SRILANKA:

The drug regulatory authority of Srilank is Cosmetics, Devices, & Drug Regulatory Authority (CDDA). The Cosmetic, Devices and Drugs (CDD) Act No. 27 of 1980 (as amended by Act No. 38 of 1984, No. 25 of1987 and No 12. of 1993) provides the legislative framework for controlling the use of cosmetics, medical devices and medicinal drugs in the country. The regulations under the CDD Act were published in Gazette Extraordinary No. 378/3 of 02/12/1985 and further amendments are made occasionally.

The main provisions of the CDD Act with regard to the drugs are:

Only drugs which are registered with the Authority can be manufactured, imported, offered for sale or used in the country;

Licenses are required for importation, manufacture, wholesale trade/retail trade, and transportation of drugs;

All drugs registered with the CDDA should conform to specified standards;

And

Labeling on the packs and advertisements regarding drugs should conform to the relevant regulations.

The registration of drugs is one of the main functions of the CDDA. The first step of the drug registration procedure is the evaluation of the manufacturer's compliance to good manufacturing practices (GMP) standards. Applications for the registration of drugs are accepted only if the production facilities of the relevant manufacturer conform to required standards of GMP.

Sri Lankan regulatory standards are expected to improve under the health ministry's plans to set up a Pharmaceuticals Standards Regulatory Authority to ensure drugs used in the country meet certain quality standards. The establishment of the new authority will provide the ministry with additional powers to take legal action against low quality drugs importers. Presently, regulatory approvals are managed by a single person, the Director General of Health Services, which leaves the system open to corruption. The new authority would be staffed by a Ministry of Health-appointed board. Plans to establish a National Medicinal Drug Regulatory Authority (NMDRA) were originally tabled in 2005.

Foreign manufacturers are evaluated by their company profiles, while local manufacturers are inspected by a team of officers attached to the Office of Medical Technology and Supplies (MT&S) and the National Drug Quality Assurance Laboratory (NDQAL) for GMP compliance.

Every foreign manufacturer has to appoint an agent in Sri Lanka who is responsible for registration and other activities related to their products in Sri Lanka.

The manufacturer should submit registration applications to the Office of the Director of MT&S through the local agent along with samples for quality testing. The Drug Evaluation Sub Committee (DESC) comprises specialists in medical and pharmaceutical fields and, with the administrative sector of the Ministry of Health, makes recommendations on the registration of drugs. Quality, safety and efficacy are considered the main criteria for registration.

Drugs Registration Procedure:

Imported Drugs:

Approval of the manufacturer

The first step of registering drugs from a new manufacturer (whose drugs are not registered with the DRA previously) is to submit the company information by the **Authorised Local Importer** representing the manufacturer. If the company profile is found to be satisfactory, registration applications will be accepted by CDDA.

Steps involved:

- Submission of information about the company
- Receiving of company profile by a Pharmacist (1)
- Assigning a serial number to the application.
- Issuing of a letter to the applicant indicating the serial number.
- Evaluation of company profile in the order of the serial number by a Pharmacist.
- Check the evaluation report by Chief Pharmacist.
- Submission of report to Director for a decision.
- Communication of decision to applicant (Approval / rejection / require more information.

Registration of drugs:

The authorised local importer representing the manufacturer of a respective drug has to submit an application with drug samples to the Cosmetics Devices and Drugs Authority (CDDA) for the registration of the drug. This application should be according to the format given in the Schedule IV, Form A of CDD Regulations (See the specimen given under the application form). A sample license should be obtained from the CDDA in order to facilitate customs clearance when importing these into the country and license fee is Rs. 2000/= at present.

Once the registration dossier is handed over to the CDDA, it will be entered in a register allocating a serial number to the application. An acknowledgement letter is issued to the importer

with the **serial number** which will be the reference number for the application. Importer should pay processing fee for each application.

The Processing fees at present are:

1. New Chemical Entities for Sri Lanka (NCE) - Rs. 50,000/= + VAT
2. New Dosage form application for Sri Lanka (NDF) - Rs.25,000 /= + VAT
3. New fixed dose combination products (NFDCs) - Rs.50,000 /= + VAT
4. New product of existing drugs - Rs.10,000 /= + VAT
5. Re-registration application - Rs.10,000 /= + VAT

All applications (except new chemical entities) will have to go through the pharmaceutical evaluation first.

