

# Pharmaceutical IP and competition law in Cambodia: overview

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Country Q&A | [Law stated as at 01-Sep-2019](#) | Cambodia

A Q&A guide to pharmaceutical IP and competition law in Cambodia.

The Q&A gives a high level overview of key issues including patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit [Medicinal product regulation and product liability in Cambodia: overview](#).

To compare answers across multiple jurisdictions, visit the Pharmaceutical IP and competition law [Country Q&A tool](#).

The Q&A is part of the global guide to life sciences law. For a full list of jurisdictional Q&As visit [global.practicallaw.com/lifesciences-guide](#).

## Patents

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

### Conditions and legislation

The following legislation applies to patents:

- Law on the Patents, Utility Model Certificates and Industrial Designs (and its amendment).
- Prakas (ministerial regulation) on the Procedure for Granting Patents and Utility Model Certificates.
- Law on Compulsory Licensing for Public Health

Inventions are patentable in Cambodia. An invention is defined as an idea of an inventor that permits in practice the solution to a specific problem in the field of technology.

To be eligible for patent protection in Cambodia, the invention must meet the following conditions:

- Be new.

- Involve an inventive step.
- Be capable of industrial application.

Pharmaceutical patents are currently excluded under the Cambodian regulatory framework. Article 4 of the Law on the Patents, Utility Model Certificates and Industrial Designs excludes the following from patent protection:

- Discoveries, scientific theories and mathematical methods.
- Schemes, rules or methods for doing business, performing purely mental acts or playing games.
- Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised on the human or animal body (this does not apply to products for use in any of those methods).
- Pharmaceutical products under Article 136 of the Law.
- Plants and animals (other than micro-organisms) and essentially biological processes for the production of plants or animals.
- Plant varieties.

Although Cambodia's WTO membership requires member states to provide patent protection for pharmaceuticals, the WTO has granted Cambodia an exemption under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) until 2033, due to its status as a "least-developed country".

Under Rule 45 of the Prakas on the Procedure for Granting Patents and Utility Model Certificates, pharmaceutical invention holders can currently submit an application for a patent, but the application will not be considered until the expiry of the transitional period. These are known as "mailbox" applications.

The patent protection period for mailbox applications that are granted after the transitional period will start retroactively from the date of the application, and are protected for the remainder of the patent period.

### **Scope of protection**

A patent owner has the exclusive rights to exploitation of the patented invention. Exploitation includes making, using, offering for sale or selling the patented invention in Cambodia, or importing the patented invention into Cambodia. In addition, the patent owner has the right to institute proceedings against infringers of its patent.

Article 44 of the Law on the Patents, Utility Model Certificates and Industrial Designs specifically states the rights under a patent do not extend to the following:

- Acts in respect of articles that have been put on the market in or outside Cambodia by the owner of the patent or with the patent owner's consent.
- Use of articles on aircraft, land vehicles, or vessels of other countries that temporarily or accidentally enter the airspace, territory or waters of Cambodia.
- Acts done only for experimental purposes relating to a patented invention.
- Acts performed by any person, who in good faith before the filing (or the priority date of the application on which the patent was granted in Cambodia, where priority is claimed) was using the invention or was making effective and serious preparations for such use.

In addition, the government can decide to exploit a patent without the agreement of the patent owner if:

- Required by public interest, relating to national security, nutrition, public health or the development of other vital sectors.
- A judicial body has determined that the patent owner's manner of exploitation is anti-competitive.
- The patent owner receives payment for the exploitation of the patent by the government.

If a patent owner does not (sufficiently) exploit their invention, they can be subjected to non-voluntary licensing of the invention. Anyone can request the Ministry of Industry and Handicraft to issue them a non-voluntary licence to exploit a patented invention that is not exploited (sufficiently) within four years from the filing of the patent, or three years from issuance, whichever period expires last.

The patent owner receives payment for the non-voluntary licence from the licensee.

