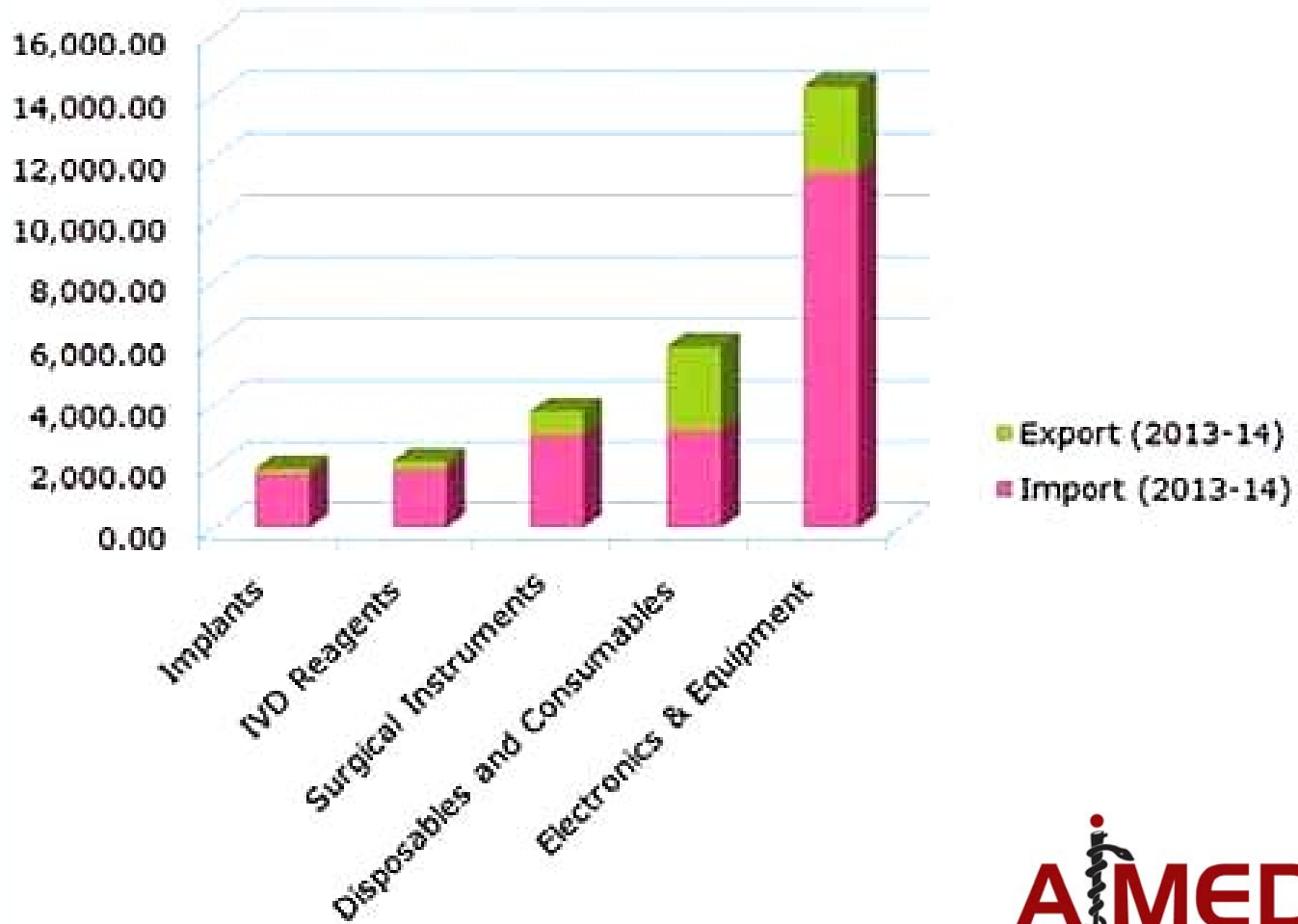

MAKE IN INDIA FOR THE WORLD !