New chemical entities first go to the Drug Evaluation Sub Committee (DESC) of the CDDA. Then the dossiers subjected to a pharmacological evaluation. If the committee decides that it should be registered in this country, then it is taken for thorough pharmaceutical evaluation.

Pharmaceutical quality of products is assessed through pharmaceutical data evaluated and information on factors determining quality (starting materials/ formulation, manufacturing process, intermediate & finished product controls, packaging, stability, bioequivalence data) are carefully considered.

If the pharmaceutical evaluation of the application is satisfactory, it will be submitted to the DESC. The DESC comprises consultants from various specialties and a decision is taken at the DESC meeting accordingly. If registration is recommended, DESC decides on the Schedule under which it should be registered (i.e. I, IIA, 11B, or 111). The local agent will be informed of the decision (whether rejected or approved).

If it is approved, the Certificate of Registration will be issued by the Director Medical Technology and Supplies who is the Chairman of the DESC. Rejections will be informed giving reasons for the decision. Registration is usually valid for 5 years. The registration fee is Rs. 25000/= + VAT for a product. Under special circumstances (e.g. when the drug is a new chemical entity, the manufacturer is new to this country) a provisional registration will be issued for one year and the fee is Rs. 10,000/= per year.

Every importer should employ a registered pharmacist and should posses a whole sale license from CDDRA in order to carry out the business. The license fee is Rs. 6000/= + VAT per annum. He should also get separate import license on annual basis for each product from the CDDA (license fee is Rs. 2000/= + VAT) for importation.

Steps involved

- Import of registration samples
  - Submission of application to import registration samples.
  - Payment of sample import licence fee to the cashier of the Ministry of Health.
  - Produce receipt at the CDDA.
  - Issue the licence indicating the quantity permitted.
- Submission of registration application
  - Submission of registration application and samples to the CDDA.
  - Check for completeness by a Pharmacist.
  - If the application is incomplete, return the application with a letter indicating deficiencies.
  - Issue letter for payment of processing fee provided the application is complete.
  - Produce payment receipt to CDDA after paying the processing fee.
  - Official acceptance of application by a Pharmacist.
  - Assigning of serial number to the application
  - Issuing acknowledgement letter to applicant indicating serial number and date of submission
- Evaluation process
  - Applications are evaluated according to Serial Numbers except under special circumstances.
  - Priority is given for Re-registrations and Locally manufactured products (keeping to the order of serial numbers).
  - Applications for New Chemical Entities (NCE) are submitted to the Drug Evaluation Sub-committee at the monthly meeting.
  - At the DESC meeting NCE applications are referred to Consultants for evaluation (mainly Efficacy & Safety).
  - Evaluation reports are discussed at the DESC and a decision is taken by the DESC as to whether the NCE is acceptable to Sri Lanka.
  - If more information is required that is also informed to the company.
  - Samples are sent to NCL for quality testing
  - All generic and branded generics are evaluated according to serial numbers
  - Recommendation for final decision is given by the DESC.
  - Decision of the DESC is communicated to the applicant
  - After approval a Certificate of Registration will be issued on payment of the prescribed fee

