MEDICAL DEVICE REGULATIONS IN INDIA

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CDSCO

INDIAN – HEALTHCARE SYSTEM

- **INDIAN HEALTHCARE FACILITIES**

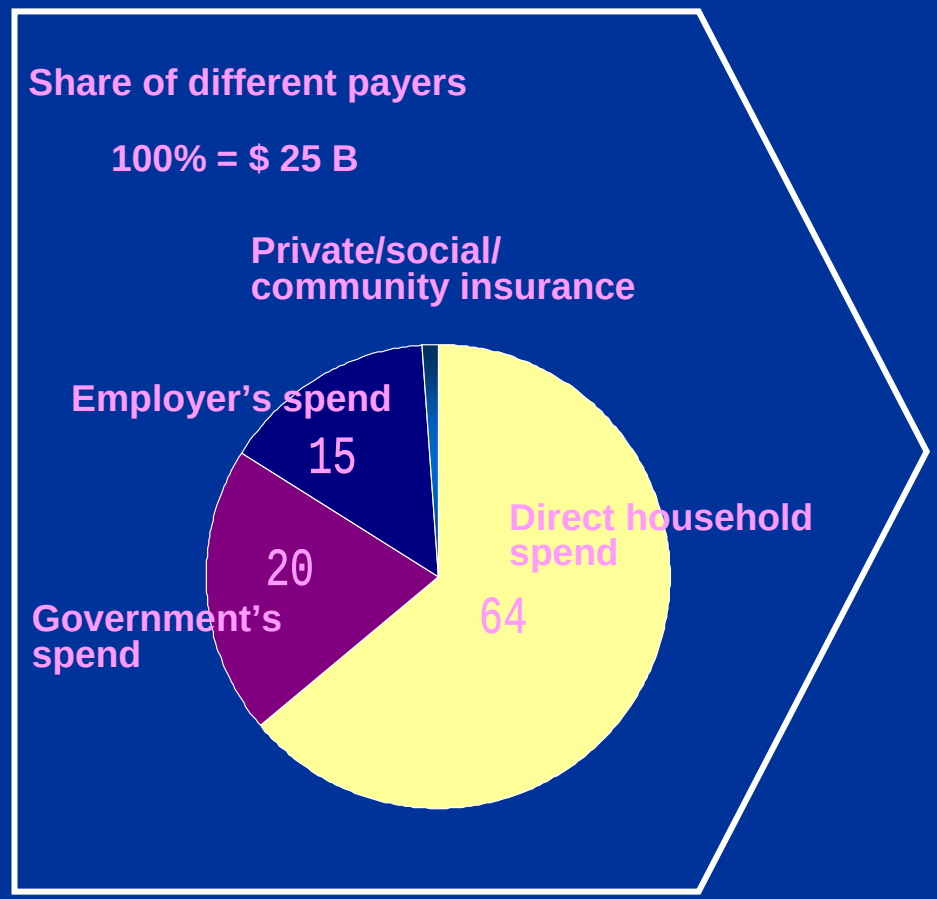
  1. **Government, Public Hospitals, Teaching Institutions**
  2. **Private Hospitals.**
  3. **Primary Health Centers & Rural Hospitals**

- **the ration of pvt. Hospitals to Govt. hospitals is 2:1**
- **Pvt. Hospitals purchase 70- 80% of imported medical devices.**

• **Beds**	**0.7/1000 people**
• **Extra Beds needed**	**80000 beds / per year for 10 years**
• **Expected spend on Healthcare**	**50 billion$ by 2012**
• **% of GDP**	**0.9% to grow up to 8.5% of GDP**
• **Govt. Spend expected**	**up 6% by 2010**

HEALTHCARE – INDIA ECONOMICS

- Primarily a self paid system
- Under evolved health insurance sector (state & private): ≤ 4% population
- Private health insurance is expected to grow in future
- Emergence of large corporate hospital chains
- CII estimates Healthcare to be a $ 20 Billion industry with a 13% annual growth rate
- Government expenditure on Healthcare has increased from 5.7% in 1997 to 17.9% in 2001. Balance 82% is by the Pvt sector



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.

