INDIA UPDATES ON MEDICAL DEVICES

Aseem Sahu
Deputy Drugs Controller (India)
CDSCO (HQ), MoH&FW,
FDA Bhawan, New Delhi

Overview

- Introduction
- Current regulation
- Reforms & initiatives taken
- Proposed regulatory framework

INDIA-GEOGRAPHY

- Seventh-largest country by area all over world.
- Second-most populous country (with over 1.2 billion people).
- 29 states and 7 union territories.
- Seventh largest economy in the world as measured by GDP
- Third largest economy by Purchasing Power Parity(PPP)
- India is classified as a newly industrialised country, one of the G-20 major economies a member of BRICS and a developing economy with an average growth rate of approximately 7% over the last two decades.

CDSCO - GEOGRAPHICAL LOCATION

CDSCO (HQ), DELHI

- North Zone (Ghaziabad)
- West Zone (Mumbai)
- South Zone (Chennai)
- East Zone (Kolkata)
- Zone (Ahmadabad)
- Zone (Hyderabad)

29 States

7 Union Territories

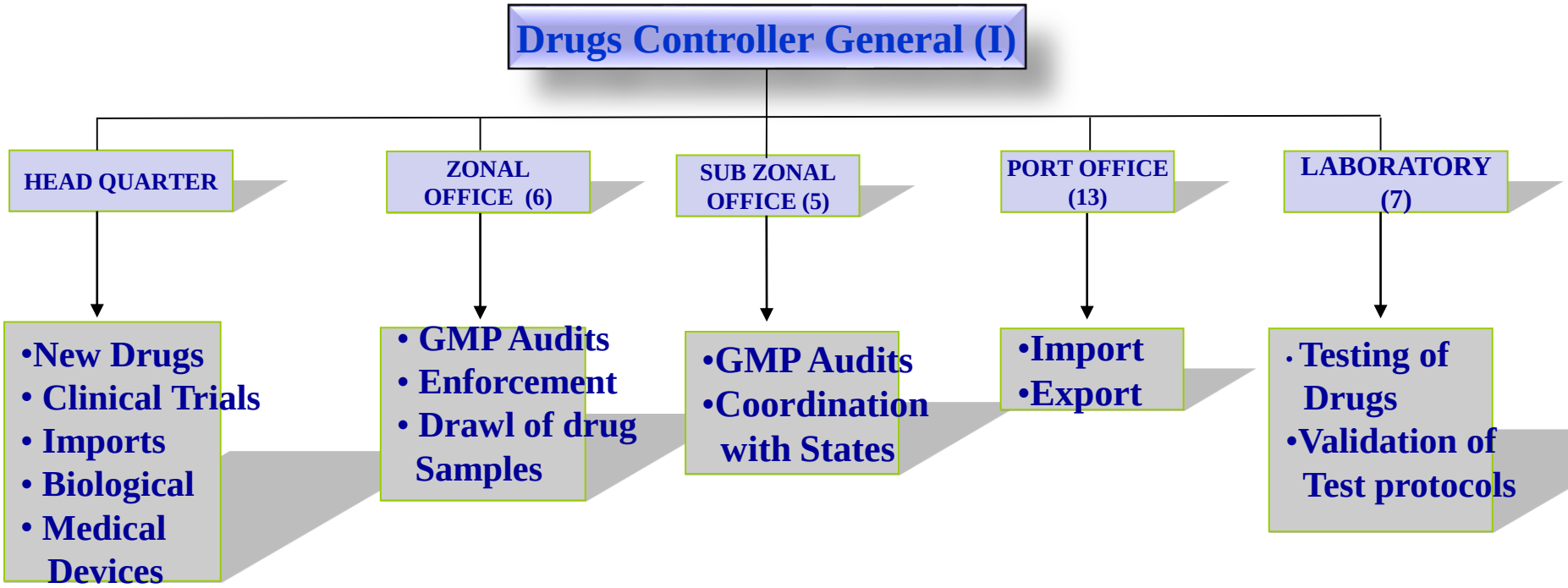
Port Offices/Airports : 13
Laboratories : 7

