JSS Academy of Higher Education & Research, Mysuru
(Deemed to be University – Accredited 'A+' Grade by NAAC)

JSS College of Pharmacy, Ooty
(An ISO 9001:2015 Certified Institution)

Department of Pharmacy Practice

A Brief Report on Invited Impact Pharmacy Lecture Series 2023 – Lecture 08
(New connections and New learning)

Date: 17.03.2023

Name of the presenter:
Dr K Bangarurajan
Advisor (Regulatory) CDSCO HQ for international cooperation
Professor, JSS College of Pharmacy, Mysuru

Title of the presentation:
Regulatory requirements for import of new drugs, medical devices and cosmetics

Program Organized by:
Dept. of Pharmacy Practice & Pharmacy Education Unit
JSS College of Pharmacy, Ooty

New Connections and New Learning: Pharmacy Practice- "Learning in the flow of work"

Making learning is a part of everyday work – and everyone's experience at work differs of course and it multiplies at different places. Internship training for Pharm D students is an opportunity to learn new and provide service to the needy patient population. To enhance their learning experience, the institute has created new connections and learning opportunity at various practice settings. Our students are very excited to be at new practice site(s) to learn and demonstrate/shape their competencies.

Dr K Bangarurajan did his B Pharm from Madras Medical College, Chennai, M Pharm from Banaras Hindu University, Varanasi and PhD from JSS College of Pharmacy, Ooty. He began his career as Lecturer at JSS College of Pharmacy, Ooty and joined in the Drugs Control Dept, Tamilnadu in the year 1986 as a Drugs Inspector and served as a Senior Drugs Inspector and Assistant Director of Drugs Control. He joined the CDSCO, New Delhi in the year 2010. He also served as Joint Drugs Controlled (India), CDCSO, New Delhi and looked after the Global Clinical Trial, BA/BE study for export, international cooperation, Enforcement and legal division. At present, he is working as Advisor (Regulations) in CDSCO, HQ for International cooperation. Awarded with IPA-AU PACT, Dr Venkateswarlu Memorial Lecture Award 2019. He has made remarkable contributions in National and International seminars, workshops which shows his urge for upgrading knowledge of the complex pharma spectrum which undergo rapid changes.

Dr Bangarurajan started his presentation with a note about his career at JSS College of Pharmacy, Ooty and how teaching played a major role in updating his knowledge and in-turn how he utilized the opportunity to serve to the country in drug control dept.

The pharmaceutical industry in India is currently valued at $50 Bn. India is a major exporter of Pharmaceuticals, with over 200+ countries served by Indian pharma exports. India supplies over 50% of Africa's requirement for generics, ~40% of generic demand in the US and ~25% of all medicine in the UK. India also accounts for ~60% of global vaccine demand, and is a leading supplier of DPT, BCG and Measles vaccines. 70% of WHO's vaccines (as per the essential Immunization schedule) are sourced from India.

Indian pharma accounts for 60 percent of global vaccine production and contributes to 40 to 70 percent of the World Health Organisation (WHO) demand for Tetanus and Pertussis (DPT), Diphtheria and Bacillus Calmette–Guerin vaccines.

Further, he also added that Today the Indian pharmaceutical industry is truly global in its nature with Indian companies responsible for approximately 40 percent of all generics consumed in the United States and 25 percent of all medicines dispensed in the United Kingdom are manufactured in India. India supplies two-third of antiretroviral drugs globally, contributing to the international fight against AIDS. Indian pharma's affordable generic alternative led to an 18-fold increase in the number of AIDS patients being treated between 2003 and 2009. North America buys 34 percent of India's total pharmaceutical exports, which is the country's largest export market followed by Africa at 19 percent.

In India, the manufacturing, Import, distribution and sale of drugs are regulated by the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945. License is provided for the Import of new drugs & cosmetics subject to those specified in Rule 10 & 10A. No new drug is allowed to import into India without the sanction of the Licensing Authority in writing. Each drug whose composition is not recognized as safe for use by the experts and that has not been used to any extent or for any appreciable period are to be regarded as a new drug.