Figure 1: Registration of Generic Applications

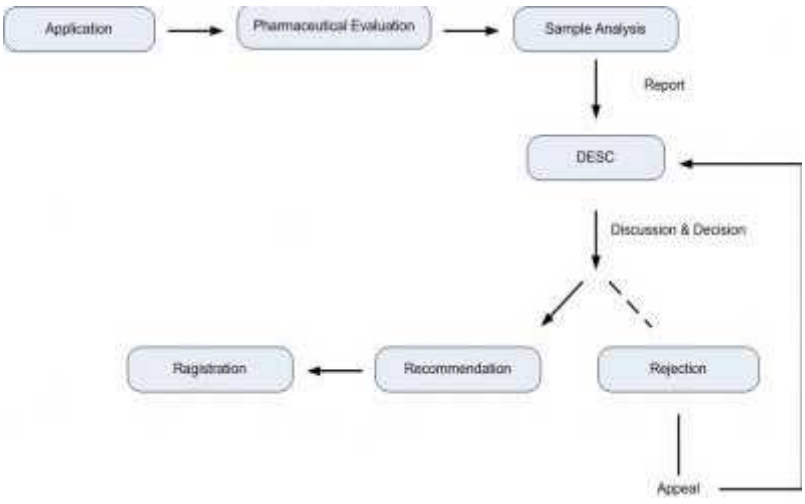


Figure2: Registration of NCEs, NDF & NFDC

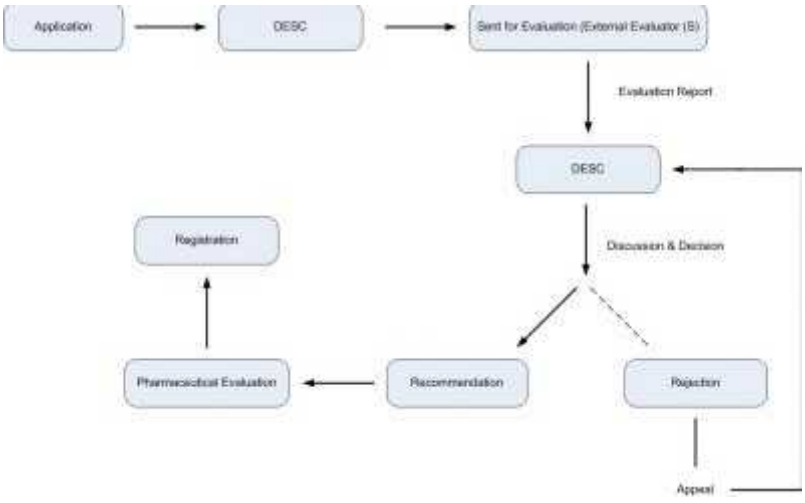
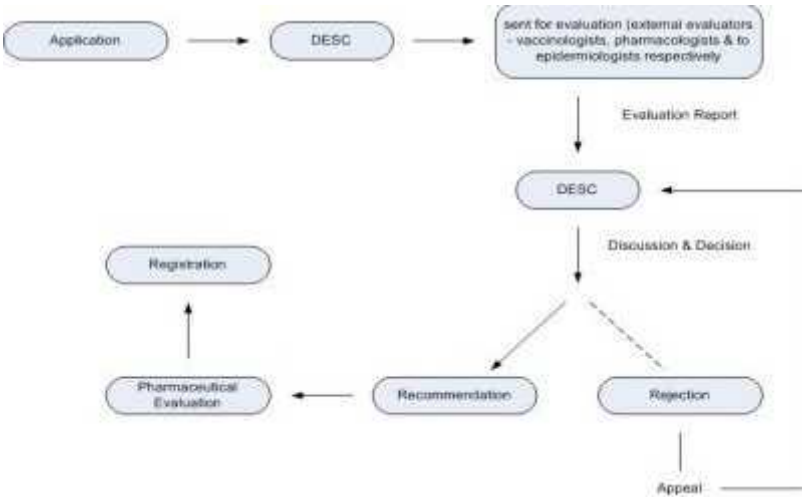


Figure 3: Registration of Vaccines



The DESC makes use of the World Health Organization (WHO)'s GMP certification scheme – regarding the quality of pharmaceutical products moving in international commerce – when assessing GMP standards and the registration status of a product in its country of manufacture. The Director of MT&S's approval (or the rejection) of the registration is based on recommendations of the DESC. The registered drugs are entered in a register maintained at the MT&S director's office and periodically published through Government gazette not

Links:

Link to view list of recent New Chemical Entities:

http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=59&Itemid=100&lang=en

Link to view list of recent Quality Failures:

http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=62&Itemid=102&lang=en

Link to Srilankan Approved Product Database:

http://www.cdda.gov.lk/index.php?option=com_product&Itemid=127&lang=en

Link to Drugs Local Manufacturers:

http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=92&Itemid=120&lang=en

Link for Guidelines:

http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=88&Itemid=88&lang=en

Regulatory Developments:

- According to leading medical professionals in the country, Sri Lanka only needs around 800 medical products (with the WHO suggesting a maximum of 1,000). However, as much as ten times this figure is imported into the country. Imports are also reportedly wasted due to their questionable quality, as well as due to a poor match between demand and supply, resulting in a major strain on public healthcare resources.