CDSCO SUB ZONES

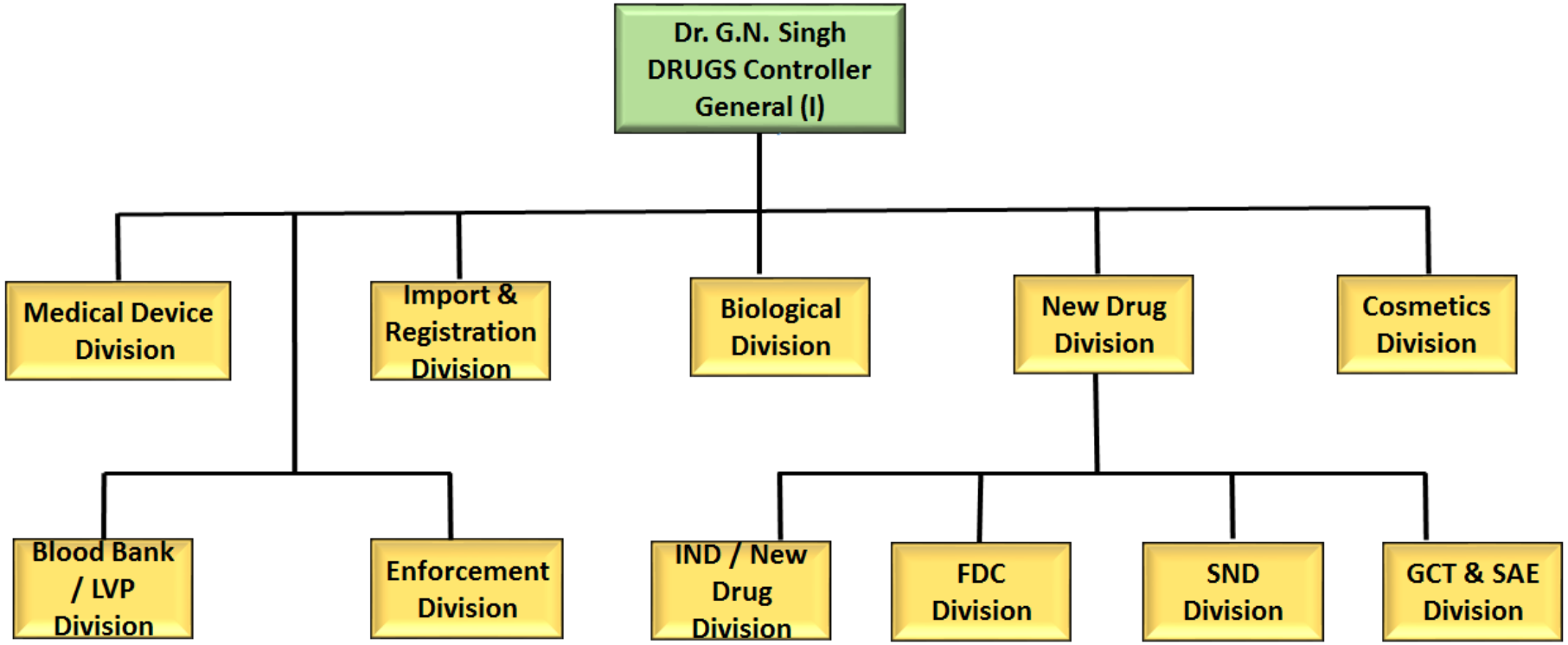
- Sub Zone (Bengaluru)
- Sub Zone (Chandigarh)
- Sub Zone (Jammu) and (Goa)
- Sub Zone (Indore)