CDSCO and its role:

The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control. Under the Drugs & cosmetics Act,1940, approval of new drugs as well as conducting clinical trials, putting down regulations for cosmetics and drugs are implemented through this act. The aim of CDSCO is to be transparent, accountable as well as keep a uniformity in the services it provides.

Drug and Cosmetics Act:

The Drugs and Cosmetics Act restricts the import of:

- Drugs or cosmetics of substandard quality.
- Any misbranded or spurious cosmetic.
- Any adulterated or spurious drug.
- Any patent or proprietary medicine with no description of the formula or list of active ingredients included in it, along with the quantities thereof.
- Any drug which purports or claims to cure or mitigate any such disease or ailment in the form of a statement, design, or device accompanying it.
- Any cosmetic includes an ingredient that may render it unsafe or harmful for consumption.
- Drugs or cosmetics are prohibited from import under these provisions.

Import of medical devices:

The Ministry of Health and F.W. under Gazette notification S.O. 1468 (E) dated 6/10/2005 declared the following sterile devices to be considered as drugs under Section 3 (b) (iv) of the Act.

1. Cardiac Stents. 2. Drug Eluting Stents. 3. Catheters. 4. Intra Ocular Lenses. 5. I.V. Cannulae. 6. Bone Cements. 7. Heart Valves. 8. Scalp Vein Set. 9. Orthopedic Implants. 10. Internal Prosthetic replacements.

It was also notified vide GSR 627 (E) dated 7/10/2005 that control over manufacture of these devices would be exercised by CLAA i.e. DCG(I) under the said Rules. The Ministry of Health and Family Welfare have now approved the following procedures to be adopted in respect of licensing of import as well as manufacture of these Medical Devices in the country.

These "Notified" device categories must obtain an Import License by submitting a Device Master File (DMF) for each product and a Plant Master File (PMF) for each manufacturing site. Once approved, the medical devices are registered under the Import License associated with the primary manufacturing location.

Import and registration of cosmetics:

Cosmetics Import Registration Certificate: Once a cosmetic product is successfully registered via the online portal (the "SUGAM" portal), an Import Registration Certificate will be issued by the Central Licensing Authority, under Rule 13 of the Cosmetics Rules 2020, for the product's import into and use in India.

All cosmetic products that are imported for sale in India need to be registered with the licensing authority as defined under Rule 21 of Drugs & Cosmetics Rules, 1945. The application should be filed along with a fee of USD 250 or its equivalent to Indian rupees for each cosmetic brand. The registration certificate (Form 43) is valid for three years from the issue date.

The session was then concluded by Dr Bangarurajan by taking questions from staff and students. More than 90 students and staff were fruitfully benefited with this invited virtual guest lecture.

