CDSCO – International Cooperation

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Outline

- Global Presence
- Export to different region
- Brief profile on Indian Pharmaceutical Industry
- Cooperation with Other Countries
- Conclusion

CDSCO

- National Drug Regulatory body
  - Drugs, Medical Devices and Cosmetics
- Under Ministry of Health and Family Welfare
- Headed by Drugs Controller General Of India
- On behalf of Central Government
- Functional NRA by WHO
- Member in ICH (Observer)
- Nodal agency for all international activities

CDSCO (HQ), FDA BHAWAN , NEW DELHI

Global presence

- India meets on its own 95% of its domestic demands through indigenous production
- Vaccines and bio-pharma products are exported to about 150 countries.
- India ranks third in the world providing over 400 APIs.
- More than 600 US FDA approved manufacturing facilities
- Around 700 EDQM certified facilities
- 442 Written Confirmation Certificates
- 1500 WHO-COPP facilities

Indian Pharmaceutical Industry – A Profile

Size of the Industry	**USD 37 Billion**
Export	USD 19 Billion
Domestic market	USD 18 Billion
Growth Rate	10-12 %
Imports	USD 4 Billion
Exported to	More than 200 countries
Volume of Production	3rd Largest in the world
Value of production	10th in the world

India's Contribution to Global Health Care

S.No	Region	% of total exports
1	North America	29
2	EU	18
3	Africa	20
4	Middle East	7
5	Asean	6
6	Latin American Countries	6
7	CIS	6

Indian Pharmaceutical Industry – A Brief Profile

Type of Manufacturing Unit	Number of Units (Approx)
Formulations	4900
Active Pharmaceutical Ingredients	1500
Vaccines	30
Medical Devices	350
Miscellaneous (Surgical dressings, Blood banks, Disinfectants etc)	2850
Other Industry	
Cosmetics	2300
Ayurveda, Unani	4800
Homeopathy	1000
Whole sale and Retails	800,000

Import of Pharmaceutical products

- Registration of the product mandatory before import
- Overseas manufacturing sites shall comply with the WHO requirements of GMPs
- Registration is valid for three years
- Site registration fee 10000 USD, product fee 5000 USD
- Provisions for Site inspection
- Site Master File, DMF, POA, Labels
- Review time 9 months (3-4 months)
- Quality check at the port of entry

Export of Pharmaceutical products

- Valid license to manufacture drugs for export
- Common GMP Standards for domestic and export purpose
- Stability data, BA/BE data
- Products have to comply with the requirements of the importing country
- Joint inspection of the facility by the Central and State authorities for WHO GMP certificate
- Quality check (Label Verifications) of the drugs at the port of exit
- Written confirmation certificate issued for export of APIs to EU countries

Quality Monitoring

- 32 State Laboratories and 7 Central Drug Testing Labs
- Test around 100, 000 samples per annum
- To evaluate quality of drugs
- **Amendments In Drugs And Cosmetics Act-2008**
  - Enhancement of punishment and fine
  - Offence made cognizable and non bailable.
  - Designating special courts for trial of offences

