Opioid Access and Documentations For MO

History of Opium in India - Some Milestones

15th century first brought by Arabs

16-17th century -Opium achieved status as a commodity by Mughal era

18th century - Opium cultivation and illicit trading started by East India company

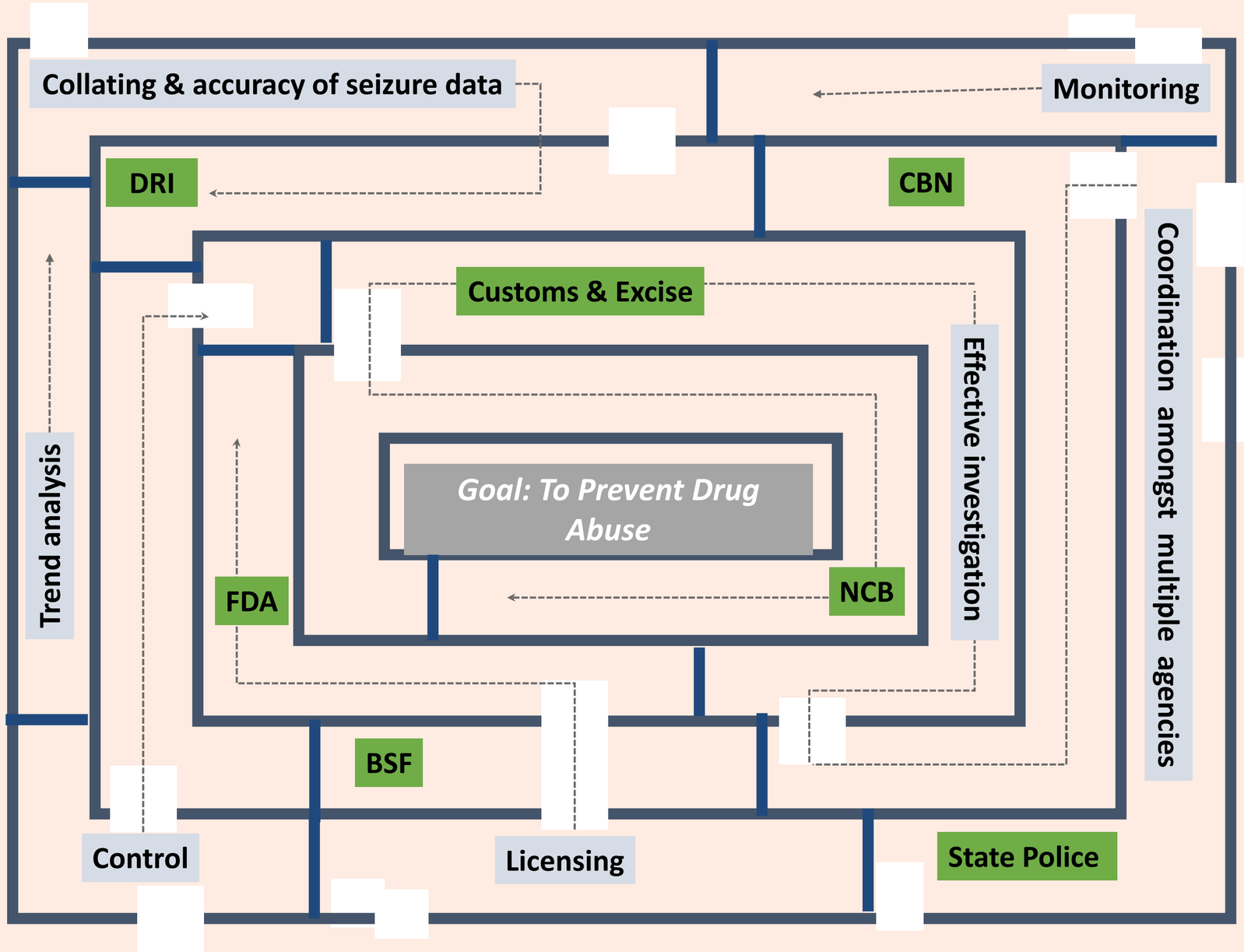
1838-1858 British won the opium war against China, the trade was legalised