Dr S Ponnusankar
Co-ordinator


Krishnarajan Bangarurajan is presenting
Drugs and Cosmetics Act and Rules:
Central Responsibilities (CDSCO):
New Drug Approvals/Medical Devices
Import of Drugs/Medical Devices/Cosmetics
Clinical Trails
Standards for Drugs
Amendments to Act and Rules
Pharmacovigilance
State Responsibilities (SLA):
License for Manufacture, Sale and Distribution
Monitoring quality of Drugs and Cosmetics
Investigations and Prosecutions
Krishnarajan Bangarurajan
Pradhiksha Murugesan
Pratheksha Suresh
Manojkumar Venkatesan
Jessica Samson
Arush Vijan 18PO 1273
91 others
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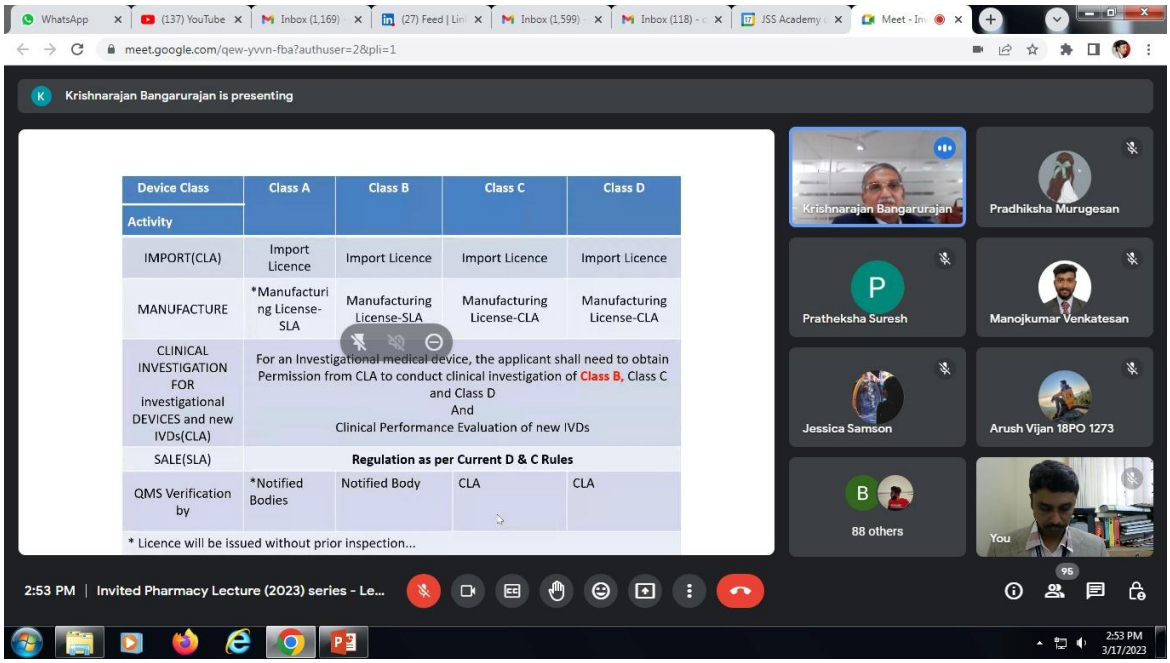
Krishnarajan Bangarurajan is presenting
Device Class / Activity
Class A
Class B
Class C
Class D
IMPORT(CLA)
Import Licence
Import Licence
Import Licence
Import Licence
MANUFACTURE
*Manufacturing License-SLA
Manufacturing License-SLA
Manufacturing License-CLA
Manufacturing License-CLA
CLINICAL INVESTIGATION FOR investigational DEVICES and new IVDs(CLA)
For an Investigational medical device, the applicant shall need to obtain Permission from CLA to conduct clinical investigation of Class B, Class C and Class D
And
Clinical Performance Evaluation of new IVDs
SALE(SLA)
Regulation as per Current D & C Rules
QMS Verification by
*Notified Bodies
Notified Body
CLA
CLA
* Licence will be issued without prior inspection...
Krishnarajan Bangarurajan
Pradhiksha Murugesan
Pratheksha Suresh
