MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP

10th PAN-RUSSIAN GMP CONFERENCE

"Manufacturing authorization system for production of medicinal products for human use in India"

GAURAV KUMAR
Deputy Drugs Controller (India)
CDSCO, Govt. of India

Introduction

DRUGS REGULATION

- *Drugs fall under the **Concurrent List** of the Constitution of India.*
- *Drugs & Cosmetics Act is a **Central Act** enforced*

  by both Central and State Governments.
- *Extended to Whole of India*

Background

- *Federal structure, enforced by both, Central and State authority*
  - ***Central*** - ***CDSCO***
  - ***State/UT*** *Drug Control Authorities (28 STATES + 8 UT DCAs)*
- ***Drugs and Cosmetics Act, 1940***
    - *Drugs Rules*
    - *Medical Devices Rules, 2017*
    - *New Drugs And Clinical Trial Rules, 2019*
    - *Cosmetics Rules, 2020*
- ***Import, Manufacture, Sale and Distribution*** *of Drugs, Cosmetics, Medical Devices, Vaccines, Veterinary medicines, blood and blood products etc.*
- *Export, through various guidelines and administrative orders*

Responsibilities

CDSCO

- New Drugs
- Clinical Trials
- Vaccines
- Medical Devices (C & D)
- All Import and Registration
- Amendments to Rules
- International cooperation
- WC
- Export NOC

STATE/UT

- Manufacturing license.
- Sale and Distribution
- Medical Devices (A & B)

JOINT

- LVP, Blood Centres
- Joint Inspections
- Sampling and Testing
- Prosecutions
- WHO-GMP

What Do We Regulate

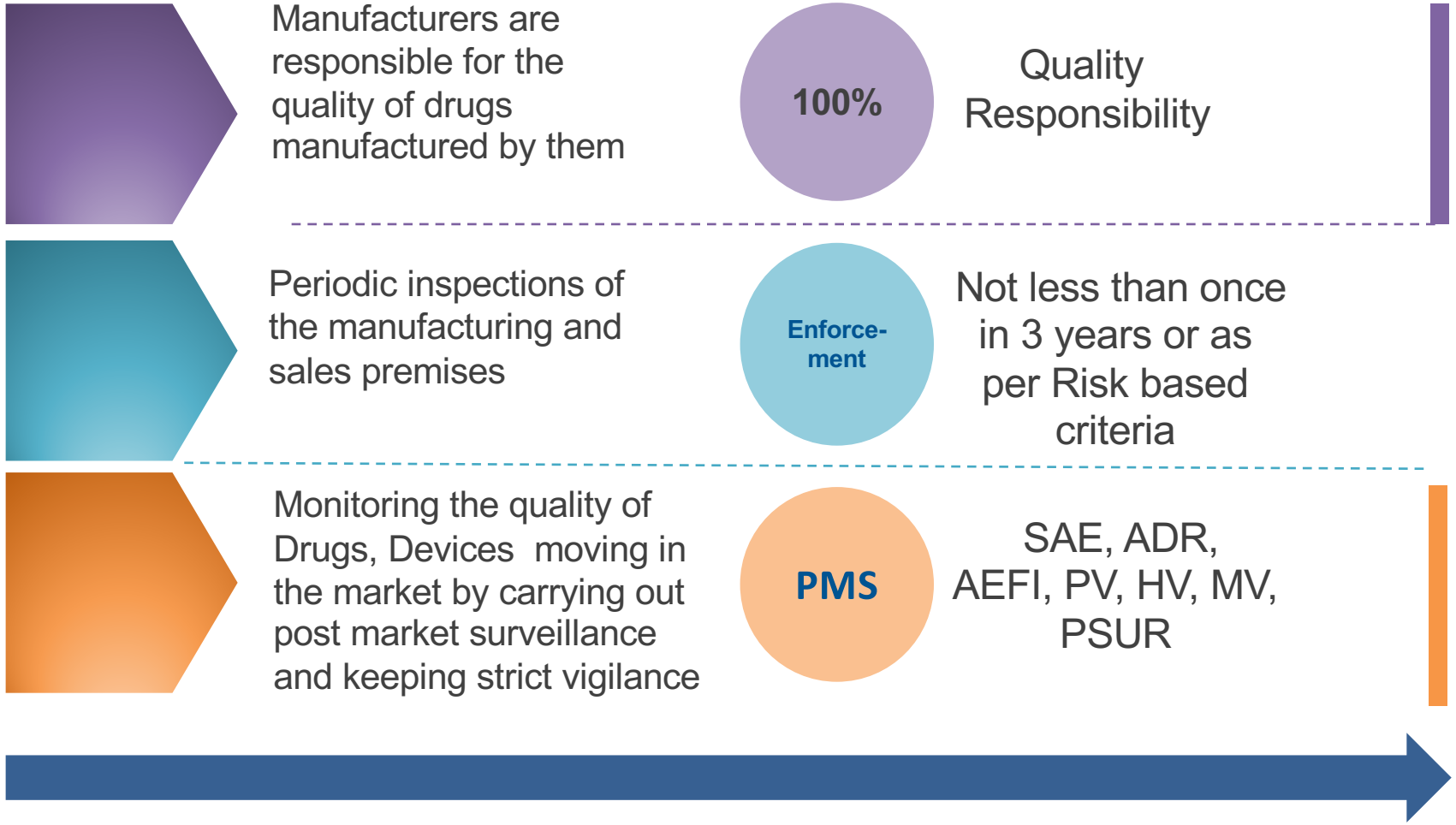
- Drugs
  (New Drugs, FDCs, Vaccines, LVPs, r-DNA, Regenerative medicines)
- Cosmetics
- Medical Devices and In-vitro Diagnostics
- Blood Banks and Blood Products
- LVPs