The Law on Compulsory Licensing for Public Health implements the TRIPS Council Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. The Ministry of Health, as the regulatory authority, can issue non-exclusive compulsory licences to manufacture, import, or export generic variants of patented pharmaceuticals for non-commercial public health use, without prior consent of the patent owner. Compulsory licences can be issued in the case of a national emergency or other circumstances of extreme urgency, or to meet market demands. If a compulsory licence is issued, remuneration, which is to be determined by a Ministry of Health regulation, must be paid to the patent owner.

However, until pharmaceutical patents are granted in 2033, the Law on Compulsory Licensing for Public Health is limited to authorising imports of pharmaceuticals patented in other WTO members. Unauthorised manufacturing, importation, or exportation of patented pharmaceuticals, or unauthorised transfer of compulsory licences are subject to fines and penalties including company dissolution.

## 2. How is a patent obtained?

### **Application and guidance**

Patent applications are made to the Department of Industrial Property within the Ministry of Industry and Handicraft. Foreign applicants for a patent must appoint a Cambodian representative to submit the application.

The official government fee for a basic patent filing of up to ten patent claims is currently set at KHR320,000. Annuity fees must be paid starting one year after the filing date. The annuity fees increase over time, as set by the Joint Prakas on Public Service Fee and Fine of the Ministry of Industry and Handicraft, starting at KHR80,000 and going up to KHR3,560,000 in the 20th year.

Mailbox applications under Rule 45 of the Prakas on the Procedure for Granting Patents and Utility Model Certificates are subject to the official government fee for a patent filing. Cambodian law does not specifically address further maintenance fees for mailbox applications. Regular patent applications must pay maintenance fees, but according to current practice this does not apply to mailbox applications.

Once the transitional period is over and a patent is granted for the remainder of the patent period, annuities are due as above.

In addition to a regular national filing, patent registration in Cambodia can be sought by using international filing systems, or may be accelerated through international co-operation systems. The following international systems for patents are currently applicable in Cambodia:

- Japanese patents: patents that have been examined and granted in Japan are generally eligible for accelerated review in Cambodia.
- Singaporean patents: patents that were granted in Singapore can be re-registered in Cambodia without undergoing extensive examination.
- Chinese patents: patents that were granted in China can be validated in Cambodia without undergoing extensive examination.
- European patents: patents that were granted in the EU can be validated in Cambodia under expedited procedures.
- Patents in the US and other countries: applicants filing patent applications from the US and other countries claiming priority under the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) can submit their original certified copies of the granted patent certificates in those countries for the Ministry of Industry and Handicraft to expedite the registration process in Cambodia.
- Patents under the Patent Cooperation Treaty 1970 (PCT): applicants can enter the national phase within 30 months from the initial filing date.

Since pharmaceuticals are excluded from obtaining patent protection until the transitional period is over, further discussions of accelerated patent registration are beyond the scope of this article.

### **Process and timing**

To file for a patent, the following documents are required in Khmer or English:

- Application form that includes the name, address, nationality and residence of each applicant.
- If the applicant is not the inventor, the application must include the name and address of each inventor and include a statement justifying the applicant's right to the patent.
- Description of the invention.
- The claims for which the protection is sought.
- Drawings, if any.
- An abstract outlining technical information, if applicable.
- Foreign patent filings of the invention.
- Power of attorney appointing a local representative.

A first-to-file system is used in Cambodia for patents. When priority is claimed under the PCT or the Paris Convention, the registrar considers the date when an application was made in the overseas jurisdiction as the filing date. The priority term starts from the filing date of the first application and is 12 months.

Depending on whether it is through the local application system or a streamlined international system, filing can take from six months to several years from the filing date in Cambodia.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

#### **Duration and renewal**

The term of a patented invention is 20 years from the filing date of the application, subject to the payment of annuity fees. A patented invention cannot be renewed.

#### **Extending protection**

Patent protection cannot be extended in Cambodia.

4. How can a patent be revoked?

Cambodian law does not address how a patent that has been granted can be revoked by the patent owner. Rule 22 of the Prakas on the Procedure for Granting Patents and Utility Model Certificates states that an application can be withdrawn by submitting a declaration to the Department of Industrial Property, but it does not provide a similar approach for patents that have been granted. However, the law does indicate that not paying annuities causes a patent to lapse.

