**Kingdom of Cambodia**

**Official Local Language:** Khmer (or Cambodian Language)

Link to legislation: Website is currently not available.

Link to published guidance documents: Specific guidance documents are currently not available online.

*Note: in this document, the term “days” refers to “calendar days” unless otherwise specified.*

**Regulatory Agency**

Name of RA: Department of Drugs and Food, Ministry of Health, Cambodia (MOH);

It is not possible to provide the name of the RA in the local language.

The Department of Drugs and Food under the MOH is responsible for the quality and control of pharmaceuticals. The Department is composed of five bureaus each with their own specialty, three of which are:

- The Narcotic Control and Pharmaceutical Trade Bureau
- The Drug Regulation Bureau
- The Registration and Cosmetics Bureau

The Narcotic and Pharmaceutical Trade Bureau, in collaboration with the Ministry of Commerce, oversees:

- The licensing of pharmaceutical companies
- The registration of import/export companies
- The publishing of the drug import permit as per the international convention on narcotics control
- The registration of traditional medicine

The Drug Regulation Bureau oversees:

- The development of drug legislation and regulations
- The development of policies and guidelines - e.g. GMP Guidelines
- The conduct of inspections at manufacturing plants, drug import/export companies, and pharmacies/retail outlets
- The translation of drug package inserts into Khmer
- Drug advertisements

The Registration and Cosmetics Bureau oversees:

- The drug registration process
There are no regulations detailing the need for RA approval for a clinical trial in Cambodia. However, to use a drug for a clinical trial; the RA, via the Narcotic and Pharmaceutical Trade Bureau, needs to authorise drug import.

Prior to import, however, the pharmaceutical products and materials, which also include raw materials, bulk, and finished products, must be registered for import with the MOH Department of Drugs and Food Administration through the Registration and Cosmetics Bureau, if not already registered with the MOH. Registration requires submission and review of the following documents by the Registration and Cosmetics Bureau:

- Administrative information including the application (not available online), summary of product information, GMP certificate, and certificate of pharmaceutical product
- Quality information including the list of ingredients per dosage unit and batch, description of the manufacturing process, certificates of analysis for all ingredients used, control procedures used, stability, bioavailability, and bioequivalence data
- Pre-clinical information including pharmacokinetic and toxicology data
- Previous human experience with the drug

There is no information available detailing the submission format, language requirements, or the applicant for the registration. There are no timelines regarding the review period and no information regarding notification of successful registration. The Registration and Cosmetics Bureau should be contacted directly to establish submission requirements.

Documentation requirements vary for different types of products, trials and where products are manufactured.

Link to documents and forms: Not currently available online.

Ministry of Health
No. 151-153, Kampuchea Krom Blvd. (St. 128)
Phnom Penh
Cambodia
Attn: Not available.
Tel: Int. + 855 23-722-873
Fax: Int. + 855 23-426-841/725-833
E-mail: moh_cabinet@online.com.kh
Office Hours: Not available.
Web site: No longer available
Contact information for the Registration and Cosmetics Bureau is not currently available.

Fees: No fees are charged for Registration.
Importation

An Import Licence is required from the Ministry of Commerce prior to importing pharmaceutical drugs and products into Cambodia. The applicant for the import licence should be a pharmacist or a pharmaceutical company registered with the Ministry of Commerce and authorized by the MOH. It is not specified if a local representative of a pharmaceutical company is acceptable and if so, whether Power of Attorney is required.

There is a standard application form for the import of Pharmaceuticals that is not currently available online, but may be obtained directly from the Ministry of Commerce. It is not clear if the import licence application is made before or in parallel to the EC application or if EC approval is required prior to application.

The import application is received by the RA and then is passed on to the Narcotic and Pharmaceutical Trade Bureau. The Ministry of Commerce, in collaboration with the Narcotic and Pharmaceutical Trade Bureau, are responsible for the issue of import licences.

Applications are validated and can be rejected if the submission does not meet the ‘ordinary criteria’, i.e. failure to register the drug with the MOH. In cases of unregistered drugs, the MOH will either recommend registering the drug or request the submission of full supporting documentation. If the application is rejected, the applicant has the right to appeal through the judicial and administrative procedures as explained in the Memorandum of Foreign Trade Regime of Cambodia, Part III, 6. There are no details available on the communication process between the Ministry of Commerce and the applicant. It is not specified in what form the communication will be and within what time frame a response is obtained.

Each import shipment requires a separate import licence which can be issued within one week after submission of the required documents and application form. There is no information available stating if this timeline differs for different types of drug or phase of study. The format of the import licence is not specified and there is no indication if notification of study start is required. An import licence is valid for six months from the date of approval. An extension may be granted upon written request but the licence is non-transferable between shipments.

The documents needed for the import licence application are unknown. Applicants should contact the Ministry of Commerce and the Narcotic and Pharmaceutical Trade Bureau to determine document requirement needs.

Language and format requirements for the application and supporting documents are unknown.