- More recent reports in the local press similarly suggest that the lack of a mechanism to restrict registrationhas led to the dumping of thousands of non-essential drugs in Sri Lanka. According to Ceylon Daily News, more than 9,000 varieties of medicinal drugs are imported, compared with a requirement of less than 350 types by the country. According to the People's Movement for the Rights of Patients (PMRP), patients have to pay high prices on medicinal drugs due to the presence of thousands of brand names in the market. Christine Perera, a member of the PMRP, stated that the dumping of non-essential drugs has been attributed to the non-implementation of the National Medicinal Drug Policy (NMDP), which was drafted in 2005.

- In June 2010, India's Pharmaceutical Exports Promotion Council (Pharmexcil) urged the authorities to examine Sri Lanka's policy on biosimilars, which it considers 'unjustified'. From the start of February 2010, Sri Lanka mandated that biosimilars need to have been registered in at least one developed reference country, such as the UK or the US. Moreover, the submission of clinical trials data is also required in order to compare the biosimilar with the originator. In a related previous development, in December 2009, India's commerce ministry said it was to protest formally about discrimination against Indian pharmaceutical companies by the Sri Lankan drug authorities.

- However, in April 2011, a total of 10 Indian drug companies were blacklisted by Sri Lankan authorities, according to Minister of Health Maitripala Sirisena, although their names have not been disclosed. This comes after the companies were found to be violating tender procedures, supplying substandard products and disregarding delivery schedules, which are requirements stipulated for their registration with the ministry. The minister had ordered the Director General of Health Services to cancel the tenders awarded to the erring companies and acquire drugs from other countries to counter the shortage of quality drugs in government hospitals, despite India's moves to avert the ban.

Medical Devices:

The regulatory information outlined in this document are primarily drawn up in accordance to the legal requirements of the Cosmetics, Devices and Drugs Act No. 27 of 1980 and Cosmetics, Devices and Drugs Regulations – The gazette of the Democratic Socialist Republic of Sri Lanka (Extraordinary) No. 378/3 of 1985.

DEVICES DEFINITION

Defined in the Act, "Device" includes; any article, instrument, apparatus or contrivance, including any component, part of accessory thereof; manufactured or sold for use in

1. the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof, in man or animal,
2. restoring, correcting or modifying a body function or the body structure of man or animal,
3. the diagnosis of pregnancy in human beings or animals, or
4. the care of human beings or animals during pregnancy and at and after birth of the off-spring, including care of the off-spring and includes a contraceptive device but does not include a drug;

Provisions under the Act

- All devices, manufactured, imported, sold and distributed and offered for sale in Sri Lanka should be registered under the provisions of the Act.
- Device manufacturers and importers within or outside Sri Lanka intending to market their products in Sri Lanka should register their products.

Application for Device Registration:

- The application for registration shall be made along with the required documents in Schedule I, Form A (Regulations 4(3)) of Cosmetics, Devices and Drugs Regulations (The gazette of the Democratic Socialist Republic of Sri Lanka (Extraordinary) No. 378/3 of 1985.)
- The documents required for registration should be in English and submitted in a hard file cover
- The documents for registration are processed only if they are complete and as per specifications.
- Separate applications should be made in respect of each device to be registered. [i.e. products containing different specifications, different brands]
- Products of foreign manufacturers should be submitted through a local agent

Pre-requisites for registration of a device

- Obtaining Sample Import Licence
  by submitting

  - a copy of business registration certificate of the applicant[should indicate the board of directors, Secretarial board (BR 1)]
  - letter of authorization from the manufacturer appointing the local agent

Data Requirements

All the certificates for registration of device should be signed by an Authorized Officer.

General Documents/ Requirements

1. Schedule I, Form A & Form B
2. Copy of sample import licence
3. Free sale certificate
4. Fully packed samples (two) of devices in the form that is intended to be marketed [as a registration sample (including Lot no., Man. Date, Exp.date, Manufacturer's & Importers details and when required sufficient quantity for analysis)]
5. List of countries which the device is approved or registered for sale with copies of registration certificates

Technical Documents

1. Label/ catalogue/ User Manual
2. Patient Information Leaflet

Responsibility of Market Authorization Holder:

(i.e. THE APPLICANT FOR PRODUCT REGISTRATION/ LOCAL AGENT)

The applicant should be responsible for the product and all information supplied in support of his application for registration of the product.

