is later.

Where a patent covers more than one approved pharmaceutical substance, the PTE must be based on the substance that was approved first, even if that means a shorter PTE.

Data exclusivity

Data exclusivity is independent of patent rights and refers to a 5-year period, starting on the date of marketing approval, during which a generic or biosimilar manufacturer cannot rely on an originator's data submitted to the Therapeutic Goods Administration (TGA) to obtain regulatory approval for its generic or biosimilar product.

This effectively means that the TGA cannot grant marketing approval for a generic small molecule or biosimilar medicine until 5 years after the original small molecule or biologic medicine has been granted marketing authorisation.

Data exclusivity only applies to therapeutic goods (including biologics) that contain a new active component. In Australia, there is no data exclusivity for new uses, new indications (including orphan or paediatric indications), new dosage forms or combinations of existing compounds.

Australia

China

Authors: Dr Siqi Wang, Head of Patents | Dr Xiaoli Liu, Special Counsel

Patent term extension

On request by the patentee, the China National Intellectual Property Administration (CNIPA) may grant patent term compensations for patents covering new drugs that have obtained marketing authorisation.

The compensation period is calculated based on the period between the marketing approval date in China and the patent filing date, reduced by 5 years, provided that:

- it cannot exceed 5 years, and
- the total remaining patent term after marketing approval must not exceed 14 years

Eligible "new drugs" approved by the National Medical Products Administration (NMPA) that have not been marketed in China or overseas include:

- "Innovative drugs" – refers to new chemical drugs, new biological products, and new Traditional Chinese Medicine (TCM) that have not been marketed in China or overseas (Class 1).
- "Improved new drugs" are limited to those registered by the NMPA under the following categories:

  Chemical drugs
  - Class 2.1 (esters/salts of known active ingredients)
  - Class 2.4 (new indications)

  Preventive biological products
  - Class 2.2 (improved vaccines based on bacterial or viral strains)

  Therapeutic biological products
  - Class 2.2 (new indications)

  Traditional Chinese medicine
  - Class 2.3 (new indications)

Eligible patents include products, preparation processes, or medical uses of active pharmaceutical ingredients.

During the compensation period, the scope of protection for the patent is limited to the technical solutions relating to the new drug and the approved indication(s).

To be eligible for a PTE, the following conditions must be met:

1. the grant date of the patent must precede the marketing authorisation date,
2. the patent is valid when the PTE request was submitted,
3. the patent has not been previously granted a PTE, and
4. the patent claims include the relevant technical solutions relating to the new drug, which are based on the structure, composition, and content of the approved product, or the approved manufacturing process or indications.

A PTE request must be submitted within 3 months after the new drug receives marketing approval. For pharmaceutical products granted conditional marketing authorisation, the request must be submitted within 3 months after obtaining formal marketing authorisation, while the compensation period calculation is based on the conditional marketing authorisation date.

Where a new drug is covered by multiple patents, only one of those patents can be selected for PTE. Where a patent covers multiple new drugs, PTE can be applied based on only one of the new drugs.

Data Exclusivity

On 27 January 2026, the State Council of the People's Republic of China released the Implementing Regulations of the Drug Administration Law (2026 Revisions), which will take effect on 15 May 2026.

The 2026 Revisions establish a medicinal product trial data protection regime, providing up to six years' protection for undisclosed trial data and other eligible data, and requiring the National Medical Products Administration (NMPA) to formulate detailed implementing measures in due course.

In the meantime, the "Implementation Measures for the Protection of Drug Trial Data (Trial, Draft for Comments)" (the **Trial Measures**), released by the NMPA in March 2025, may offer useful insights.

In the Trial Measures, data protection (i.e., data exclusivity) is provided for innovative drugs, improved new drugs, and generic drugs with respect to self-obtained and undisclosed trial data and other data submitted by an applicant.

During the data protection period, if other applicants apply for drug marketing authorisation or supplementary application relying on the same data without the consent of the drug marketing authorisation holder, NMPA will not grant permission.

If other applicants submit drug registration applications using data obtained by themselves, their applications may be approved if they meet the requirements but will not be granted data protection.

An application for data protection should be submitted at the same time as submitting an application for drug marketing authorisation.

Innovative drugs

A 6-year data exclusivity period may be granted for innovative drugs from the date of their first marketing authorisation in China. For an original drug that has been marketed overseas before its marketing approval in China, the data exclusivity will be calculated as 6 years minus the period between domestic application acceptance date and oversea listing date.

For innovative drugs that have been approved for multiple indications but have the same approval number, each indication will be given data protection according to the registration category.

Improved new drugs

A 3-year data exclusivity period may be granted for improved new drugs from the date of their first marketing authorisation in China. For an improved drug that has been marketed overseas before its marketing approval in China, the data exclusivity will be calculated as 3 years minus the period between domestic application acceptance date and oversea listing date.