LEGAL ENACTMENTS TO REGULATE IMPORT, MANUFACTURE, SALE OF DRUGS

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)

THE DRUGS AND COSMETICS ACT AND RULES
THE DRUGS AND COSMETICS ACT, 1940
(23 OF 1940)

THE DRUGS AND COSMETICS RULES, 1945

LEGISLATION CONTROLS MANUFACTURE, SALE AND IMPORT OF

- New Drugs
- Conventional Drugs
- Vaccine & Sera
- Whole human blood & Blood products
- rDNA technology derived Therapeutic products
- Cosmetics
- Empty Gelatin capsules
- Medical Devices
- Bandages
- Homoeopathic medicines
- Drugs of Indian System of Medicine

ORGANISATION CHART

DIRECTORATE GENERAL OF HEALTH SERVICES

CENTRAL DRUGS STANDARD CONTROL ORGANISAITON

DRUGS CONTROLLER GENERAL (INDIA)

HEAD QUARTER

- Jt. Drugs Controller (I)
- Dy. Drugs Controller (I)
- Asstt. Drugs Controller (I)
- Technical Officer
- Sr. Tech. Asstt.
- Supporting Staff

Medical Devices

ZONAL OFFICES (4)

- Dy. Drugs Controller (I)
- Asstt. Drugs Controller (I)
- Drugs Inspector
- Sr. Tech. Asstt.
- Supporting Staff

North Zone: Ghaziabad
South Zone: Chennai
East Zone: Kolkata
West Zone: Mumbai

SUB ZONAL OFFICE (3)

- Asst. Drugs Controller (I)
- Technical Officer
- Sr. Tech. Asstt.
- Supporting Staff

Ahmedabad
Hyderabad

PORT/AIRPORT OFFICE (7)

- Asstt. Drugs Controller (I)
- Technical Officer
- Sr. Tech. Asstt.
- Supporting Staff

Ahmedabad, Chennai, Delhi, Kochi, Kolkata, Nhavaseva, Mumbai

LABORATORIES (6)

- Director/
- Dy. Director
- Sr. Scientific Officer –I
- Sr. Scientific Officer –II
- Research Officer
- Sr. Scientific Asstt.
- Jr. Scientific Asstt.
- Supporting Staff

CDL, Kolkata
CIPL, Ghaziabad
CDTL, Mumbai
CDTL, Chennai
RDTL, Guwahati
*CDL, Kasauli
*IVRI, Izzatnagar
*NIB, Noida
**RDTL, chandigarh

*Not under CDSCO
**To start shortly

MEDICAL DEVICE REGULATORY BODIES

CDSCO

- **CDSCO has HQs in New Delhi and has 4 zonal offices, 3 Sub Zonal offices, 7 Port (Airport) offices**

  Central Drug Standards Control Organization (CDSCO) is under the Director General of Health Services, Ministry of Health & Family Welfare (MOHFW), Government of India.

2. DRUG CONTROLLERS OF THE STATE FOOD AND DRUG ADMINISTRATION

35 departments – one in each state, under the respective State Governments. The State Drugs Control have their own laboratories