Any interested person can request a Cambodian court to invalidate a patent. A patent can be invalidated if the court is convinced that the patent does not meet the requirements of a patent under Cambodian law, or that the patent owner is not the inventor or the inventor's successor in title.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

#### **Conditions for infringement**

The law states that a patent is infringed if anyone, without the agreement of the patent owner, performs any of the exploitation acts as defined by law, which are exclusive to the patent owner. These acts include making, using, offering for sale or selling the patented invention in Cambodia, or importing the patented invention into Cambodia.

In addition, the law provides that the patent owner can take action against any person who performs acts that make it likely for infringement to occur, providing a broader basis for liability in relation to patent infringement.

### **Claim and remedies**

A patent owner can institute court proceedings against an infringer. The court has the discretion to grant an injunction, award damages or provide any other remedy allowed under Cambodian law it deems appropriate. An injunction can include seizures and border measures.

There are also criminal sanctions for patent infringement. An infringing act can lead to fines of up to KHR20 million and/or imprisonment of up to five years.

Ministries often provide an alternative dispute resolution option for IP infringements. However, the Department of Industrial Property has not yet formulated a formal mechanism for patent infringement.

6. Are there non-patent barriers to competition to protect medicinal products?

There are currently no non-patent barriers to competition to protect pharmaceuticals in Cambodia.

There is no trade secrets law in place in Cambodia. The laws applicable to pharmaceutical product registration do not address how the Department of Drugs, Food, Medical Equipment and Cosmetics should treat confidential information relating to pharmaceutical products.

## **Trade marks**

7. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

### **Conditions and legislation**

The following legislation is applicable to trade marks:

- Law concerning Marks, Trade marks and Acts of Unfair Competition.
- Sub-Decree on Implementation of the Law concerning Marks, Trade marks and Acts of Unfair Competition.

A trade mark is a mark that is used on, or in connection with, goods or services for the purpose of indicating that they are the goods or services of the proprietor of the trade mark, and that they are different from goods or services bearing the trade marks of others.

A trade mark must be in the form of a photograph, drawing, brand, name, word, text, letter, numeral, signature, group of colours, shape, figurative element or three-dimensional object, an invented picture, or any combination thereof.

A trade mark may be eligible for registration if it meets the following criteria:

- The mark is visually capable of distinguishing the goods or services in the market.
- The mark is not contrary to public order, morality or good custom.
- The mark is not misleading, is not likely to deceive or cause confusion, and is not identical or confusingly similar to another trade mark, whether registered or unregistered.

Cambodia has joined the Madrid Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, with the protocol becoming effective from 5 June 2015.

### **Scope of protection**

A trade mark cannot be validly registered if it does not meet the above criteria. A trade mark cannot be registered if it is identical with, an imitation of, or contains as an element:

- An armorial bearing, flag or other emblem.
- A name, abbreviation, initial, official sign, or hallmark adopted by any state, inter-governmental organisation, or any organisation created by an international convention.

Registration of a trade mark that includes these elements is allowable if the applicant receives authorisation from the relevant authority.

Medicinal brands are not excluded under the trade mark laws and can be registered in Cambodia if they meet the criteria set out above. There is no separate procedure or registry for medicinal trade marks.

8. How is a trade mark registered?

### **Application and guidance**

Applications for trade mark registrations are submitted to the Department of Intellectual Property Rights, part of the Ministry of Commerce. Guidance on the procedure is provided in both English and Khmer language at [www.cambodiaip.gov.kh](http://www.cambodiaip.gov.kh).

The applicant can choose between a single-class application system and a multi-class application system. The current official government fee is KHR160,000 for one mark in one class, regardless of whether it is a single-class application or multi-class application.

### **Process and timing**

It takes about six to nine months for the Department of Intellectual Property Rights registrar to examine a trade mark application and issue a trade mark certificate. However, delays are not uncommon.

During the examination, the registrar may identify objections to the trade mark registration. Objections can be overcome by providing supporting evidence or amending the trade mark application. If no arguments or supporting evidence to overcome the objection is filed, the application is considered withdrawn. A withdrawn application can be revived at a later stage.