Global awakening – Organized Conventions; Shanghai(1906), Hague(1912) & Geneva(1925) on national and international regulations to curb this form of usage of opioids

In early 20th century the British government in India shaped its narcotic laws, Thus the NDPS Act of post-independent India also retained the regulatory language and continued

ENFORCEMENT FRAMEWORK FOR LICIT ENTITIES: “A Maze”

- Lack of balancing NDPS Act-1985(30yrs)
- Even after knowing its utility for pain management
- Complex regulations and lack of uniformity
- Harsh punishments for minor errors

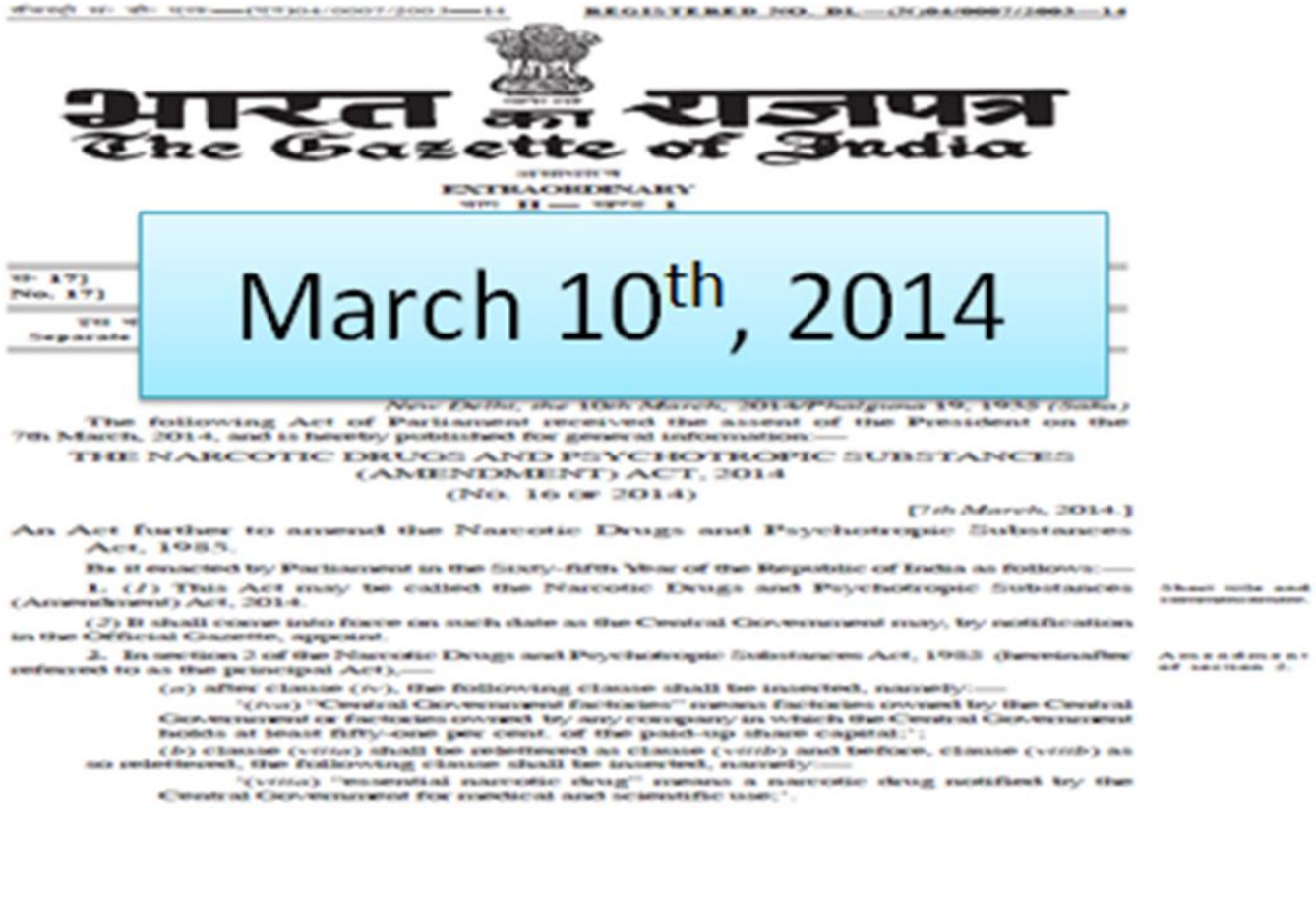


Enforcement Authority

Responsibility

A BALANCED APPROACH TO THE USE OF OPIODS IN ACUTE AND CANCER PAIN – DR. SUSHMA BHATNAGAR

NDPS-ACT- 2014



REGISTERED NO. DL—(N)04/0007/2003—14

भारत का राजपत्र
The Gazette of India

EXTRAORDINARY

March 10th, 2014

New Delhi, the 10th March, 2014/Phalguna 19, 1935 (Saka)

The following Act of Parliament received the assent of the President on the 7th March, 2014, and is hereby published for general information:—

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (AMENDMENT) ACT, 2014

(No. 16 of 2014)

[*7th March*, 2014.]

An Act further to amend the Narcotic Drugs and Psychotropic Substances Act, 1985.

Be it enacted by Parliament in the Sixty-fifth Year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Narcotic Drugs and Psychotropic Substances (Amendment) Act, 2014.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

61 of 1985.

Amendment of section 2.

2. In section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (hereinafter referred to as the principal Act),—

(*a*) after clause (*iv*), the following clause shall be inserted, namely:—