3. Central Laboratories (6)

REGULATORY RESPONSIBILITIES

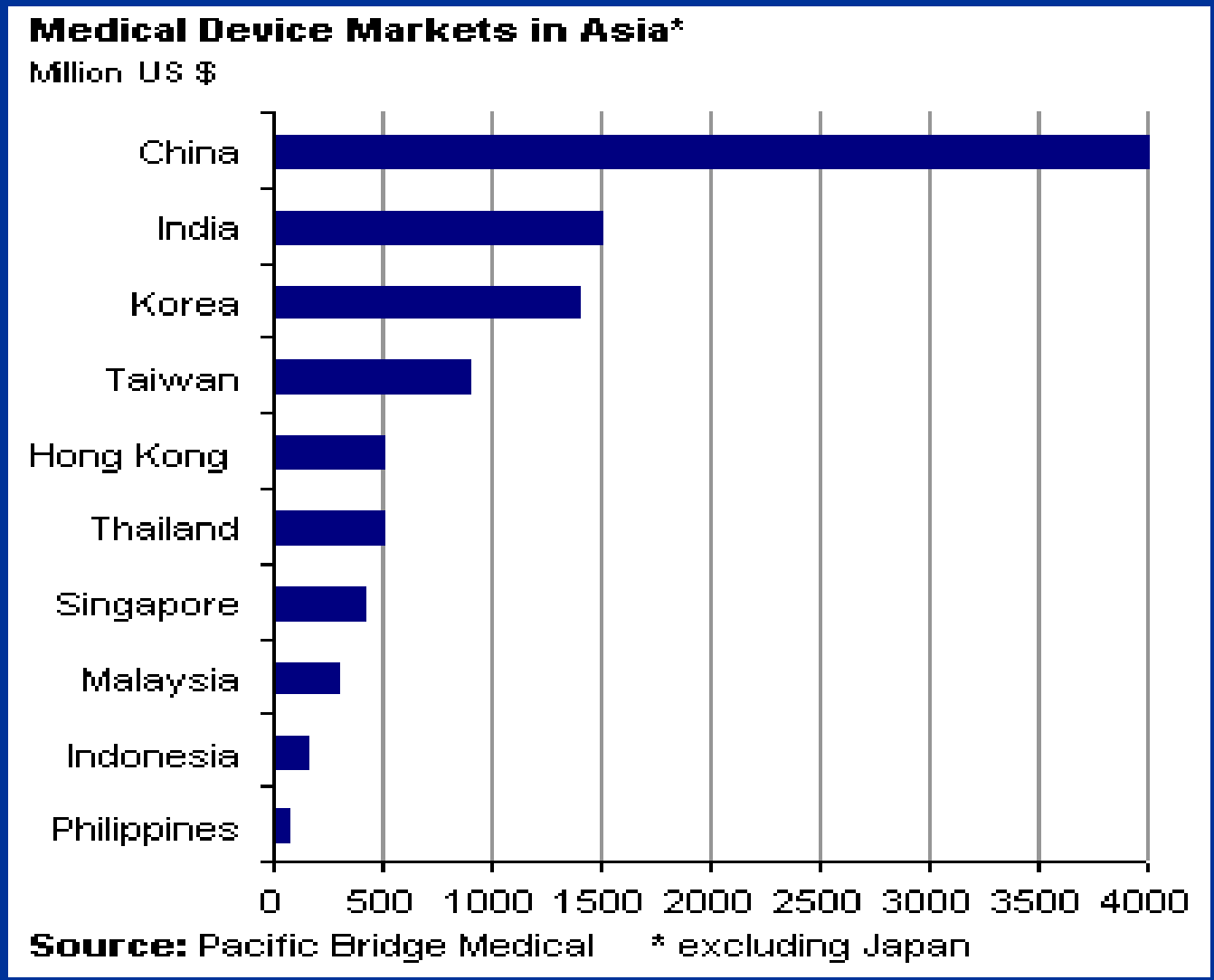
Central Govt.

- Imports
- New Drugs approval
- Laying down Standards
- Regulatory policies and legal dispensation
- Approval of Clinical Trials
- Licensing of critical products

State Govt.

- Licensing of manufacture & sale of drugs
- Quality monitoring
- Investigations
- Recalls
- Prosecution

MEDICAL DEVICE MARKET ASIA



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STATUS OF APPLICATIONS FOR IMPORT REGISTRATION OF MEDICAL DEVICES AS ON 20th OCTOBER, 2007

No. of applications received	No. of RC issued	No. of applications scrutinized but pending for want of mandatory documents.	Yet to be scrutinized
385	329	46	10

STATUS OF APPLICATIONS FOR IMPORT LICENCE OF MEDICAL DEVICES ON FORM 10 AS ON 20th OCTOBER, 2007

No. of applications received	No. of Form 10 issued	No. of applications scrutinized but pending for want of mandatory Documents.	Yet to be scrutinized
479	474	4	1

- 379 applications have been processed up to 20 October 2007
- From January 2007, the time taken for clearance of Registration Certificate for each application is 1 to 3 months and time taken for Form 10 license is 15 days.

REGULATING MEDICAL DEVICES - 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 DEVICE DEFINED AS DRUG

As per DRUGS & COSMETICS ACT:

4[*(b)* "drug" includes—

5[*(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, including preparations applied on human body for the purpose of repelling insects like mosquitoes;]

(*ii*) such substances (other than food) intended to *affect the structure or any function of the human body* or intended to be used for the destruction of 6[vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]

- **7[*(iii)* all substances intended for use as components of a drug including empty gelatin capsules; and**

- ***(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 in the Official Gazette, after consultation with the Board;]**

EVOLUTION OF MEDICAL DEVICE REGULATIONS

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NEED TO CONCEDE REGULATIONS

Ad hoc Approach

- Largely unregulated market
- 1989 - 1995 Few Disposable Devices of class 1 status few were classified as drugs under Drugs & Cosmetics Act like
  - Contraceptives
  - Hypodermic Syringes
  - Needles
  - Perfusion sets
  - In vitro diagnostic devices for HIV
  - Surgical Sutures
  - Medicated Tapes
  - Surgical dressing