National Drug Survey

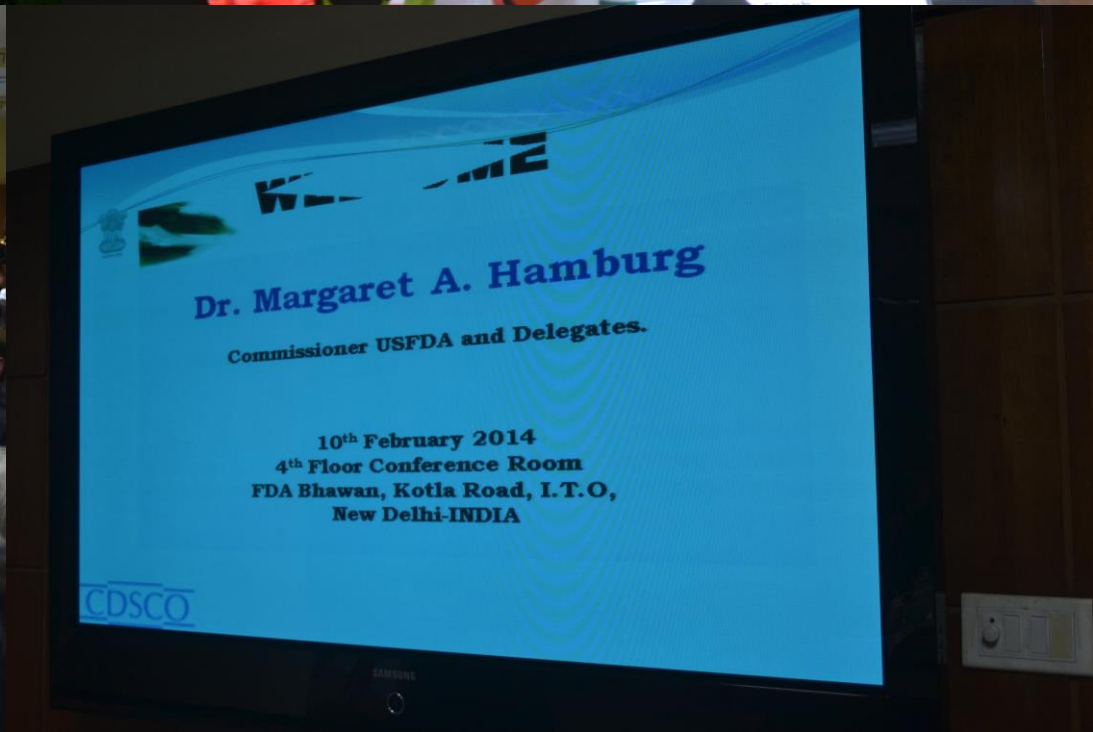
To estimate NSQ and Spurious drugs

- Systematic Study, well designed, no bias
- Around 47000 samples drawn
- Samples from retail outlets and Govt.Hospitals
- With help of National Institute of Statistics
- Drawn by Inspector in presence of NGO
- Tested at National laboratories
- All Therapeutics categories covered
- Out comes of the study

Cooperation with other Countries

- CDSCO has signed MoU on cooperation in the field of regulation of pharmaceuticals with the following Countries:
  1. Russia
  2. Japan
  3. US
  4. Sweden
  5. Brazil
  6. UK
  7. Afghanistan
  8. Argentina
  9. Indonesia


s, Margaret. A. Hamburg
Commissioner, USFDA


Dr. Margaret A. Hamburg
Commissioner USFDA and Delegates.
10th February 2014
4th Floor Conference Room
FDA Bhawan, Kotla Road, I.T.O,
New Delhi-INDIA
CDSCO

A MoU was signed between CDSCO and Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, Japan on December 11, 2015 at CDSCO (HQ), New Delhi.

MoU was signed between CDSCO and MHRA , UK at CDSCO (HQ) on October 5, 2015. The delegates of MHRA were led by Sir Michael Rawlins, Chair, MHRA.

Areas of Cooperation

- Regulation of Medical Products and Cosmetics, and exchange of information thereon;
- Pharmacovigilance of Medical Products & Medical Devices;
- Participation in scientific conference, symposiums, seminars and forum organized by both countries;
- Capacity building in mutually agreed areas;
- Visits to each other's country to understand the regulatory processes of both countries;
- Coordination at the international fora; and
- Any other areas of common interest.

Out come of MoUs

- Strengthened the relationship between both countries.
- Results in exchange of information and cooperation on Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and Good Pharmacovigilance Practice (GPvP).
- Established dialogue and cooperation
- Helped in Exchanging of safety and quality information,
- Exchanged Best practices between both the countries
- Participation in each other country conferences and symposiums to learn about each other regulatory aspects.

Conclusion

- Adequate regulation
- Quality Medicines at affordable Price
- Hub for Generic Medicines
- Focus on Innovation
- Supply to UN, WHO etc
  - Vaccines
  - Antiretroviral drug (HIV Drugs)
  - TB and Anti-malarial Drugs
- International co-operation through MoUs

Committed to have exchange of regulatory information between ROSZDRAVNADZOR (Russia) and CDSCO (India) for Quality improvements of medicines

благодарю вас