Manojkumar Venkatesan
Jessica Samson
Arush Vijan 18PO 1273
88 others
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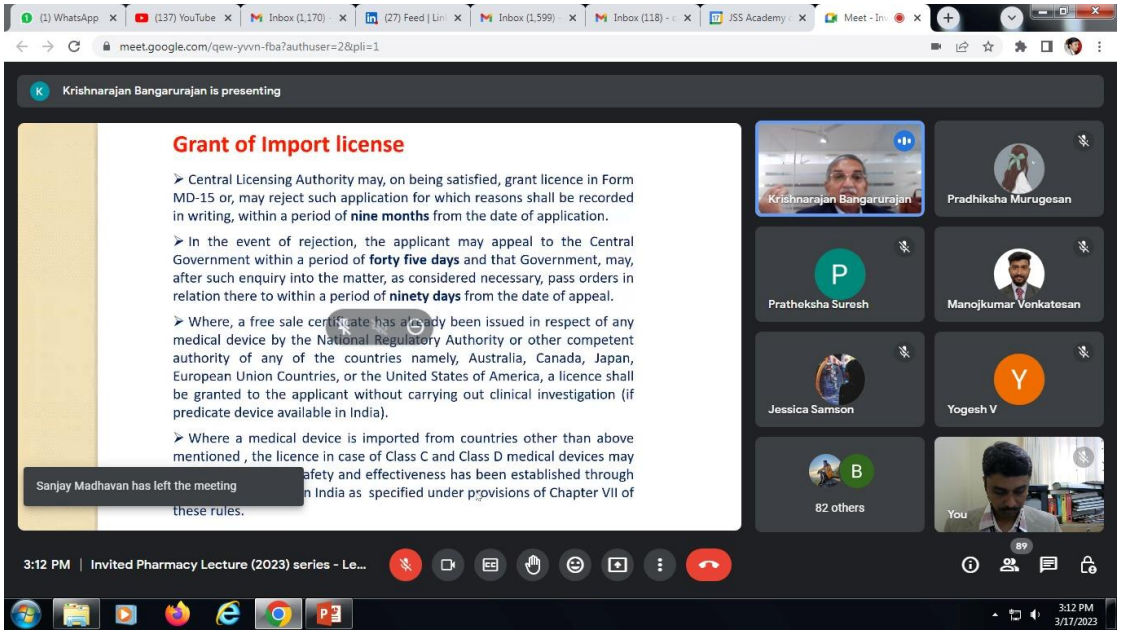
Krishnarajan Bangarurajan is presenting
Grant of Import license
➢ Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.
➢ In the event of rejection, the applicant may appeal to the Central Government within a period of forty five days and that Government, may, after such enquiry into the matter, as considered necessary, pass orders in relation there to within a period of ninety days from the date of appeal.
➢ Where, a free sale certificate has already been issued in respect of any medical device by the National Regulatory Authority or other competent authority of any of the countries namely, Australia, Canada, Japan, European Union Countries, or the United States of America, a licence shall be granted to the applicant without carrying out clinical investigation (if predicate device available in India).
➢ Where a medical device is imported from countries other than above mentioned , the licence in case of Class C and Class D medical devices may
afety and effectiveness has been established through
n India as specified under provisions of Chapter VII of these rules.
Sanjay Madhavan has left the meeting
Krishnarajan Bangarurajan
Pradhiksha Murugesan
Pratheksha Suresh
Manojkumar Venkatesan
Jessica Samson
Yogesh V
82 others
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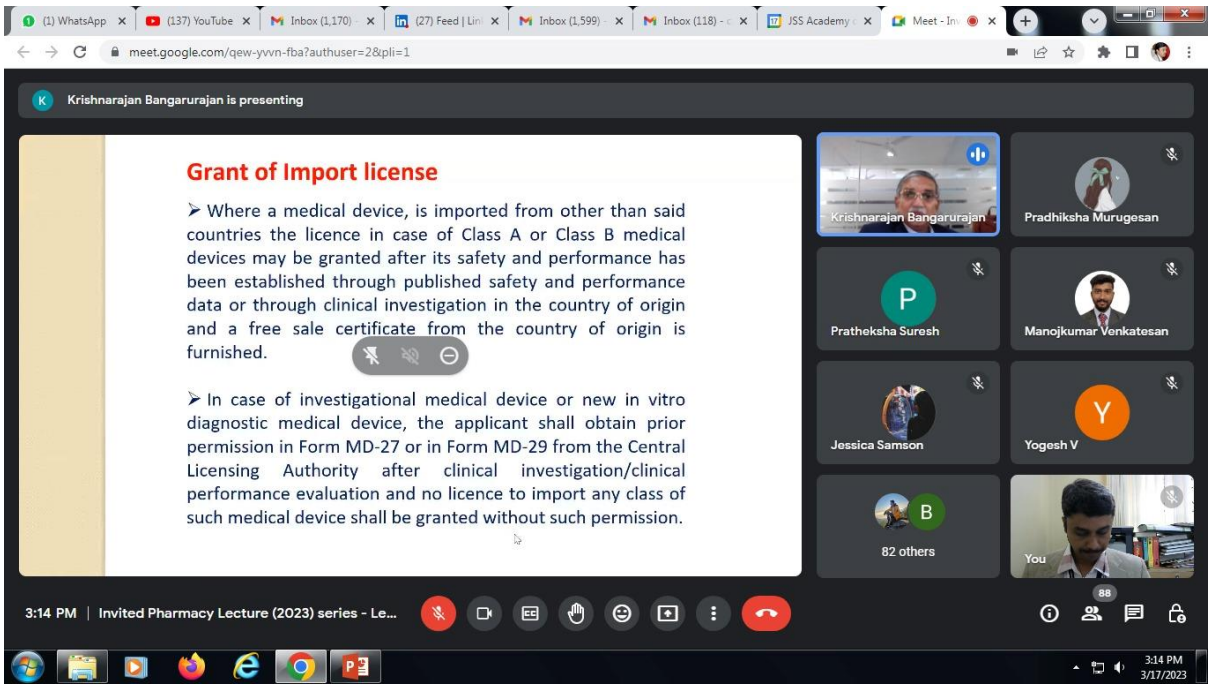