•Proposed Zonal/Sub Zonal Offices (1):
•Guwahati

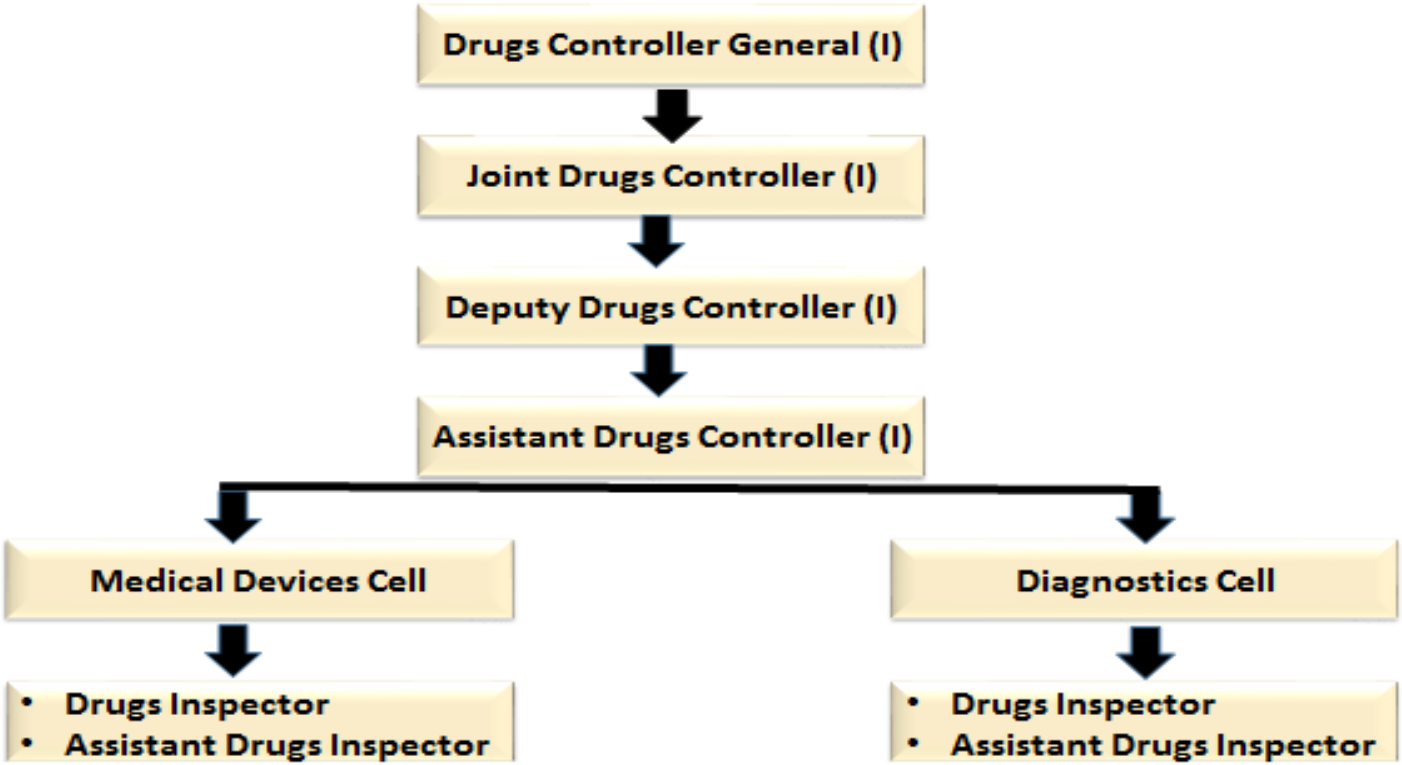
Regulatory Framework (CDSCO)



Major Division of CDSCO



Organogram of Medical Device Division



Drugs and Cosmetics Act 1940 and Rules 1945

This Act is a **Central Act**, enforced by both Central and State Govts.

Objective :

To ensure safety, efficacy and quality of Drugs & Cosmetics. It regulates manufacture, import, Sale & Distribution of Drugs including **Medical Devices** and Cosmetics.

Medical Device Definition :

Section 3 (b) (i)

all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment , mitigation or prevention of any disease or disorder in human beings or animals, ……

Section 3 (b) (iv)

"Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the Board"

Notified Medical Devices

S. No	Name of the device	SLA/CLAA	Date of notification
1	Disposable Hypodermic Syringes	SLA	17-03-1989
2	Disposable Hypodermic Needles	SLA	17-03-1989
3	Disposable Perfusion Sets	SLA	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV and blood grouping sera	SLA	27-08-2002
5	Cardiac Stents	CLAA	06-10-2005
6	Drug Eluting Stents	CLAA	06-10-2005
7	Catheters	CLAA	06-10-2005
8	Intra Ocular Lenses	CLAA	06-10-2005
9	I.V. Cannulae	CLAA	06-10-2005
10	Bone Cements	CLAA	06-10-2005
11	Heart Valves	CLAA	06-10-2005
12	Scalp Vein Set	CLAA	06-10-2005
13	Orthopedic Implants	CLAA	06-10-2005
14	Internal Prosthetic Replacements	CLAA	06-10-2005
15	Ablation Devices	*CLAA	25-01-2016

Regulatory requirements for Medical Devices

Requirements for – Notified medical devices/ IVD kits:

- **Manufacturing License for manufacture**
- **Both Registration Certificate and import license for Import**

Requirements for-non-notified IVD products:

- **Manufacturing License for manufacture**
- **Only import license for Import**

Procedure for registration & Import Licence

Non-notified IVDs

Applicant submit application in **Form 8** (for IL) with fee, Legal, Regulatory and Technical documents through SUGAM portal.