Structured approach

2002 - ICMR (Indian Council of Medical Research) submitted its proposal named "Indian Medical Device Regularity Authority" to Ministry of Health in collaboration with DRDO (Defense Research & Development Organization)& Society for Biomedical Technology SBMT – triggered by sub standard import

- Report submitted by Institute of Nuclear Medicine & Allied Sciences
- Dec 2004 Expert Committee formed by Ministry of Health, GOI
- June 2005 Usage of unapproved DES at JJ Hospital, Mumbai in Mumbai FDA action, Court intervention
- Court directed Drug Controller General of India (DCGI) to regulate Medical Devices stringently.

EVOLUTION OF MEDICAL DEVICES REGULATIONS

REGULATIONS IMPLEMENTED

- **06th OCT 2005** Gazette Notification – 10 sterile medical devices listed as drugs
  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. **Orthopaedic Implants**
  10. **Internal Prosthetic replacements**

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

- Guidelines would be effective from **1st MARCH 2006**

- 28 Apr'06 Application submission deadline extended by 60 days to 29 Jun'06
- 16 Jun'06 Clarification on Guidelines issued
- 29 Jun'06 Deadline for application submission ends
- 30 Aug'06 Clarification- Sterile / Non Sterile Products and Batch Release Certificate
- 6th Dec Notification 31st Dec 2006 deadline
- 6th Sept '2007 Clarification issued on FSC, Reg Status, Peripheral Stents, Inclusion of Cardiac Patches and Occluders to be considered as Internal Prosthetic Replacement, Testing of DES, CTS required

INDIGENOUS MANUFACTURE OF MEDICAL DEVICES

- For existing manufacturers details of their existing licence along with the products manufactured have to be submitted.

- Any other certification like CE can help in obtaining a licence.

INDIGENOUS MANUFACTURE OF MEDICAL DEVICES

- The premises have to primarily comply with Schedule M III (requirement of factory premises for manufacture of Medical Devices)

- However, some aspects of Schedule M have to be complied with. (like sterile areas, validation, calibration, etc.)

INDIGENOUS MANUFACTURE OF MEDICAL DEVICES

- Subsequent to successful inspection and recommendation of the Joint Inspection Team, the State Licensing Authority prepares the licence and sends to CLAA for the approval.

- The CLAA may ask for more details before approving the licence.

EXPERT COMMITTEES

- The CDSCO has constituted three Expert Committees :
  1. Expert Committee for Cardio Vascular Device
  2. Expert Committee for Ophthalmic
  3. Expert Committee for Orthopaedic