- Clinical Trials
- Ethics Committee
- Clinical site registration
- Subordinate Legislations (Rules, Regulations, Guidances, orders)
- Veterinary Drugs
- Phyto-pharmaceuticals
- Radiopharmaceuticals
- Import
- Export
- International Collaborations

Functions - CDSCO

Head Quarters	Regional Offices
New Drugs (New Drugs, IND, SND, FDC)	CoPP (WHO-GMP Scheme) (For export registration)
Global Clinical Trials (IND, NCE, NBE, New Drugs)	Import and Export (Through notified port offices)
Biologicals (Vaccines, r-DNA, NBE, Regenerative medicines, Blood centres and Blood products)	Laboratory Inspections (Approved Testing Laboratories)
Medical Devices (Market authorizations for Class C&D)	NOC for Export (Unapproved, and banned drugs)
Clinical Site Registrations	Sampling (To ascertain the quality of Drugs, Cosmetics and Medical Devices)
Import and Registration (Drugs, Cosmetics, Biologicals, Medical Devices)	Joint Inspections (Including Vaccines, r-DNA, LVPs and Blood Centre)

Scheme of Drug Regulations



"System of Licensing and Inspections"

Manufacturing Authorization:

- *Legal permission - To manufacture drug products*

  - Issued by State Licensing Authority

- *Manufacturers shall comply with the provisions of the Act and of the Rules*

  including GMP

- *As per the Drugs Rules license are granted under various Schedules for Import, Manufacture, Sale and Distribution of drugs i.e. which specifies the requirements for*
  - ***Biological and Special Products,***
  - ***Blood Centers,***
  - ***Ophthalmic Preparations,***
  - ***Narcotic and habit forming Drugs***
  - ***Patent & Proprietary medicines,***
  - ***Disinfectants fluids etc***

- *Validates - the manufacturer's capability to produce safe and effective drugs*

Regulation on inspection

Drugs and Cosmetics Act and Rules provides

- ***Legal provisions*** *authorizing the inspectorate to inspect and enforce GXP throughout the supply chain are specified in Section 22 (Power of Inspector) of Drugs & Cosmetics Act,*
- *Rule 51 - Duties of Inspectors of premises licensed for sale,*
- *Rule 52- Duties of Inspectors specially authorized to inspect the manufacture of drugs,*
- *Rule 78 & 78A - Specifies various conditions of license which also includes the provision for inspection of the manufacturing premises.*
- *Rule 79 - Specifies inspection of manufacturing site before grant of license.*

Regulation on inspection

GMP and Requirements of Premises, Plant and Equipment for Pharmaceutical Products	
Part I	Good Manufacturing Practices for pharmaceutical products: Main principles
Following Parts provides specific requirements for manufacture of	
Part II	Sterile products, parenteral Preparations (small volume injectables and large volume parenteral) and Sterile ophthalmic preparations
Part III	Pharmaceutical products containing hazardous substances-Steroids , Sex hormones, cytotoxic substances etc
Part IV	Biological products
Part V	Radiopharmaceutical Products
Part VI	Phytopharmaceuticals
Part VII	Investigational Pharmaceutical products for clinical trials in humans
Part VIII	Oral dosage forms (tablets and capsules)
Part IX	Oral Liquids (syrups, elixirs, emulsions and suspensions)
Part X	Topical products (external preparations)
Part XI	Metered- dose- inhalers
Part XII	Active pharmaceutical Ingredients
Part XIII	Plant and equipment

Summary

- *Regulation is established in India through a system of licensing and inspection*
- *There are joint responsibilities of CDSCO and State regulators for licensing and inspection of all drugs, biologicals including vaccines.*
- *Joint inspections with State licensing authorities for grant of licence and periodic inspections.*
- *Risk-based inspection is mandated in the Rules*
- *The manufacturer has to comply with the requirements of GMP and Requirements of Premises, Plant and Equipment for Pharmaceutical*
- *Marketers are also made responsible for ensuring quality of the pharmaceutical products marketed by them around the world.*
- *QR code/Bar code on all APIs and top 300 brands of formulations.*


THANK
YOU!


СПАСИБО