The following documents are required by Customs:

- Certificate of Origin; 1 copy
- Pre-Shipment inspection certificates
- Commercial invoice; 1 copy
- Insurance Certificate; 1 copy
- Bill of lading or a certified copy (or Airway Bill); 3 copies
- Packing List: 1 copy
- Import Licence: 4 copies
- GMP Certificate

The following information is required in the cargo manifest:
- Bill of lading
- Port of loading and unloading
- Consignee and Consignor
- Description and gross weight of goods
- Quantity, mark, number and type of packages
- Certificate of analysis for the batch being imported

Details on customs clearance and procedure, laws and regulations can be found at: [http://www.customs.gov.kh/](http://www.customs.gov.kh/) (English)

Additional information for import policies and regulations for pharmaceuticals in Cambodia can be found at: [http://www.moc.gov.kh/](http://www.moc.gov.kh/)

Further details on the Ministry of Commerce website at: [http://www.moc.gov.kh/](http://www.moc.gov.kh/) (English)

Address for submission:
Ministry of Commerce
No 20 A-B Norodom Blvd.
Phnom Penh 12203
Kingdom of Cambodia
Attn: Not available.
Tel: Not available.
Fax: Int. +855 23-210-728
E-mail: wtooffice@camnet.com.kh
Office Hours: Not available.
Web site: [http://www.moc.gov.kh/](http://www.moc.gov.kh/) (English)

Fees:
Import: dependent on the classification of the product being imported and are continuously being revised by the Ministry of Economy and Finance. Additional information and details can be found at: [http://www.moc.gov.kh/](http://www.moc.gov.kh/)
Customs: KHR 15,000 per import declaration for services rendered.

**Labelling and GMP requirements**
The laws and regulations on labelling are stipulated as per the Law on the Management of Quality and Safety of Products and Services which can be found at the following link: [http://www.moc.gov.kh/](http://www.moc.gov.kh/)

Labelling requirements are as follows:
- Name of product
- Details of ingredients
Composition
Users’ guidelines (directions for use)
Manufacturing Date
Expiry Date
Producer name and address
Source
Quantity
Batch number
Other requirements to guarantee safety and health of consumers

Language Required: Khmer

The manufacturing standards requirements and documentation required as evidence of standards are not specified.

**Ethics Committee**
Clinical trials are regulated by the National Institute of Public Health under the MOH.

All clinical trials must obtain approval from the National Ethics Committee for Health Research under the MOH which acts as the Central Ethics Committee (EC), before a trial may commence. There are no local ECs. There are no details as to where clinical trials may be carried out. For multicentre studies, one application is made to the EC by a main corresponding Principal Investigator on behalf of all the sites using the Application Form for Initial Review from the EC. Multi-Site Collaboration must be indicated as ‘Yes’ on the application form.

The EC meets once every two months on the last Friday of that month. All documents are to be submitted at least two weeks prior to the meeting date. The review process should take between one to two months. If clarifications are required by the EC, the researchers will be invited to a scheduled face to face meeting to provide the required information.

Approval from the EC is given in writing on a letter signed by the chairman of the committee. The letter will only state the name of the main corresponding principal investigator (PI), identify the clinical trial by title, and state the date of the convened meeting and date of approval. The letter will also state that continuing review is required by the EC in the form of progress reports, where the progress reports and final report should be submitted with full contact details; and that these reports should be submitted by the site PI. The letter will specify the frequency of continuing review which will not be less than once per year. The EC requirements for safety reporting are not stated in the approval letter. The duration of the initial approval is not defined by the EC and there are no requirements for the study to start within a certain period following the approval. Notification of study start is not required by the EC.

Documentation requirements vary for different types of products, trials and where products are manufactured.

The following documents must be submitted:
• A standard application Form
• Research Proposal - A detailed list of documents required in the research proposal may be found here.

A standard application form is used. The application form is in English but the supporting documents and the research proposal must be in Khmer and either English or French. The format of the supporting documents required for submission is not specified, but 20 hard copies of the complete package and an electronic copy must be submitted.

The applicant is the main corresponding principal investigator.

All proposals must be submitted to:
National Institute of Public Health
Secretariat
No 2 Kim II Sung Blvd
Khan Tuol Kok
Phnom Penh
Cambodia
Tel: Int. +855 23-880-345
Fax: Int. +855 23-880-346
E-mail: research03@online.com.kh
Website: No longer available

Working Days/Hours: Not specified

Fees: USD 400.00

**Informed Consent**
The following information should be included in the Informed Consent Form:
• Name of institutions and investigators conducting the study
• Rationale, purpose, and methods of the study
• Importance of participation
• Direct benefit to the participants that might reasonably be expected. If no direct benefits are expected, the participants should be made aware of this.
• Description of the participant payment process for the duration of the study, if applicable
• Requirements for the participants to fulfil before and during their participation
• Duration of participation
• Anticipated risks or discomforts to the participants, both physical and psychological
• Measures to take care of foreseeable risks
• Compensation or services provided for any risks or complications related to the study
• Any standard or alternative procedures or courses of treatment available, locally or elsewhere, that might be as advantageous to the participants as the procedures or treatment being tested
Indication that participation is voluntary, and they have the right to withdraw from the study at any time without any punishment or changes to the services they would otherwise receive.