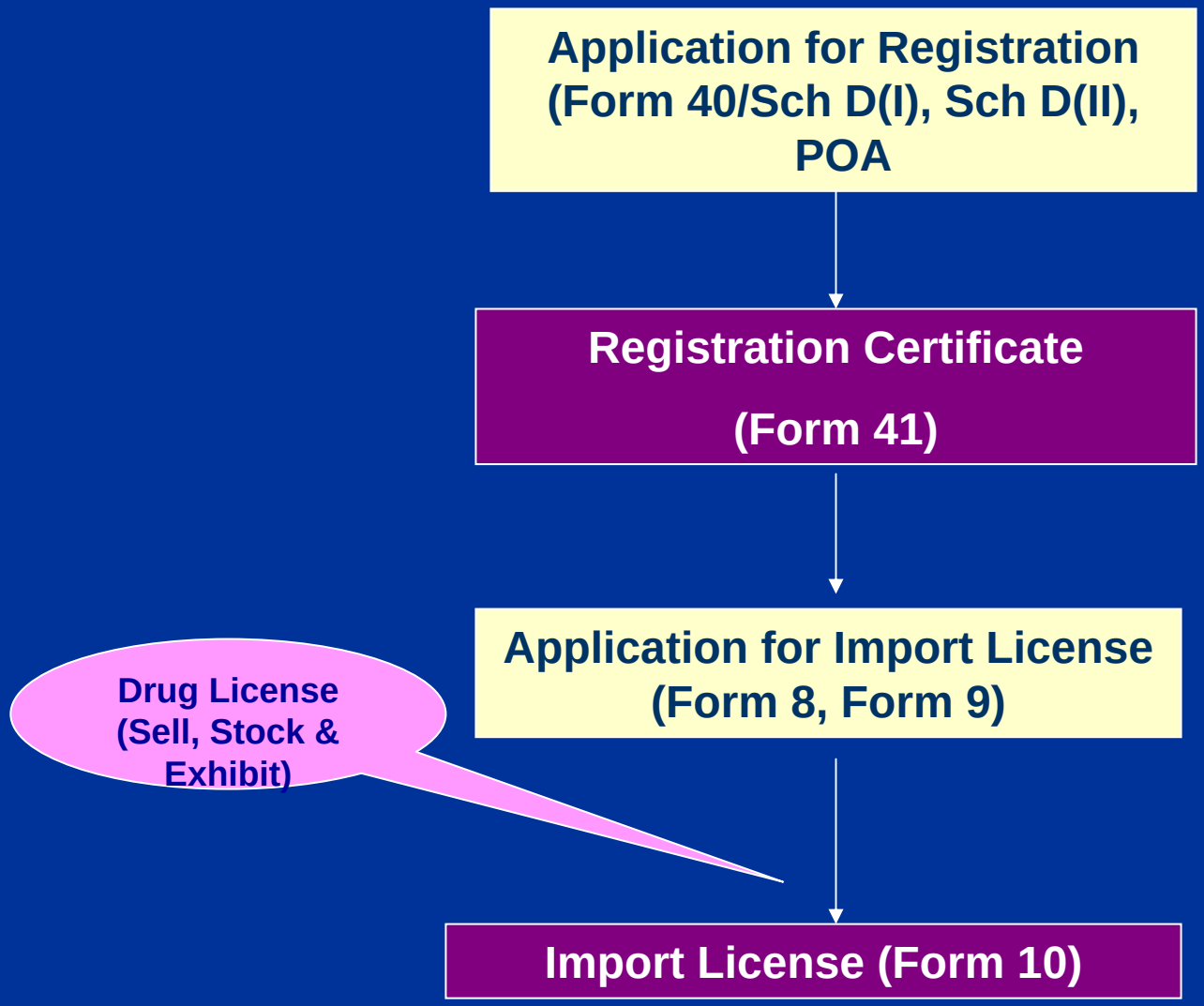
Medical Devices falling into any of the three categories are examined by the above committees and a decision is taken for their use in the country.

IMPORT OF MEDICAL DEVICES

Import of Medical Devices is controlled by the Central Govt.

Applications for import are entertained directly by the CDSCO.

IMPORT PROCESS



Application fee :

Mfg site registration
$1500 per site

Product registration
$1000 per product

Application fee :
INR 1000 ($22)

From Manufacturer

From State FDA

From CDSCO

IMPORT FOR TEST & ANALYSIS

Test Licence (Form 11)

- This is required for importing small quantity of Medical Devices for test / analysis including Clinical Trials Study.

- Importance of Test Licence is immense in the case of some of the Medical Devices like Cardiac Vascular Devices which have to be introduced first time in the county.

CHALLENGES TO BE RECKONED

- Problems faced by the inspecting authorities

1. How to carry out an inspection
2. Standards of Medical Devices
3. Testing of Medical Devices

CHALLENGES TO BE RECKONED- INSPECTIONS

- How to carry out an inspection

Inspections are to be carried out normally as for any other product with special emphasis on critical manufacturing areas / critical processes. This may include sterile room operations and sterile procedures. Issues like modern concepts of manufacturing of devices can be helpful.

CHALLENGES TO BE RECKONED-STANDARDS

- Standards of Medical Device

Some of the Medical Devices have standards specified in BIS or ISO. However, most devices do not have any fixed standards. In such cases the manufacturers' standards have to be taken.

There are some general standards in ISO and other relevant document like standards of plastics, toxicity test, etc.

Relevant standards are IS0 13485, CE Directive 93/42/EEC on Medical Devices.

CHALLENGES TO BE RECKONED - TESTING

- **Testing of Medical Device**

  Physical parameters should be compared with standards by the manufacturer itself. Designs of Medical Devices being ever changing and also changes from manufacturer to manufacturer. Therefore, testing posses a problem until manufacturers' methods are used.

CHALLENGES TO BE RECKONED- RISK BASED ASSESSMENT

Risk Based Assessment and Parametric Release of Medical Devices always help in circumventing final testing without compromising the quality of a Medical Device. Though this is in use in advanced countries, we have to yet come to terms with it.