If no objections are found by the registrar, the trade mark registration is approved, and a trade mark certificate is issued. The registrar publishes the trade mark in the *Official Gazette*, and opposition can be filed against the trade mark registration within 90 days of publication.

9. How long does trade mark protection typically last?

A trade mark registration is valid for ten years from the filing date of the application. A trade mark owner can apply for renewal rights at the end of that period. A period of six months is allowed for late renewals.

A trade mark owner must use a trade mark in Cambodia once it has been registered. Between the fifth and sixth years after the registration date, and after each renewal date, the trade mark holder must file an affidavit of use or non-use with the Department of Intellectual Property Rights to avoid cancellation of the trade mark registration.

If a trade mark owner fails to submit the affidavit of use/non-use, registration is not automatically abandoned, but the trade mark will be vulnerable to cancellation on a third party's request.

10. How can a trade mark be revoked?

A trade mark can be cancelled by the registrar if the:

- Trade mark owner does not apply for renewal within the prescribed timeframes.
- Trade mark owner requests the registrar to cancel its mark.
- Trade mark owner ceases to have an address for service in Cambodia.
- Registrar is convinced by sufficient evidence that the owner of the registered trade mark is not the legitimate owner.
- Registered mark is similar or identical to a well-known mark owned by a third party.

In addition, the trade mark can be cancelled on a third party's request on the ground that the trade mark has not been used for a period of five years, although the trade mark owner can remedy this by various means before the trade mark is actually cancelled.

A trade mark can also be invalidated. Any person can request invalidation of a registered trade mark. An invalidation is deemed effective if the person satisfies the registrar that the trade mark does not fulfil the registration requirements (see [Question 7](#)).

Invalidation is effective from the date of registration, and is published and recorded by the registrar.

11. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

### **Conditions**

To establish a trade mark infringement, a trade mark must be used in relation to the goods or services that it has been registered for, without the registered trade mark owner's consent.

The element of use includes the use of a mark that is identical or confusingly similar to the registered trade mark.

Well-known trade marks can be infringed by using the trade mark on any goods or services, and not necessarily those they have been registered for.

### **Claim and remedies**

Infringers of trade marks are subject to criminal penalties, including fines of up to KHR10 million and/or imprisonment of up to one year for imitation offences. For forgery of a trade mark, the penalties increase to fines of up to KHR20 million and/or imprisonment of up to five years.

In addition to the criminal penalties, a trade mark owner can also pursue civil remedies in the form of injunctions against infringers, awards and monetary damages. Moreover, the court has the power to order preliminary injunctions or temporary restraining orders, such as border measures or seizures. The court can issue a preliminary injunction or temporary restraining order to prevent infringement or imminent infringement, or to preserve evidence.

12. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

The following authorities are the main regulatory powers against counterfeiting in the pharmaceutical sector:

- **Ministry of Health.** Officers of the Ministry of Health have the authority to perform post-marketing inspections to identify illegal pharmaceuticals in the market, including counterfeit pharmaceuticals. In addition, Ministry of Health officers have the authority to investigate manufacturing facilities to identify illegal manufacturing sites.
- **Cambodian Counter-Counterfeit Committee (CCCC).** The CCCC is a ministerial-level committee comprised of members from 14 ministries/agencies. The CCCC is currently focusing its enforcement initiatives on hazardous counterfeit products that may affect the public, including pharmaceuticals, cosmetics and medical devices. Its role is to co-ordinate an appropriate response among their members to handle incidents of infringement.

In pharmaceuticals counterfeiting cases, the CCCC co-ordinates a response with the Ministry of Health, which is the main regulatory authority for pharmaceuticals, and, depending on the facts of the matter, the Customs Department or Economic Police may become involved as well.

The CCCC has recently conducted several raids, turned over evidence to the courts, destroyed large amounts of counterfeit products, and has successfully pursued criminal cases against counterfeiters.

The following enforcement actions are available to trade mark owners in case of an infringement:

- **Private action.** Enforcement of intellectual property rights is a fairly new concept in Cambodia. In case of an infringement, current practice often requires the trade mark owner to engage in a private action and negotiate a solution before involving the authorities, although this depends on the particulars of the infringement.
- **Administrative action.** The Department of Intellectual Property Rights offers administrative proceedings in which it conducts one or more hearings and serves as a mediator between the infringer and the trade mark owner. The Department of Intellectual Property Rights does not have the authority to issue orders or awards, or impose a seizure or destruction of goods, but it has an excellent track record in convincing infringers to enter undertakings to cease their unlawful activities.