'(*iva*) "Central Government factories" means factories owned by the Central Government or factories owned by any company in which the Central Government holds at least fifty-one per cent. of the paid-up share capital;';

(*b*) clause (*viiia*) shall be relettered as clause (*viiib*) and before, clause (*viiib*) as so relettered, the following clause shall be inserted, namely:—

'(*viiia*) "essential narcotic drug" means a narcotic drug notified by the Central Government for medical and scientific use;';

BASIS OF NDPS AMENDMENTS 2014

- “A balanced and pragmatic approach”
- Bring uniformity and simplify procedures with respect to availability of opioids within the country

Ensure adequate availability of Narcotic Drugs, Psychotropic and controlled substances for medical and scientific purposes

Simultaneously prevent abuse, diversion, trafficking and mitigate diversion from licit to illicit channels

By Ensuring Balance in National Policies on Controlled Substances

LEARN NEW DEFINITIONS

Essential Narcotic Drugs (ENDs): The list of ‘notified’ medicines which have been identified by the office of Drug Controller General of India, for the purpose of medical use in an RMI for managing moderate to severe pain.

Medical Institutions: A hospital, dispensary, a clinic or an institution that offers services or facilities requiring diagnosis, treatment or care of illness, disease, injury, deformity or abnormality established, administered or maintained by the government or Municipal Corporation, Municipal Council or Zilla Parishad or any person or body of persons.

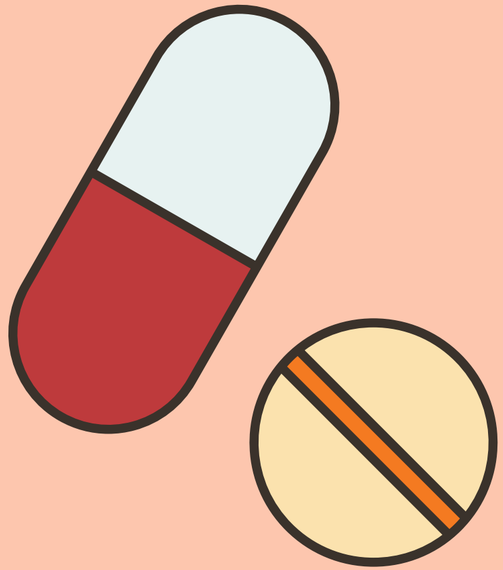
Recognized Medical Institutions (RMI): A medical institution, officially recognised by the State Drug Controller for the purpose of purchasing, possessing and dispensing essential narcotic drugs for medical and scientific purposes.