TOWARDS HARMONIZATION

- The changes in Indian regulatory requirements are going ahead and tremendous progress has been made to make Indian regulations pertaining to drugs and pharmaceuticals in compliance with international regulatory norms such as EMEA, CIOMS, ICH so as to achieve the goal of global harmonization

- India has been recognizing European certificates at the time of import without verification. CE and ISO issued by European agencies are accepted in this country.

PROPOSALS TO ATTAIN HARMONIZATION

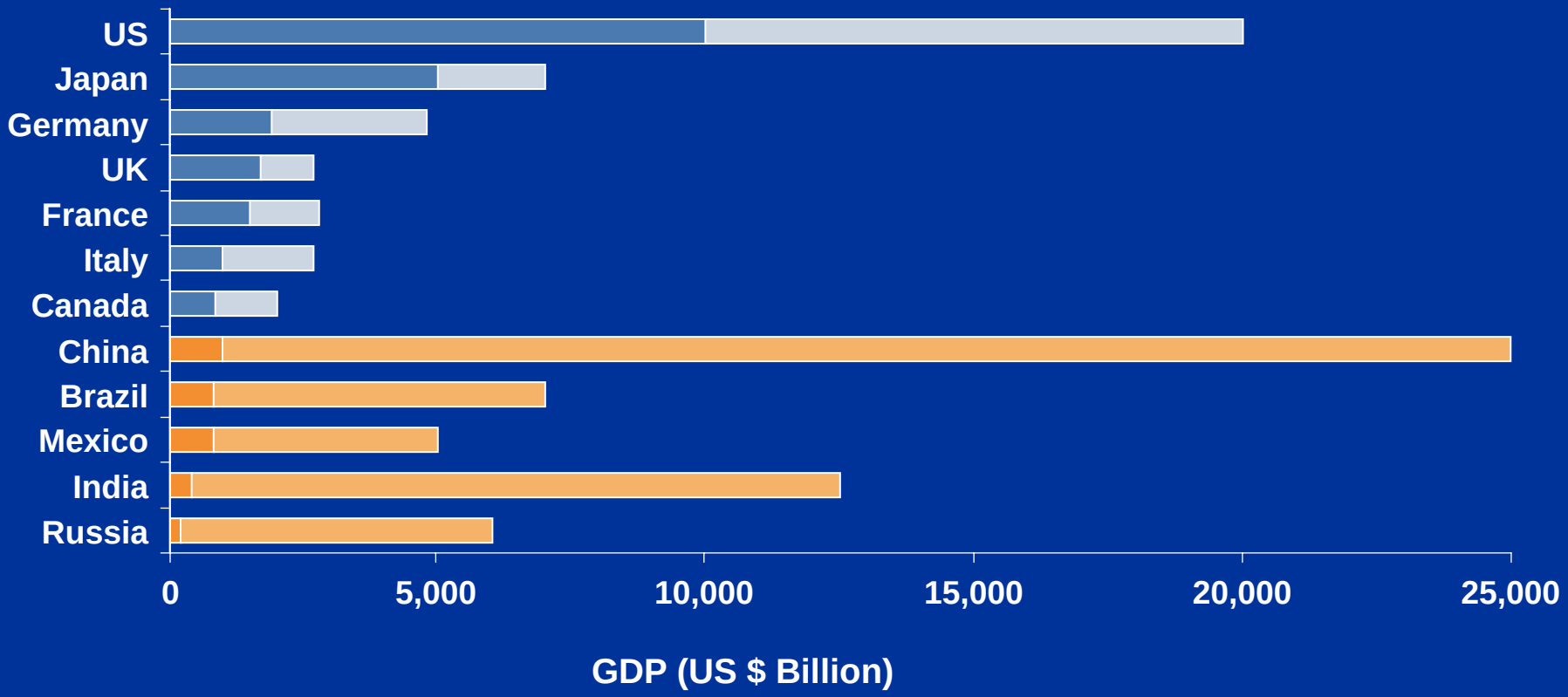
1. Gradual mutual recognition of each others documents, such as GMP, ISO etc

2. Exchange visits of regulatory personnel to get a deep understanding of each others regulations, norms and working.

LEADING TOWARDS GREENER PASTURES

Let us not neglect this interesting and important field. We have a duty to see that the devices that go to a patient is useful for the purpose for which it is made.

YEAR 2000 VS. YEAR 2020 PREDICTIONS



INDIA EMERGING AS ONE OF THE TOP GLOBAL ECONOMIES

CDSCO

Thank you