Generic drugs

A 3-year data exclusivity period may be granted to the first approved generic drug (including those manufactured overseas) and biologic that have been marketed overseas but not in China. The data exclusivity period is calculated starting from the date on which the generic drug or biologic obtains marketing authorisation.

Further information on data and market exclusivity in China can be found here.

Singapore

Author | Maik Brinkmann, Principal, Life Sciences Practice Group Leader Asia

Patent term extension

Singapore's Patents Act provides an extension of up to 5 years beyond the standard 20-year term for certain patents covering pharmaceutical products.

To be eligible for a PTE, the patent must fulfil **at least one** of the following requirements:

- there was an unreasonable delay by the Registrar in granting the patent, or
- there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product.

An unreasonable delay by the Registrar is deemed to occur if **any one** of the following conditions are met:

- the interval between the date of filing of the patent application, and the date of issue of the certificate of grant, excluding any period attributable to an act or omission of the applicant, exceeds 4 years, or
- the interval between the date of filing for a search and examination report or an examination report, and the date of issue of the certificate of grant, excluding any period attributable to an act or omission of the applicant, exceeds 2 years.

An unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval is deemed to occur if **all of the following** conditions are met:

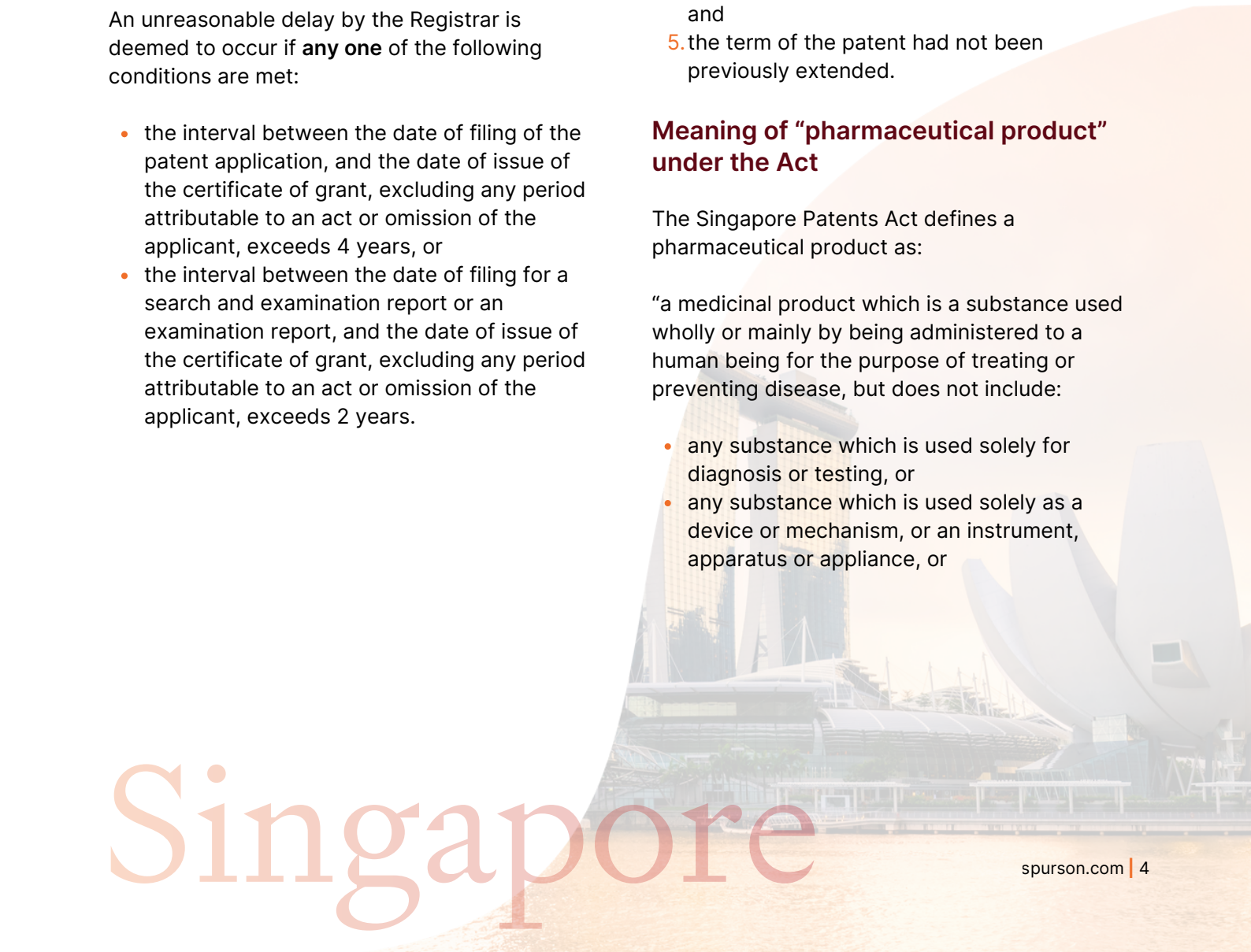
1. the patent relates to an active ingredient that is a "pharmaceutical product" within the meaning of the Act,
2. marketing approval needed to be obtained in Singapore for the pharmaceutical product,
3. there had been a curtailment of an opportunity to exploit the patent due to a delay in obtaining the required marketing approval,
4. the pharmaceutical product is the first pharmaceutical product to obtain marketing approval which uses the active ingredient, and
5. the term of the patent had not been previously extended.

