MEDICAL DEVICES

WHAT IS HAPPENING IN INDIA

CDSCO

M. Mitra
Central drugs Standard Control Organisation
Directorate General of Health services
Government of India

India has a semi federal structure of regulatory set up.

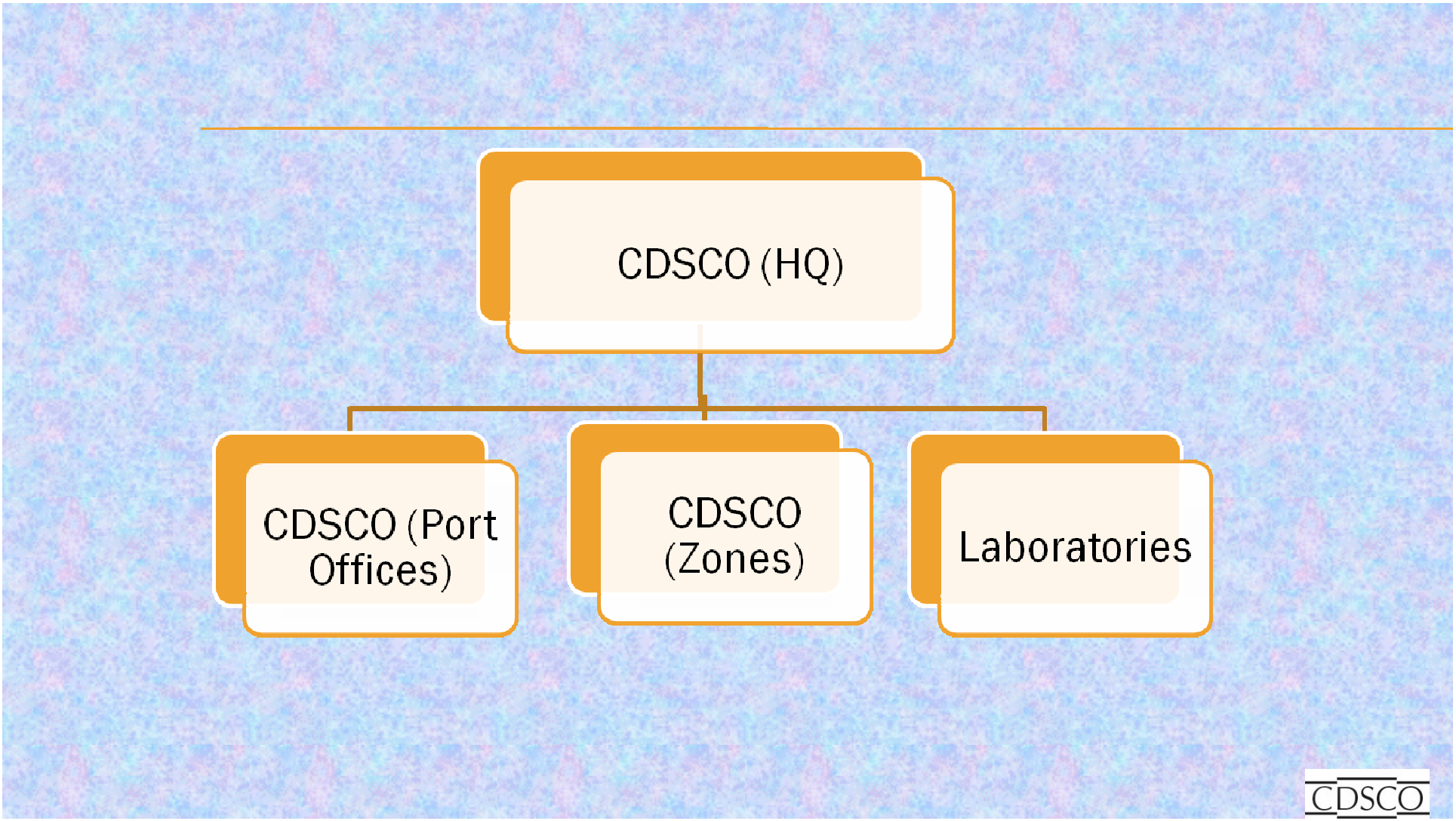
Responsibilities are shared by:

- The CDSCO (The Central Drugs Control)
- States (The States Drugs Control)

CDSCO

- The CDSCO is the Office of the Drugs Controller (India) situated in New Delhi
- The CDSCO is supported by four Zonal Offices and two Sub-Zonal offices
- There are Seven Laboratories to for testing of capacity of samples

CDSCO


CDSCO (HQ)
CDSCO (Port Offices)
CDSCO (Zones)
Laboratories
CDSCO

The Centre and the States have separate sets of activities

Central functions: control of sera & vaccines, Large Volume Parenterals, Blood & Blood Products, New Drugs, Import, Medical Devices, Policy & Regulations, *prosecutions*

State Functions: All other manufacturing activities, control of sale of drugs, *prosecutions*

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India is one of the largest exporter of drugs in the world. Some of the manufacturing establishments can be compared with the best in the world.

The total export in value terms is

- Current Market Size- 5.7 Billions USD
- Projected Market Size By 2010-9.48 Billions USD
- Growth Rate of Pharma Industry-9.5 % per annum
- Global Ranking- 4th Largest Producer of Pharmaceutical products by Volume.

CDSCO

How it all started

Medical devices are not drugs in the conventional sense. Most countries regulate devices by a separate set of regulations. India had to include devices within the framework of the Drugs & Cosmetics Act as there is no separate regulation for the same.

Medical Devices were being sold freely on the Indian market till 2005 when due to a court order nearly overnight 10 devices were notified as drugs vide GSR No. 1468E dated 6/10/2005.

And

Medical devices were brought under the purview of Central License Approving Authority vide GSR No. 627(E) dated 7/10/2005

- 06th OCT 2005 Gazette Notification – 10 sterile medical devices listed as drugs

- 07th OCTOBER 2005 control over manufacture and marketing of these devices to be exercised by CLAA - DCG(I) and also it enclosed the guidelines on import of Medical Devices

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(i) Cardiac Stents

(ii) Drug Eluting Stents

(iii) Catheters

(iv) Intra Ocular Lenses

(v) I. V. Cannulae

(vi) Bone Cements

(vii) Heart Valves

(viii) Scalp Vein Set

(ix) Orthopaedic Implants

(x) Internal Prosthetic replacements.

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EXTRAORDINARY

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PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

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(स्वास्थ्य विभाग)

अधिसूचना

नई दिल्ली, 7 अक्तूबर, 2005

सा.का.नि. 627(अ).—केन्द्रीय सरकार, औषधि और प्रसाधन सामग्री नियम, 1945 के भाग VII के नियम 68क के उपनियम (1) के उपबंधों के अनुसरण में, निम्नलिखित औषधियों के विनिर्माण, विक्रय या केन्द्रीय सरकार द्वारा नियुक्त केन्द्रीय अनुज्ञप्ति अनुमोदन प्राधिकारी द्वारा वितरण के लिए अनुज्ञप्ति किए जाने के लिए विनिर्दिष्ट करती है; अर्थात् :—

(i) हृदयीय स्टैंट

(ii) औषधि क्षालित स्टैंट

(iii) नाल शलाका

(iv) अंत: रक्षित लैंस

(v) अन्त: शिरा प्रवेशिनी

(vi) अस्थि सीमेंट

(vii) हृदय कपाटिका

(viii) शिरोवल्क शिरा सैट

(ix) अस्थि संबंधी रोप

(x) अन्तर कृत्रिमांग प्रतिस्थापन

[फा. सं. 11014/2/2005-डीएमएस एंड पीएफए]

रीता तेवतिया, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 7th October, 2005

G.S.R. 627(E).—In pursuance of provisions of sub-rule (1) of rule 68A of Part VII of the Drugs and Cosmetics Rules, 1945, the Central Government hereby specifies the following drugs to be licensed for manufacture, for sale or distribution by the Central Licence Approving Authority appointed by the Central Government, namely :—

(i) Cardiac Stents

(ii) Drug Eluting Stents

(iii) Catheters

(iv) Intra Ocular Lenses

(v) I. V. Cannulae

(vi) Bone Cements

(vii) Heart Valves

(viii) Scalp Vein Set

(ix) Orthopaedic Implants

(x) Internal Prosthetic replacements.