Unleashing the Export potential

Rajiv Nath
Forum Coordinator





source:Dept.ofpharma



AGENDA

- | | |
|--|-----------------|
| 1 - Strategy of Make in India | 2 : 30 - 3 : 00 |
| 2 - Building Cooperative Bridges | 3 : 00 - 3 : 05 |
| 3 - Update on | |
| i) Andhra , Telegana & U.P. | 3 : 05 -3 : 25 |
| ii) Kalam Institute & E-Auction | |
| iii) India Biomedical Skill Development Consortium | |
| iv) On INDIA INVEST & Msips by Meity | 3 : 25 - 3 : 30 |
| 4 - List of Medical Devices for MDR' 17 | 3 : 30 - 3 : 45 |
| 5 - Learning from ICA | 3 : 45 - 4: 00 |
| 5 - Details of Administrative Structure | 4 : 20 - 5 : 00 |
| 6 - Membership Terms | |
| 7 - Any Other Business tabled by Members | 5 : 00 - 5 : 30 |

Make in India - Achievements

- Kalam Institute of Healthcare established at Vizag
- ICMED (Indian Certification of Medical Devices by QCI) Voluntary QA
- Medical Devices Rules 2017
- Price caps on Stents & Knee Implants
- Medtech Parks at Vizag & Hyderabad

Make in India - Achievements

- Indian Biomedical Skills Development Consortium
- Amendment of Legal Metrology (Packaging Commodities) Rules
- Workshops on CE, ICMED, MDR 17 in multiple cities + Exhibitions
- 3rd Festival of Innovation @ Rashtrapati Bhawan March '17

World is watching India

2nd Japan India Medical Products Regulation Symposium - April @Tokyo

3rd Global Forum on Medical Devices by WHO in May '17 @ Geneva

1st World Conference on Access to Medical Products by WHO - Oct '17

22nd AHWP Conference - Dec '17 @Delhi



#1 -Correct Import Duties

1st Steps taken on January 19th on 78 Devices for addressing Inverted Duty Structure by raising duty to 7.5 %

Next 2.5% Concessional Duty on inputs for mfg. on Balance 21 IVD/Devices of 30.06, 38.22 & 90.27 need similar support