Meaning of "pharmaceutical product" under the Act

The Singapore Patents Act defines a pharmaceutical product as:

"a medicinal product which is a substance used wholly or mainly by being administered to a human being for the purpose of treating or preventing disease, but does not include:

- any substance which is used solely for diagnosis or testing, or
- any substance which is used solely as a device or mechanism, or an instrument, apparatus or appliance, or



- any traditional medicine, any homeopathic medicine, any quasi-medicinal product, any raw material which is used as an ingredient in the preparation or manufacture of any medicinal product, any medicated oil or balm, any substance which is a type of food, a food additive or a food supplement, or any substance which occurs naturally in any plant, animal or mineral".

The Health Sciences Authority (HSA) is the relevant authority that regulates the marketing of medicine in Singapore. At the time of applying for a PTE, a patentee must submit a Certificate from the HSA as evidence that the patentee qualifies for an extension of term under the Act.

An unreasonable curtailment of an opportunity to exploit a patent is deemed to occur if both of the following conditions are met:

1. marketing approval was obtained after issue of the certificate of grant, and
2. the interval between the date of applying for marketing approval and obtaining marketing approval, excluding any period attributable to the applicant, exceeds two years.

Timeline for filing PTE and the period of extension

The patentee must apply to extend the term of the patent by the later of six months from the date of grant of the patent, or the date marketing approval was obtained. Further, the patentee must file the application for an extension of term while the application is in force and within 6 months before the original patent term expires (i.e., 6 months before the end of the 20-year period).

If it was determined that there was an unreasonable delay by the registrar in granting the patent, the patent will be extended for the period in which the interval between filing and grant, or the start of examination and grant, exceeds 4 or 2 years respectively.

If there was a delay under both conditions, then the term of the patent will be extended by the longer of the two. An example scenario would be if, excluding delays attributable to the applicant, it had taken 6 years to issue a patent from the time of filing to the time of grant, and examination had taken 3 years from the time of filing a request for examination to
the time of grant. Such a patent would have experienced a 2-year delay under the first condition and a 1-year delay under the second condition. The term of extension would be 2 years.

If there had been an unreasonable delay caused by the process of obtaining marketing approval, the period of extension will be the shortest of the following periods:

- a period equivalent to the interval between the date of issue of the certificate of grant and the date marketing approval was obtained;
- the period by which the interval between the date the application for marketing approval was filed and the date marketing approval was obtained exceeds 2 years; or
- a period of 5 years.

If it is found that the patent had experienced a delay during grant of the patent and grant of the marketing approval, it is possible to apply for PTE on both grounds and the resulting extension term will be the cumulative.

Data exclusivity

The HSA offers 5 years of data exclusivity for new therapeutic products, starting from the date of marketing approval by the HSA.

During that period, confidential information received in support of a registration for the new therapeutic product is protected and the HSA cannot use the confidential information to determine whether to grant other registrations. Confidential information may include trade secrets and commercially valuable data.

A 5-year exclusivity period also applies to safety and efficacy data generated for the registration. This means that subsequent applications for similar products cannot rely on the earlier product's data to obtain approval during the exclusivity term.

According to section 26(1) of the Health Products (Therapeutic Products) Regulations 2016, the 5-year period of data exclusivity applies only to an "innovative therapeutic product application".

According to section 26(1) of the Health Products (Therapeutic Products) Regulations 2016, the 5-year period of data exclusivity applies only to an "innovative therapeutic product application".

An "innovative therapeutic product application" is defined to be an application for a therapeutic product referring to a substance that is a) an ingredient in the manufacture or preparation of the therapeutic product to which the application relates and b) has not been previously referred to as an ingredient in the manufacture or preparation of any other therapeutic product in any other application.

Thus, the data exclusivity will not apply to new indications for a previously registered therapeutic product. An orphan drug may be eligible for data exclusivity if an application for such a drug was not previously registered.