Name(s) and contact address of attending physician(s) or contact person(s) in case of need or emergency.

The consent form can be separate from or combined with the information sheet. Two original copies should be signed, one for the participant and another for the investigator. In addition, it is recommended that ICH GCP requirements are met.

Language Required: Khmer and either English or French

**Advertisement**

As per the Law on the Management of Quality and Safety of Products and Services, article 21, the following apply to general drug advertisements and not specifically to recruitment for a clinical trial and must be accurate and true on all advertisements:

- Product expectation;
- Identity, type, nature, place of origin, physical or nutritional quality, contents, quantity, manufacturing methods and date of production;
- Expiry date, usage guidelines and terms;
- Methods of sales, product availability, price (if applicable);
- Other warranties.

There is no information available whether approval is necessary by the RA and EC.

Further details can be found at: [http://www.moc.gov.kh/](http://www.moc.gov.kh/)

**Data Protection**

Details are not available on any privacy laws in place.

**Insurance and Indemnity**

Details are not available on the insurance and indemnity requirements.

**Amendments**

At this stage no details are available if the RA should be notified of major or minor protocol amendments.

For Major amendments no details are available on what should be submitted to the EC. The review timeline is similar to that of an initial review and the committee will communicate their decision to the investigator via a letter. Amendments which are minor revisions to a previously approved protocol or are non-procedural items (e.g. names of personnel etc.) will be processed by an expedited review.

Fees: None

**Safety Reporting**

Details are not available on the safety reporting requirements to the RA.
Any serious side effects, adverse drug reactions, and the interventions undertaken must be reported to the EC. Serious adverse events must be reported to the EC by the investigators or the sponsors within seven days after the event. All serious adverse events must be reported on the EC Serious Adverse Event Form and the following information must be provided:

- Subject identification
- Onset/Date of event
- Signs and symptoms
- Diagnosis
- Severity
- Relationship to study drug
- Progression of the serious adverse event
- Modification in the protocol if required

The EC will send a letter to notify the investigator of the committee’s decision and any recommended action.

**Progress and Annual Reports**

No details are available on what is required by the RA, whether there is a specific form, the timelines, and if the reports are acknowledged or approved by the RA.

The main Corresponding PI submits one report to the EC covering all sites.

An annual progress report is required by the EC for continuing review of the research. The EC will determine the frequency of continuing review which will not be less than once per year.

The following should be submitted:

- The EC Continuing Review Form
- Study protocol
- Informed consent form
- Summary of the informed consent form in Khmer
- Study questionnaires (if applicable)
- Any other relevant consent forms (e.g. consent form for females who become pregnant)
- Study advertisement (if applicable)
- Summary of safety report for the study
- Data Safety Monitoring Board report (if applicable)
- Annual progress report

The following information should be provided to the EC for continuing review:

- Number of subjects planned to be enrolled as defined by the protocol
- Number of subjects enrolled during the period
- Number of subjects who continue to be in the study
- Number of subjects who completed the study
- Number of subjects withdrawn
- Changes/amendments (e.g. to protocol, informed consent form, investigators, funding, etc)
- Any serious adverse events
- Any new information
- Any complaints from subjects
- Any community concerns

The submission will be reviewed and continuing approval will be issued by the EC in the form of an official approval letter which will state:
- Project title
- Project number
- Investigator name
- Name(s) and address(es) of institution(s) where the research is being conducted
- If any recommendations are given by the committee
- The documents (name and version date) that were reviewed
- Approval date

The letter is signed and dated by the EC chairperson.
The address for submission to the EC will be provided in the EC approval letter

Progress and Annual Reports should be submitted, if required, to the RA at the address provided in the RA section.

The address for submission to the EC will be provided in the EC approval letter.

The acceptability of setting an annual global birth date for the annual report could not be confirmed.

**End of Trial Notification**

No details are available concerning end of trial notification requirements to the RA.

The [EC Final Report Form](#) and any relevant documentation must be submitted to the EC upon notification from the EC to submit the form. The EC final report form must be completed in English. The Main Corresponding PI submits the end of trial notification to the EC. The EC will send an acknowledgement letter to the main corresponding PI.

The EC defines premature study termination as follows:
- When subject enrolment and follow-up are discontinued before the scheduled end of the study
- When safety or benefit of study participants is doubtful or at risk
- When recommended by local authorities and scientists

In such cases, the main corresponding PI must submit, as soon as possible:
- [The EC Study Termination Memorandum](#)
- Brief summary of protocol, results and accrual data
**Clinical Trial Report**
A clinical trial report is not required by the RA.

At the end of the study, a final clinical trial report must be submitted to the EC. The EC will determine the due date for the final clinical trial report for each approved protocol and notify the investigator. There is no information concerning the content requirement of the final report and the language it must be completed in.