He should be responsible for updating any information relevant to the product/ application. The CDDRA should be informed in a timely manner any change in product information during the course of evaluation, and after product registration, especially if the information pertains to rejection/ withdrawal, additional data on product quality, effectiveness and safety or current Good Manufacturing Practice (cGMP) compliance of the manufacturers.

He should provide additional documents for renewal of registration, six months before the expiry of certificate of registration.

The marketing authorization holder must assume responsibility for the quality, safety and effectiveness of his products.

Fees for Registration:

The fees for registration of device are specified in Schedule II of the regulations and last amendment is the gazette notification no. 1601/15, May, 2009 and will be subjected to revision from time to time.

Processing Fee:

Processing fee for the registration of a Device is Rs. 3000 + VAT

Registration Fee:

The registration fee per product should be paid prior to the issuance of registration certificate.

1. Full registration for an imported device – Rs. 7,500 + VAT
2. Full Registration for a locally manufactured product – Rs. 5,000 + VAT
3. Provisional Registration for an imported drug – Rs. 2,000 + VAT
4. Provisional Registration for a locally manufactured product – Rs. 1,000 + VAT
5. Renewal of a certificate of registration/ re-registration (PR/ FR) – Rs. 5,000 + VAT
6. In case if the imported need a duplicate copy of the certificate, Rs. 1,000 + VAT per product should be paid and it will bear the words "duplicate copy".
7. Any amended copy of a certificate Rs.1,000 + VAT.

If the market authorization holder fails to comply with the conditions of registration of that device, the authority may remove the name of the device from the register of device after seeking the opinion from the Medical Device Evaluation Sub-Committee.

Licence to import devices

1. Licence to import registered devices – Rs. 3,000 + VAT
2. Licence to import samples for test, examination fee – Rs. 2,000 + VAT
3. Amended copy of the certificate of import licence – Rs. 1,000 + VAT

Licence fee to Manufacture devices

- Licence to Manufacture devices- Rs. 1,000 + VAT

Mode of Payment

The payment should be made to the shroff counter of the Ministry of Health.

Any payment made is not refundable once a application has been submitted and payment confirmed. Applications without the correct fees will not be entertained.

Multiple Applications

A separate application is required for each product i.e. product containing different specifications or by a different manufacturer shall require a separate application for product registration.

Regulatory Outcome:

Decisions of the Medical Device Evaluation Sub-Committee (MDESC)

A regulatory decision is made based on the outcome of the evaluation of the submitted documentation. The evaluation may be done by both external expertise and internal evaluators. The decision is submitted to the Medical Device Evaluation Sub-Committee (MDESC) for further opinion. The MDESC may, in the interest of public safety, reject the registration of any product. The final decision will be notified to the applicant

Product Identification Number

A identification number will be allocated by the authority when a product application is deemed to have satisfied the registration requirements. The identification number is specific for the product registered with the name, identity, characteristics, origin (manufacturer) and market authorization holder. It may NOT be used for any other product.

The following prefixe is used before the product identification number.

DVR - Registration of new device

DVR - RR - Re Registration of registered device

Award of Registration Certificate

The registration certificate will be issued format given in Schedule IV, Form A (Regulation 5(2)) of regulations.

The registration certificate will be issued within 30 working days from the date of receipt of complete documents unless otherwise a longer period is required in case of which the party will be notified.

Validity Period of Registration

The Full Registration of a product is valid for a period of five years and is specified in the certificate.

The Provisional Registration of a product is valid for a period of one year and is specified in the certificate.

When additional data are requested, the applicant will have to furnish additional information requested by the authority within 3 months to facilitate further evaluation.

If the product is rejected, the market authorization holder will be able to appeal for registration

Renewal of Registration

Application for renewal should be made before six months from the date of expiry of registration.

A grace period will extend until the decision is given to the application for renewal.

If the requirements for registration are not satisfactory the application will be rejected completely.