The Officer in charge of the RMI: Any person registered as medical practitioner under the Indian Medical Council Act 1956, or registered as dentist under the Dentist Act 1948, and who has undergone training in the medical use of ENDs.

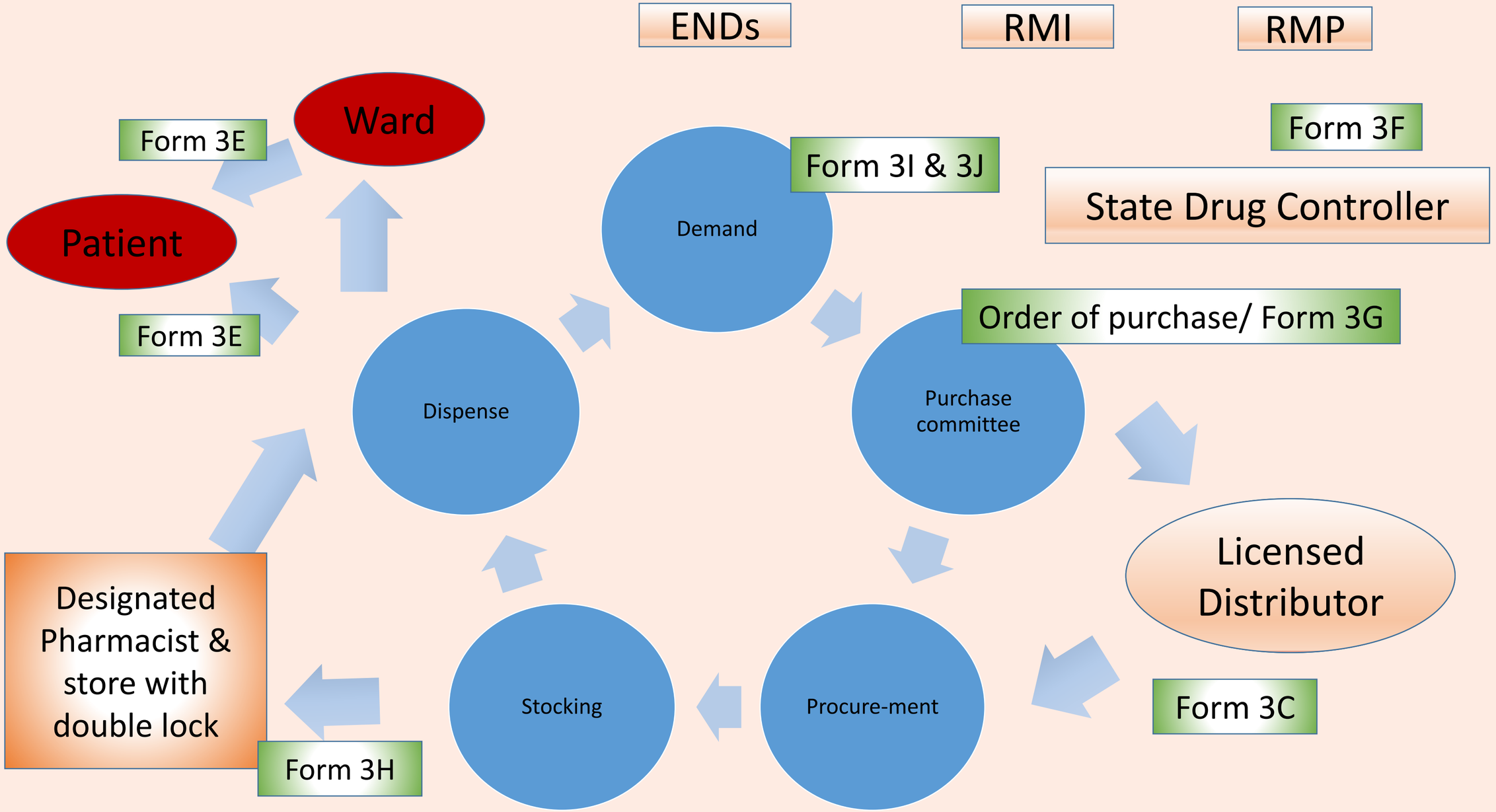
OPIOIDS IDENTIFIED FOR MEDICAL USE

(approved by the Drug Controller General of India)