10- 15% Basic Duty needed to offset 11% Import cost reduction post GST

#2 BUY INDIAN POLICY

10-15% preferential pricing policy of Indian Origin Devices

5% preferential pricing for ICMED certified manufacturers

3% preferential pricing for Design India Certified Mfr

Penal Action against GoI hospitals that use exclusionary USFDA clause

#3 Consumer Protection

Enforce MRP on unit pack at
Customs

Reform DPCO,
Rationalise Price Controls,

Tax based disincentive on MRP

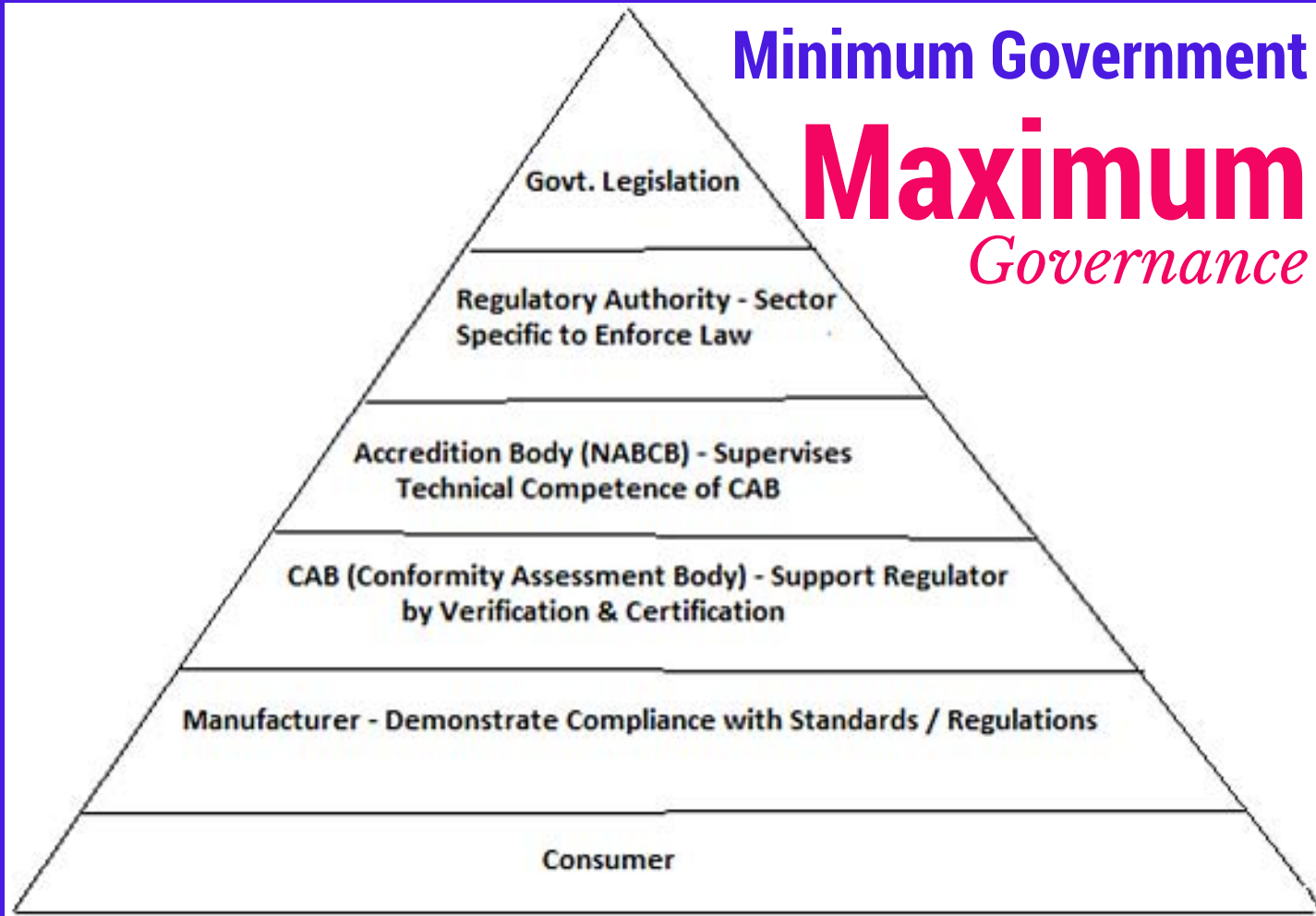
Cap Trade Margins @ 50 -100% on
Import Landed/Ex Factory Price

#4 REGULATIONS

Incorrect Regulations discourage Investments

Minimum Government

Maximum
Governance



4 - Regulatory Framework

Separate Law & Regulator - IHPRA

Regulate Market Access
Authorisation Holder & Mfg.Site

Pseudo manufacturing to be illegal

3rd Party Certification for C&D Class
of devices as done for A&B

Penal provisions like Auto Industry

Interim Strategy : Standards & Non Tariff Barriers

ICMED Certification by QCI

Make IS: 13485 Mandatory

Additional Products in MDR' 17

Restrict Imports of Preowned Equipment

FSC by DGFT under Authorisation of Moh&FW

PROPOSED LIST OF ADDITIONAL ITEMS FOR MDR'17

- 1 - Pacemakers
- 2 - ICU Ventilators
- 3 - Dialysis Machines
- 4 - CT Scanners
- 5 - MRI
- 6 - Digital Mammography
- 7 - C.I. Analysers
- 8 - X-Ray & C Arm Equip.
- 9 - Flexible endoscope
- 10 - Heart Lung M/c
- 11 - Ultra sound M/c
- 12 - Incubator
- 13 - Diagnostic Analysers
- 14 - Phaco emulsication Equip.
- 15 - Laproscopy Camera
- 16 - Electrosurgical Diathermy
- 17 - Ultrasonic Scalpels
- 18 - Multi channel Monitors
- 19 - Defibrillators
- 20 - Infusion Pumps
- 21 - Anaesthesia Stations
- 22 - BiPAP Ventilators
- 23 - External Pacemaker
- 24 - Foetal doppler
- 25 - Bloodgas Analyser
- 26 - Blood Collection Tubes
- 27 - Surgical Blades & Scalpels
- 28 - Digital Hearing Aids
- 29 - Blood Pressure Instruments
- 30 - Glucose Monitoring Instrument
- 31 - Electronic Stethoscope
- 32 - Electronic Thermometer

5 - Enabling Governance

- DEPT. OF MEDICAL DEVICES
- Medical Devices Promotion Council
- Ministry of Healthcare Products

**THE VISION :
INDIA AMONGST
TOP 5
MANUFACTURING HUBS
OF
MEDICAL DEVICES**





Make in India

**Thank
You**