Cancellation of Registration

The authority may cancel the registration of any product if:

1. Any of the conditions of registration of the product has been contravened or changed,
2. Any complaints on quality failure of product have been reported from National Pharmacovigilance Centre or any other national or international sources or customers.
3. The information which was furnished at the time of application is later found to be false or insufficient.
4. For any other matters as specified by the authority at the time of cancellation.

Appeal against DRA/MDESC Decisions:

Any applicant/ market authorization holder aggrieved by the decisions of the CDDA may make a written appeal to the CDDA/MDESC. All notice of appeals must be made within thirty days from the date of the CDDA notification.

Change in Particulars of Registered Products

Any change in product name, product specifications, packaging, indications, contents of product label, package insert, or product literature, or any relevant particulars of the registered product should not be made with the prior approval of the authority.

The registration of the product maybe cancelled if changes are made without the prior approval of the authority.

Any change of product which affects quality, safety & efficacy of the product should require a new application for registration.

Other Information:

Criteria for Registration

A product will be registered only if it satisfies all requirements of the CDDA, especially with respect of safety, quality and effectiveness of the product.

Other criteria that may be taken into consideration include:

1. Necessity of the product as a medical device in patient use
2. Product advantage

Product Label

The following information should be present on the labeling of the product.

Outer label/ Secondary packaging material

- Name of product [Approved name and brand name (if any)]
- Name and address of the manufacturer/ marketing authorization
- Whether the product is sterile or not and mode of sterilization
- Storage conditions specifying the temperature
- Manufacturing date, Expiry date and Lot no.

Product Information Leaflet/ Patient Information Leaflet

Product information leaflet may be attached with certain products to acknowledge the user indicating the way of handling the product.

Regulatory Information on Clinical Trail:

The importance of Research and Development in the attainment of national health, social and economic goals is well recognized. Clinical trials of therapeutic interventions following the principles of scientific experimentation that elucidate the efficacy and safety of such therapies from the basis of modern medicine by generating evidence to assess whether these treatments are of genuine benefit to our patient.

The Ministry of Health has always been committed to providing support for the conduct of useful Clinical Trials in this country. As part of our continuing process of improvement in effort to facilitate and regulate clinical research, Sub Committee on Clinical Trial (SCOCT) was established in January 2009.

It is recommended that all Clinical Trial involving drugs including complementary medical devices & Cosmetics are notified to CDDRA.

Objectives of SCOCT

The Sub Committee on Clinical Trial was established under the Cosmetics Devices Drug Regulatory Authority (CDDRA) of Sri Lanka, with a broad mandate to,

- Provide regulatory approval as well as issue relevant license and certificates required for the conduct of Clinical trials
- Ensure implementation of Good Clinical Practice (GCP) standard in the conduct of Clinical Trials.
- Monitoring safety & wellbeing of clinical trial subjects.

- Review regulatory requirements and other guidelines on an ongoing basis to ensure conduct of Clinical Trials to accepted international standards.

  The following criteria will be applied when granting approval for clinical trials;

- Phase I trials will not be allowed
- Phase II
  - Only multicenter trials approved in a reference authority and WHO sponsored trial will be allowed.
  - Reference authorities for the purpose are USA, Canada, European countries governed by regulation of EMA, Australia, New Zealand, Japan and Singapore.
  - Multicenter trials registered in any other countries will be reviewed on a case by case basis.
- Phase III
  - Multicenter trials approved in a reference authority
  - WHO sponsored trials.
  - Trials on diseases prevalent in Sri Lanka.
  - Phase III trials will be reviewed on a case by case basis
- The patient to be included in Clinical trial should have received the optimal therapy according to evidence based guide lines.

Application for regulatory approval to conduct a Clinical Trial

Application for Clinical Trials (CTL) in triplicates should be furnished to CDDRA in order to obtain regulatory approval to conduct a clinical trial in Sri Lanka.

The regulatory approval should be sought for Clinical trials when,

1. Using drug which are not registered in Sri Lanka (NCEs)
2. Using a registered drug for a new indication.

The following requirements should be fulfilled in order to obtain the regulatory approval

- Ethical approval form a recognized Ethics Review Committee
- Approval from the head of the relevant institution where the trial is conducted

Parallel submission to the relevant ERC for Ethical approval is allowed, however approval from all collaborating institutions has to be obtained in order to obtain the final regulatory ethical approval from the CDDRA.