- Morphine
- Methadone
- Codeine
- Hydrocodone
- Oxycodone
- Fentanyl
- Tramadol listed in 2018



PROCUREMENT OF ANY DRUG BY INSTITUTE/CLINIC



Appendix 14 - Order of Purchase

(See Rule – 57F)

To

(Name and Address of the supplier)

1. Name and address of the recognized medical institution, which places the order.
2. Description of the quantity for which order is placed.
3. Whether the institution has been recognized by the Drug Controller.
   (A photocopy of the recognition is to accompany each order of purchase).'
4. Whether this order is covered by the estimate approved by the Drug Controller.
   (A photocopy of the approved estimate is to accompany each order of purchase).
5. Details of other orders of purchase made during the year.

Sl No	Quantity	To whom order was placed

Station

Signature of the person authorized to place order

Name and Designation

1. Form3B
2. Form3C
3. Form3D
4. Form3E
5. Form3F
6. Form3G
7. Form3H
8. Form3I
9. Form3J

FORMS

PREREQUISITES FOR RMI

- The institution must have an Officer in-charge of ENDs responsible for managing ENDs at the RMI
- The Officer in-–charge must be a qualified doctor and registered with the MCI or the DCI and be trained in the medical use of opioids
- The institution must have the facility for safe storage for ENDs; a double locking system e.g. a cupboard with two locks
- The facility should have basic infrastructure facilities and staff for evaluating and managing the treatment of the patients who would need ENDs
- The facility should provide proof of space and personnel for the mandated record keeping
- The facility should have capacity to maintain a register of consumption for each opioid

RESPONSIBILITIES OF RMI

- RMI shall ensure and maintain the Minimum Mandatory Requirements
- Government hospitals must submit the annual consumption report
- The drugs shall be prescribed only by Registered Medical Practitioners
- Every RMI shall designate one or more RMP who shall be using essential narcotic drugs. When there are more than one registered medical practitioners, one of them shall be designated as Overall officer-In-Charge
- The RMI shall ensure that the RMP, has completed the certified training in medical use of ENDs as per the Rules
- The drugs shall be purchased only from authorized chemists/ dealers. The list for the same should be available with the authorizing State agency. The list of licensed manufacturers would be available with the Narcotic Commissioner at the centre

- ENDs shall be prescribed as per the rules and dispensed only to selected patients, registered with the RMI

- END stock with the RMI shall not be transferred, loaned or sold to other institutions except with the written permission of the Drugs Controller of the state

- All records and registers shall be maintained for a period of two years from the last entry

- The expired stock of ENDs shall be destroyed in the presence of an official designated by the State Drug Controller / Commissioner of Food & Drugs Control AdministrationThe unused ENDs returned by the patients, shall be considered as receipts, provided the drugs are not damaged or otherwise unacceptable for use

- RMI shall submit the annual return before 31st of March every year even if they have not used any ENDs in the preceding year

- If there is a change in the ‘Officer in charge’, the details with date of change shall be intimated to the State Drug Controller / Commissioner of Food & Drugs Control Administration, within seven days for re-issue of the RMI certificate with endorsement of the newly employed doctor in charge of the RMI.

- The RMI shall inform the State Drug Controller / Commissioner of Food & Drugs Control Administration, in writing, in the event of any change in the constitution of the RMI operating under this approval.

- Where any change in the constitution or address the designated medical officer in charge, shall inform the Commissioner of Food & Drugs Control Administration in writing within thirty days from the date of such change, for issue of fresh Certificate of Recognition.