Notified Medical Devices & IVDs

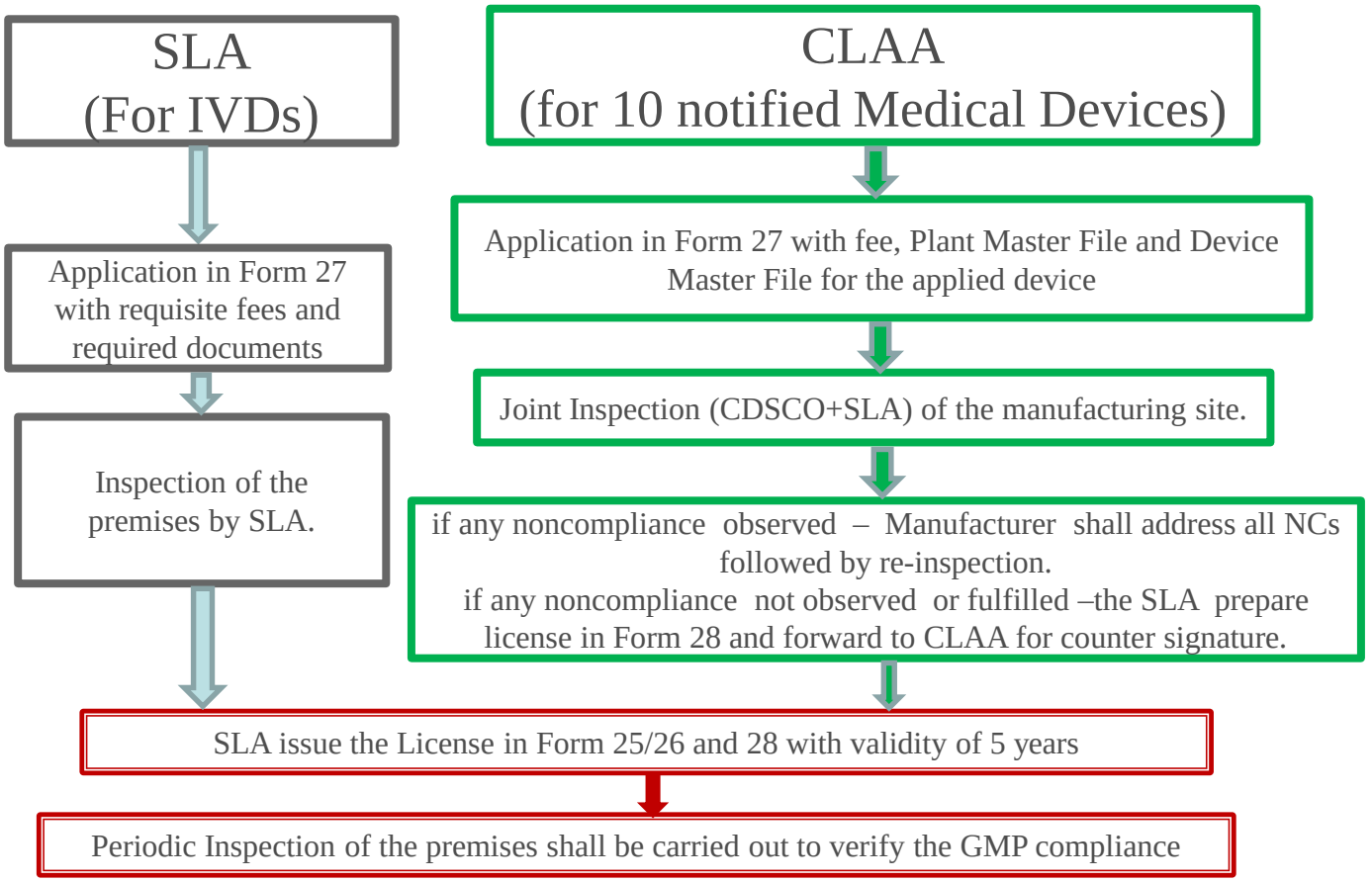
Applicant submit application in **Form 40 (for RC)** with fee, Legal, Regulatory and Technical documents through SUGAM portal.