Applications for CTL are to be made by the principal investigator. It consist of 7 parts,

1. Part A: Basic information on the proposed clinical trial
2. Part B: Information on study drug
3. Part C: Information on comparator drug
4. Part D: Information on concomitant drugs
5. Part E: Information on trial centers, investigators & responsible ERCs
6. Part F: Supporting Trial documents
7. Part G: Declaration of principal investigator/ coordinating principal investigator

The investigator must submit following documents with the CTL application,

- Clinical Trial Protocol (Version & date)
- Investigator brochure (Edition & date)
- Patient information documents and patient informed consent form (ICF) in English along with Sinhalese and Tamil translation and back translations
- GMP certificate & Certificate of analysis for manufactures
- Listing of overseas trial centers and regulatory approvals if relevant
- Principal investigators'/ coordinating PI's curriculum vitae
- Product liability letter or insurance certificate

SCOCT examines scientific merit, relevance and expected benefit of study proposals. Regulatory approval would be issued independent to the ethical approval. The applicant should initiate the study only when both regulatory and ethics approvals as well as "No Objection" letters from respective Directors/ institutional Heads of hospitals/ trial site have been obtained.

Ethics Review Committees

The principle task of Ethics Review Committees (ERC) is to ensure that the study proposals comply with internationally accepted guidelines standards and that the research subjects are adequately protected. Currently, the following eight institutional ERCs are recognized by the SCOCT and ethical approval must be obtained from at least one of them.

1. Ethics Review Committee, Faculty of Medicine, University of Colombo
2. Ethics Review Committee, Faculty of Medical Science, University of Sri Jayewardenepura
3. Ethics Review Committee, Faculty of Medicine, University of Kelaniya
4. Ethics Review Committee, Faculty of Medicine, University of Ruhuna
5. Ethics Review Committee, Faculty of Medicine, University of Jaffna
6. Ethics Review Committee, Faculty of Medicine, University of Peradeniya
7. Ethics Review Committee, Medical Research Institute, Colombo
8. Ethics Review Committee, Sri Lanka Medical Association

Compliance to Good Clinical Research Practice (GCP)

Adhering to ICH Guidelines for Good Clinical Practices (GCP) is mandatory when conducting the trials.

License to Import Drugs for Clinical Trial

Products that require a 'License to Import Drugs for Clinical Trial' are those which are not registered with the Cosmetics Devises and Drug Regulatory Authority (CDDRA) and placebos that are intended to be imported for the purpose of conducting a Clinical Trial.

After regulatory approval is obtained, applicant has to apply for a license to import each consignment of the investigational drug.

Requirements to be fulfilled after approval is obtained

It is mandatory to register all clinical trials in a primary registry of the WHO clinical trial registry network before enrolling patients to the study. Clinical Trial registry of the Sri Lanka Medical Association (SLMA) is a primary registry recognized by the WHO.

The following requirements should be complied with, after the regulatory approval is obtained and during the conduct of the trial.

- To submit the progress report at every six months and at termination or completion of the study
- To report any changes or deviation of the approved protocols
- To report all serious adverse event, and new information that may affect adversely the safety of the subjects or the conduct of the trial.

Accreditation of Ethics Committees:

Subcommittee on Clinical Trials (SCOCT) is in the process of reassessing the already recognized Ethical Review Committees. If interested, any other functioning ERC can apply for accreditation with SCOCT by furnishing the details requested in the questionnaire given herewith.

Questionnaire for ERCs :

The Research Ethics System

- What is the legislative and regulatory framework under which your ERC functions?
- Are there specific SOPs (Standard Operating Procedures) approved by the relevant authority?
- Is it confined to approving protocols submitted by members of your institution or does it accept protocols from outside?
- Is there an appropriate and sustainable system in place to monitor the quality and effectiveness of research ethics review?
- Are there procedures to harmonies standards with other ERCs in Sri Lanka?
- Are there mechanisms to ensure that ERCs' activities are coordinated with national regulatory authorities' oversight of drugs and medical devices?
- What types of research studies are reviewed? Please give a rough %?
  - clinical trials
  - interviews, survey, and focus research
  - research with biological samples
  - studies involving medical records or other personal information
  - research of health care systems
  - quality improvement research

Establishment of the ERC

- Who is the appointing official?