Administrative proceedings are transparent and credible, and currently provide a very effective mechanism for resolving most trade mark disputes in Cambodia.

- **Court action.** The trade mark owner has the right to institute court proceedings, and can bring civil and criminal charges against an infringer.

## IP and competition law issues

13. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

A draft Law on Competition is being considered by the government, but has not yet been adopted.

Competition policies relating to various business sectors (such as telecoms, banking and electricity) are administered by their respective government authorities. As of June 2019, there has been no information on new policies adopted by the Ministry of Health regarding competition in the pharmaceutical sector.

The latest draft of the Law on Competition indicates that it will establish the Cambodian Competition Commission as the regulatory power in Cambodia. The draft further addresses horizontal and vertical unfair competitive practices, and the abuse of a dominant market position.

Article 22 of the Law concerning Marks, Trade Marks and Acts of Unfair Competition adopts a broad definition of unfair competition as any act of competition contrary to honest practices in industrial, commercial or service matters.

The Department of Intellectual Property Rights has clarified that unfair competition includes passing off, discrediting a competitor and misleading advertising, but also stealing trade secrets or key employees from a competitor. There have been no publicised cases in which an authority applied the unfair competition provision beyond intellectual property rights disputes.

The Law on the Patents, Utility Model Certificates and Industrial Designs provides the government, or any third person authorised by the government, the option to exploit a patent against the will of the patent owner, if a court has determined the manner of exploitation by the patent owner or its licensee is anti-competitive. The law does not further address anti-competitive behaviour.

In Cambodia, jurisprudence is not publicly available in practice, therefore information on case law addressing these competition issues is unavailable.

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context

The Law on the Patents, Utility Model Certificates and Industrial Designs allows the government, or any third person authorised by the government, to exploit a patent if a court has determined the manner of exploitation by the patent owner or its licensee is anti-competitive.

The authorities have not issued any jurisprudence, guidance documents, or other documents that clarify anti-competitive exploitation. In addition, as pharmaceuticals are currently excluded from patent protection in Cambodia until 2033, these issues are unlikely to become relevant in Cambodia in the foreseeable future.

15. Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

There are currently no competition issues associated with the generic entry of pharmaceuticals in Cambodia.

16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

There are currently no dominance issues in the pharmaceutical sector in Cambodia.

17. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Parallel imports of pharmaceuticals have not raised competition law issues in Cambodia. However, the influx of pharmaceutical parallel imports is a major concern for the pharmaceutical sector, which is actively lobbying with the government to curb pharmaceutical parallel imports.

Although the trade mark law is considered to adopt a national exhaustion doctrine that prohibits parallel imports of trade marked products, current practice indicates authorities will not act unless an exclusive distributorship is registered with the Department of Intellectual Property Rights.

Under current regulations, exclusive distributorships of pharmaceutical products are excluded from being registered, which therefore effectively bars pharmaceutical trade marks from protection against parallel imports. It

is not clear if the regulation is intended to prohibit pharmaceuticals from exclusive distributorships, or merely from the registration of the exclusive distributorship and the rights obtained from the registration.

The law on patents does not prohibit parallel imports, as it states patent rights do not extend to articles that have been put on the market in or outside Cambodia by the owner of the patent or with their consent.

Any patented product sold in a foreign country can be freely imported into Cambodia under the patent laws, and is not considered a (prohibited) parallel import.

This indicates that an international exhaustion doctrine is applicable to patent rights, while the trade mark law is considered to include a national exhaustion doctrine of trade mark rights.

18. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made enforceable?

There is no requirement for a patent or trade mark licence agreement, and payment of royalties under it to a foreign licensor, to be approved or accepted by a government or regulatory body.

A patent and a trade mark licence agreement must be registered with the Department of Intellectual Property Rights (trade marks) or the Department of Industrial Property (patents) to be enforceable against third parties.

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