Country comparison

Country	Patent term extensions	Data exclusivity
Australia	Max. 5 years beyond 20-year patent term. Only for ‘pharmaceutical substance per se’. Key trigger | first ARTG approval.	5 years. Only for ‘new active component’. No exclusivity period for new uses or formulations of the active component.
China	Max. 5 years beyond 20-year patent term and max. patent life of 14 years after regulatory approval. For patents related to products, preparation processes, or medical uses of new drugs. Key trigger | first NMPA approval.	Max. 6 years for innovative drugs. Max. 3 years for improved new drugs and generic drugs.
Singapore	Max. 5 years beyond 20-year patent term for delay in marketing approval. Only for ‘pharmaceutical product’.Key trigger: first HSA approval.ORAny duration beyond 20-year patent term depending on the delay by the registrar in granting the patent. Only for patents granted undergoing local examination routes (i.e., excluding supplementary examination). Key trigger | delay of at least 4 years from filing to grant, or 2 years from start of examination to grant.	5 years. Only for ‘new therapeutic products’.

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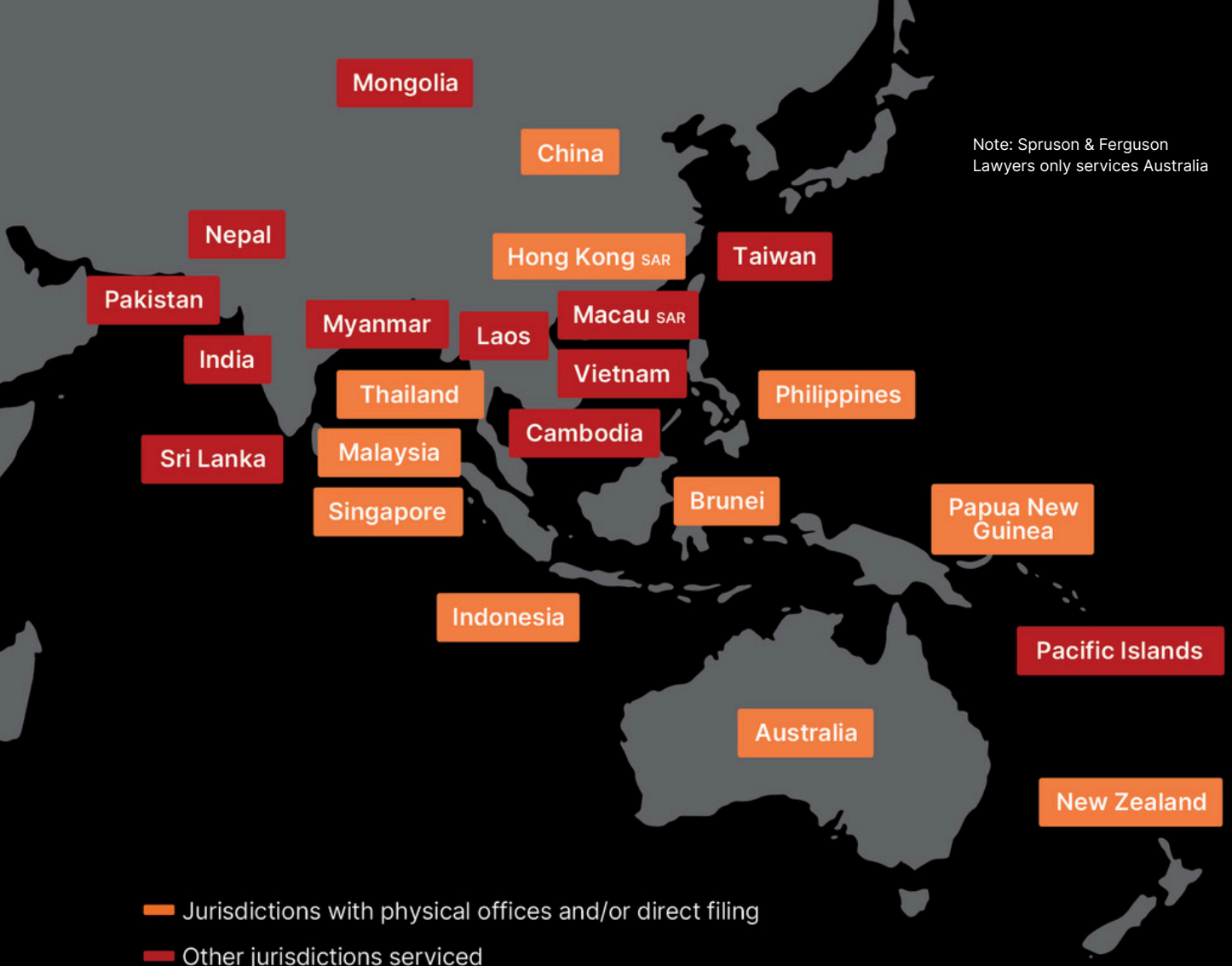

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