- Are appointments made according to SOPs?
- If not, is it ensured that ERC composition has a multisectorial and multidisciplinary membership?
- How many members are in the ERC?
- How many non-scientific and non-medical members are in the ERC?
- Does the ERC include members who are not affiliated with your institute?

Adequate staffing, facilities, and financial resources to allow the ERC to carry out its responsibilities

- Does the ERC have support staff adequate in number and training to carry out the ERC's responsibilities?
- Does the ERC have adequate resources for the staff to fulfil its assigned functions, including office space and equipment and supplies (e.g., computers, stationery, telephones, photocopying machines) to conduct administrative business, to store all committee files, and to keep documents secure?
- Does the ERC have access to appropriate space for the committee to meet and adequate means for members to communicate as needed between meetings?
- Does the ERC have adequate financial resources to permit the committee to produce high quality work?
- Are the ERC members compensated for their time and effort on the ERC?

Policies governing the ERC to ensure independence of the ERC's operations and decision making process

- Do the ERC's policies specify that its decision-making process is free from bias or influence?
- Does the ERC ensure that investigators and funders (who may attend an ERC meeting to answer questions about their research protocols and associated documents) are not present when the ERC discusses their studies or reaches decisions about them?
- Does the ERC ensure that ERC members do not participate in decisions about protocols submitted by their close colleagues?
- Do the ERC's policies specify that high-level officials of the entity creating the ERC, or of any organization that sponsors or conducts the research reviewed by the ERC (such as the director of an institution), do not serve as members of the ERC?

Training of ERC members on the ethical aspects of health-related research with human beings, and how the ERC conducts its review of research

Are the ERC members provided with training in the following aspects when they join the committee and periodically during their committee service?

- the role and responsibilities of the ERC, and the ERC's relationship with other relevant entities, according to relevant international guidelines (e.g., GCP)
- the full range of ethical considerations relevant to research with human participants
- how such ethical considerations apply to different types of research
- basic aspects of research methodology and design (for members who lack such background)

- how different scientific designs and objectives may affect the ethics of a research study
- the various approaches for recognizing and resolving the tensions that can arise among different ethical considerations and modes of ethical reasoning
- using resources prudently to maximize committee members' training opportunities.

Mechanisms to make ERC operations transparent, accountable, consistent, and of high quality

- Does the entity establishing the ERC employ reliable means to evaluate whether the staff and members routinely follow the ERC's policies, rules and SOPs with special attention to whether the ethical considerations articulated in international guidelines and national standards are being considered and applied consistently and coherently?
- Are these evaluations conducted at regular, pre-defined intervals, using a pre-defined format by knowledgeable and unbiased persons?
- Are internal assessments supplemented periodically by independent external evaluations?
- Is there a mechanism for researchers, research participants, and other interested parties to lodge complaints about the ERC? Such complaints should be reviewed by an entity other than the ERC itself, and appropriate follow-up actions should be taken.

Standards and guidance for members of the research ethics committee

- Does the ERC base its decisions about research protocols on a coherent and consistent application of the ethical principles articulated in international guidance documents and human rights instruments, as well as any national laws or policies consistent with those principles?
- Does the ERC make clear the specific ethical guidelines on which it relies in making decisions and make them readily available to researchers and the public?

Decisions on research protocols by ERC

- Are decisions on research protocols designated for full review based on a thorough and inclusive process of discussion and deliberation by all members of the ERC?
- How are decisions made? By consensus or by voting?

Are there written policies specifying the following?

- ERC's membership
- Committee governance
- Review procedures
- Decision-making communications
- Follow-up
- Monitoring
- Documentation and archiving
- Training
- Quality assurance

Does the ERC provide guidance for researchers ?

- Submitting an application - qualifications required, student applications, collaborative/multicentre trials etc. -
- Conduct of research -
- Any changes made to research protocol -
- Safety reporting -
- Ongoing reporting and follow-up -
- Termination/cancellation of a study -