- If an RMI ceases to exist, the matter shall be informed with details of balance stock of ENDs, if any, and the authorisation certificate surrendered to the State Drug Controller / Commissioner of Food & Drugs Control Administration within 30 days, who will then issue orders for the disposal of the balance ENDs.

RESPONSIBILITIES OF MEDICAL OFFICER IN-CHARGE OF RMI

- Ensure that ENDs shall be dispensed to the selected patients who are registered with the RMI
- Ensure that RMI uses ENDs in the licit manner specified in the Rules
- Ensure that prescriptions from the RMI are made rationally on valid clinical grounds
- Ensure that the stock of ENDs in the RMI are uninterrupted and adequately available for medical needs of its patients, by sending estimates, and other details to the office of FDA / SDC in time
- Ensure that ENDs are kept under safe custody to prevent possible misuse and diversion

- Maintain record in Form No. 3E for each patient, which shall be preserved for a minimum period of two years from the date of last entry

- Maintain record of all receipts and disbursements of essential narcotic drugs in Form No. 3H which shall be preserved for a minimum period of two years from the date of last entry

- Shall authorize the deputed qualified personnel to carry such quantity of ENDs as may be required for treatment of home care patients registered with the RMI. Maintain the record of issue and receipt of ENDs used for such home care patients

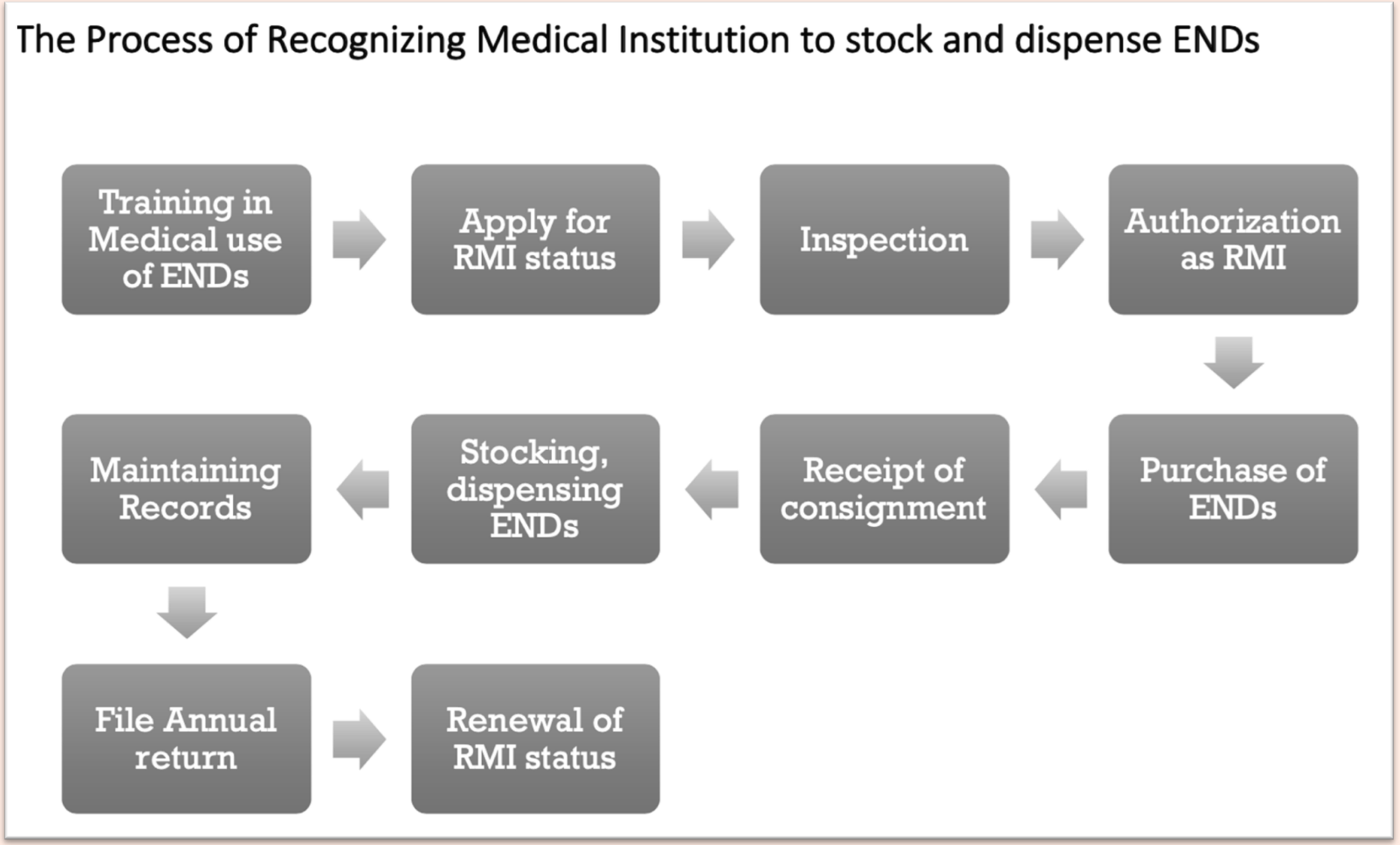
- File return for a calendar year on or before the 31st of March of the subsequent year in Form No. 3-I to the Controller of Drugs