Krishnarajan Bangarurajan is presenting
Grant of Import license
➢ Where a medical device, is imported from other than said countries the licence in case of Class A or Class B medical devices may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.
➢ In case of investigational medical device or new in vitro diagnostic medical device, the applicant shall obtain prior permission in Form MD-27 or in Form MD-29 from the Central Licensing Authority after clinical investigation/clinical performance evaluation and no licence to import any class of such medical device shall be granted without such permission.
Krishnarajan Bangarurajan
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Manojkumar Venkatesan
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Yogesh V
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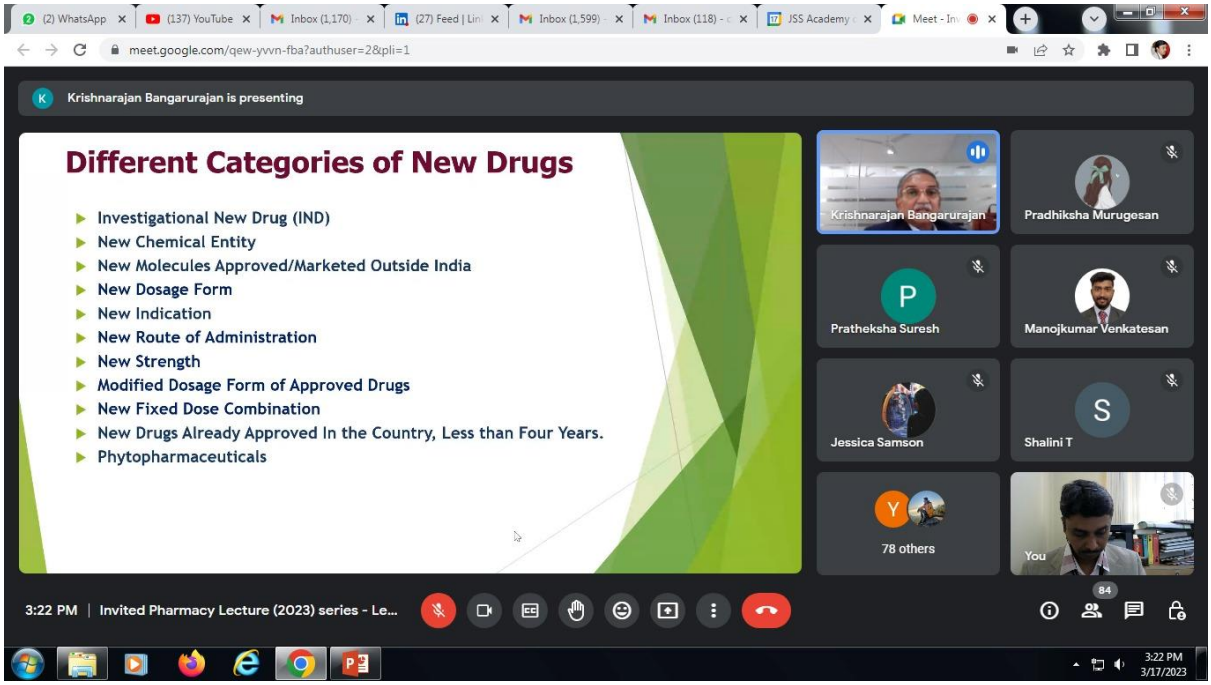
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Krishnarajan Bangarurajan is presenting
Different Categories of New Drugs
Investigational New Drug (IND)
New Chemical Entity
New Molecules Approved/Marketed Outside India
New Dosage Form
New Indication
New Route of Administration
New Strength
Modified Dosage Form of Approved Drugs
New Fixed Dose Combination
New Drugs Already Approved In the Country, Less than Four Years.
Phytopharmaceuticals
Krishnarajan Bangarurajan
Pradhiksha Murugesan
Pratheksha Suresh
Manojkumar Venkatesan
Jessica Samson