Review of the Application by CDSCO

If the requirements are found satisfactory - Import License in **Form 10** or RC in **Form 4 1** shall be granted.

If the requirements are not found satisfactory - Query will be raised. Query Reply by the applicant shall be reviewed again and if found satisfactory, IL or RC shall be granted.

Procedure for Manufacturing License



Challenges with current Regulatory Regime:

- Medical devices under the ambit of drug regulations
- Definition & Classification of Medical Devices & IVDs
- GMP Vs QMS
- Requirements for Clinical Evaluation and Investigation
- Standards and Testing
- Manufacturing, import and Market Authorization,

Current Reforms & Initiatives Taken

- SUGAM Online portal has been launched in Nov., 2015 for online submission and process of applications in CDSCO.
- Schedule M-III amended to implement Quality Management System w.e.f 29.06.16.
- Established guidelines, checklists and FAQ for import and manufacturing of Medical Devices (MD) and In vitro diagnostics (IVD).
- Recent Amendments to Rules :
  - Qualification of Technical Staff of the indigenous manufacturer
  - Labeling Provisions
  - Applicable Standards
  - Shelf Life
- Draft Rules for import, manufacture, sale and distribution of medical devices and IVDs have been published on Oct 16th 2016 for public comments. A period of 30 days was given to comment. These draft rules when finalized will be included as a separate chapter under the regime of current Drugs and Cosmetics rules of the present Drugs & Cosmetics Act.
- The process of finalizing separate Medical Device Bill 2016 enlisting comprehensive requirements for medical devices legislations is work in progress.

Medical Device Draft Rules- Chapters

Part - I	Title, Application, Commencement, Definition
Part - II	Classification of MD, Grouping of MD, Essentials Principles
Part - III	Authorities, delegation of powers, Notified bodies, Medical Devices Testing Centres,
Part - IV	Manufacture of MD- Inspection, grant of lic, Suspension, Cancellation, Test License
Part - V	Import of MD-Application, Overseas Inspection, grant of lic, Test lic, Hospital use, Personal use
Part - VI	Labelling requirement
Part - VII	Clinical Investigation- Permission, Medical management, Inspection
Part - VIII	Permission to import or manufacture medical device which does not have predicate medical device
Part -IX	Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body
Part - X	Sale of MD
Part - XI	Miscellaneous – Rejection of application, Debarment of applicant, Exemptions

Medical Device Draft Rules-Schedules

Schedule Number	Title
First	Classification of MD and IVD
Second	Fee
Third	Registration and functions of Notified Bodies
Fourth	Documents required for grant of mfg and Import lic
Fifth	Quality Management System
Sixth	Post Approval - Major and Minor Changes
Seventh	Requirements to conduct Clinical Investigation
Eight	Exemptions

Scheme of proposed regulation

Device Class Activity	Class A	Class B	Class C	Class D
IMPORT	Import Licence	Import Licence	Import Licence	Import Licence
MANUFACTURE	*Exempted	Manufacturing License	Manufacturing License	Manufacturing License
CLINICAL EVALUATION	To conduct clinical investigation CLA approval is required			
SALE	Regulation as per Current D & C Rules			
QMS	*Notified Bodies	Notified Body	Medical Device Officer	Medical Device Officer

* Voluntary only (in case if manufacturer want to)

Regulatory Authorities

Device Class / Activity	Class A	Class B	Class C	Class D
IMPORT	CLA	CLA	CLA	CLA
MANUFACTURE	*SLA	SLA	CLA	CLA
Permission to conduct CLINICAL INVESTIGATION	Permission from CLA			
SALE	**SLA**			
QMS Verification by	*Notified Bodies	Notified Body	CLA	CLA

* Voluntary only (in case if manufacturer want to)

Note: Notified Bodies shall be registered with CLA and shall be audited by CLA.

CDSCO Website: cdsco.nic.in

Email: aseemsahu@yahoo.co.in

Thank You