- Ensure that all records are available to inspectors from the DC office, for a period of two years from the date of last transaction

- Ensure that the expired stock of ENDs is destroyed in the presence of a representative of the State Drug Controller / Commissioner of Food & Drugs Control Administration

- In the event of any change in the constitution of the RMI, the designated Officer in charge, shall inform the State Drug Controller / Commissioner of Food & Drugs Control Administration in writing within thirty days from the date of such change for issue of fresh Certificate of Recognition

SUMMARY OF THE PROCESS OF RMIS



TRAINING

The Medical Institution ensures that a Registered Medical Practitioner is trained in the medical use of opioids.

Medical Training

- MD Palliative Medicine
- Diploma in Palliative Medicine
- IAPC courses- Part A and B
- 6 weeks fellowship program from IPM Calicut, Pallium India, MNJ
- 3 day course designed by Government Of India and AIIMS designed for prescription and storage of opioid in hospital

RENEWAL OF RMIS

- The application for renewal [form no 3F] is sent from the RMI, at least 60 days prior to the date of expiry of recognition (before the 30th of November each year) to the State Drug Controller stating the following.
  - Balance of each END from the year's stock
  - The total quantity purchased during the year
  - The total quantity disbursed in the current year and the balance quantity
  - The quantity needed for next year

- It is recommended that the RMI should keep enough END stock, to cover requirements for at least 3 months to ensure uninterrupted supply

- The order of purchase for the next consignment is readied and sent accordingly to the supplier to ensure at least 3 month’s buffer stock

- The RMI can repeat the order of purchase during the year as per the need, if there is unexpected increase in the number of patients needing ENDs

- If the RMI requires to revise the annual estimate, application should be submitted to the controller of drugs by 31st Aug of the calendar year. The designated RMP shall record the justification for the same while filing the annual return in Form 3I

GUIDELINES FOR INDIVIDUAL REGISTERED MEDICAL PRACTITIONERS

Any individual Registered Medical Practitioner [RMP] may hold a small stock of ENDs as indicated below, for emergency purposes in her/his own practice, without any special authorisation.

1. Morphine formulations – total quantity not more than 500 mg
2. Codeine formulations – not more than 2000mg
3. Hydrocodone -- total quantity not more than 320 mg
4. Fentanyl – 2 TD patches one each of 12.5 ug / hour and 25 ug / hour
5. Oxycodone -- total quantity not more than 250 mg
6. Methadone – the upper limit of quantity is not yet mentioned in the rules

PRESCRIBING ENDS

- Capital writing
- Dated and signed by the RMP with full name, address and her/his registration number
- Specify name, address of the person to whom prescription is given
- Mention the total quantity of the END
- Mention daily dose
- Mention the duration of the prescription

Thank You