Shalini T
78 others
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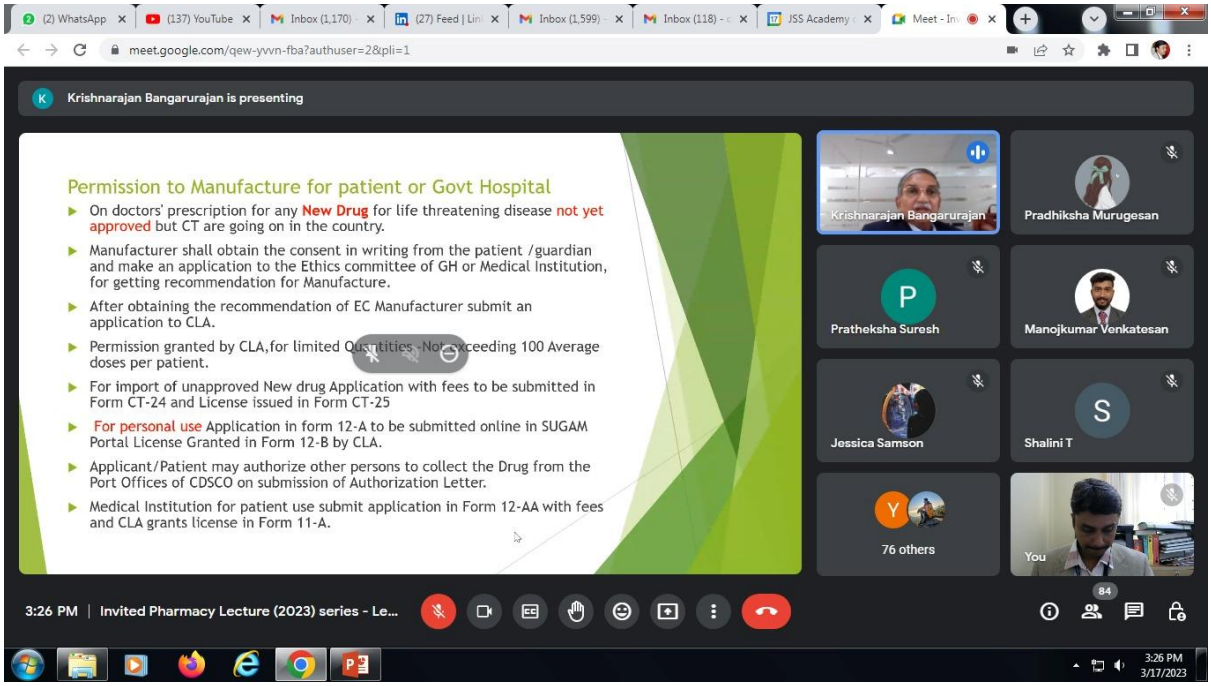
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Krishnarajan Bangarurajan is presenting
Permission to Manufacture for patient or Govt Hospital
On doctors' prescription for any New Drug for life threatening disease not yet approved but CT are going on in the country.
Manufacturer shall obtain the consent in writing from the patient /guardian and make an application to the Ethics committee of GH or Medical Institution, for getting recommendation for Manufacture.
After obtaining the recommendation of EC Manufacturer submit an application to CLA.
Permission granted by CLA,for limited Quantities -Not exceeding 100 Average doses per patient.
For import of unapproved New drug Application with fees to be submitted in Form CT-24 and License issued in Form CT-25
For personal use Application in form 12-A to be submitted online in SUGAM Portal License Granted in Form 12-B by CLA.
Applicant/Patient may authorize other persons to collect the Drug from the Port Offices of CDSCO on submission of Authorization Letter.
Medical Institution for patient use submit application in Form 12-AA with fees and CLA grants license in Form 11-A.
Krishnarajan Bangarurajan
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Pratheksha Suresh
Manojkumar Venkatesan
Jessica Samson
Shalini T
76 others
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