[F. No. 11014/2/2005-DMS & PFA]

RITA TEAOTIA, Jt. Secy.

3011 GI/2005

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Immediately after the regulation of Medical devices started we ran into rough weather.

The Drugs & Cosmetics Act. 1940 and Rules 1945 was not suitable for Medical devices.

So.....

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India is changing its laws!

It was felt by both the industry and the government that the present set of laws controlling drugs is not suitable for medical devices.

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Core groups were formed with the industry to examine the issue and suggest ways and means to solve the issue.

1st internal draft has been prepared of a set of regulations for controlling medical devices.

CDSCO

The draft includes: definition, classification, conformity assessment, etc. and some of the common provisions of the Drugs & Cosmetics Rules will still be applicable. These Rules will not infringe upon the special nature of these products.

CDSCO

- The basic draft has been taken from the GHTF guidelines with minor changes where ever required. Safety . The target of the new regulations are:
- Safety
- Efficacy
- Quality Assurance
- Synergy between various trade partners
- To attain Global Harmonization

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Classification of Medical Devices

CLASS	GHTF CLASS	EU	RISK LEVEL	DEVICE EXAMPLES	Mode of Assessment
A	A	1	LOW RISK	TE\HERMOMETERS /TONGUE DEPRESSORS	Self
B	B	2a	LOW-MODERATE RISK	HYPODREMIC NEEDLES/SUCTION EQUIPMENT	Notified body
C	C	2b	MODERATE-HIGH RISK	LUNG VENTILATOR/BONE FIXATION PLATE	Notified body
D	D	3	HIGH RISK	HEART VALVES/IMPLANTABLE DEFIBRILLATOR	Notified body/Regulator

CDSCO

The rules may come in to effect by 1st quarter of 2009.

CDSCO

How are we prepared?

Cooperation with USFDA, EU, Health Canada, WHO
and of course AHWP.

Training workshops are being planned with the USFDA (CDER) – one has already been held.

Series of Workshops being planned with the WHO.
Formation of a Technical Working group with the EU.

CDSCO

We are striving hard to regulate Devices in a manner which does not warrant any questioning. At the moment though we rely on the technical competence of other countries while registering products but this reliance will go down substantially when our regulations are in force.

CDSCO

The CDSCO has constituted three Expert Committees :

1. Expert Committee for Cardio Vascular Device
2. Expert Committee for Ophthalmic devices
3. Expert Committee for Orthopaedic implants

Medical Devices falling into any of the three categories are examined by the above committees and a decision is taken for their use in the country.

CDSCO

Data pertaining from period 1st March 2006 to 31st Oct.2008

Import Registration

Application received	registered	Under process	Pending in line
564	445	95	24

Import licenses

Application received	registered	Under process	Pending in line
673	663	3	7

All the above details and more are available in the website: *www.cdsco.nic.in*

CDSCO

34 Indigenous manufacturers have been licensed in the country for the manufacture of medical devices. These mainly include:

- Orthopedic implants
- Coronary Stents (DES/ plain metal)
- Catheters and Cannulae
- Balloon catheters
- Intra Ocular Lenses

CDSCO

Apart from medical devices, Diagnostics are also controlled by the same division as medical devices. However at the moment these will be treated as drugs and controlled as such. There has not been much problem in controlling these products. There are 3 main critical products which are licensed.

CDSCO

Widescreen Test Pattern (16:9)

India is moving forward at a fast pace in the area of regulating medical devices and this is an effort which is possible because the Government and the Industry are together in this. I hope India can lend some of its experience to the GHTF for mutual benefit.

Thank you

4x3

16x9