Industry perspectives for the new regulation in India

Asia Subcommittee of

International Policy and Strategy Committee

Y. Nagura

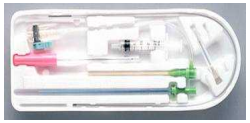
Apr. 24, 2017

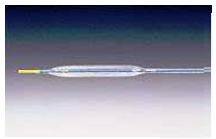
- *First of all, I would like to express our sincere thanks for the efforts by all the stakeholders to have:*
  - *Successful 1st India Japan Symposium last May in New Delhi*
  - *2nd India Japan Symposium in Tokyo*

- *Also, Japan industry much appreciate Indian authority to hold a briefing session for Japanese companies in India at the time of public comments of this new rule.*

JFMDA

- *21 Associations*
  - *CT/MRI, Intervention, CRM,CV, Neuro, Ophthalmology,*
  - *Anesthesia, IV Diagnostics, Regenerative Medicine,*
  - *Contact Lenses, Others*
- *4,280 Companies*
- *Total revenue of US$26B*
- *120K Jobs*





Why regulate medical devices?

- *Protects patients and enhances quality of life via:*

  - Block or remove unsafe and ineffective products from market

  - Timely patient access to good quality medical devices

Consideration needed

- *Have reasonable regulatory control **for patients***
  - *Balancing risks and benefits*
  - *Affordable time/costs incl. human resource both in government and industry without negative impact, e.g., device price increase, etc.*
  - *Secure supply of medical devices*

General proposal

- *Have reasonable time-line, enough transition period and step by step implementation*

- *Harmonize to internationally recognized regulation/rule/standards as much as possible*

  Reduce country specific requirements if there is valid alternative means scientifically accepted in an original GHTF region: US, Japan, EU, etc..

Soft-landing is greatly expected.

Clarification needed

- ***General time line** / process / which products registration first?*

- ***Standards**: International standards, such as ISO/IEC, are accepted in India? (Clause 7)*

- ***Shelf life**: Hardware does not require a shelf life prior to use? (Clause 47)*

Ideas

- ***Fee schedule**: Any possibility for decreased registration application fee in the initial regulation introduction stage?*

  - to reduce industry financial burden in case many multiple applications are required.

  - incentive for industry to register product

- ***Seminar:** We think it effective to have educational sessions to sufficiently train industry in the new regulation/requirements.*

Closing

- *Japan industry would like to collaborate as much as possible on the implementation of the new regulation for the* ***enhancement of QOL*** *of patients.*

- *For that purpose, we would like to keep* ***relationship / dialogue*** *with Indian authorities & industry.*

End

AIMED

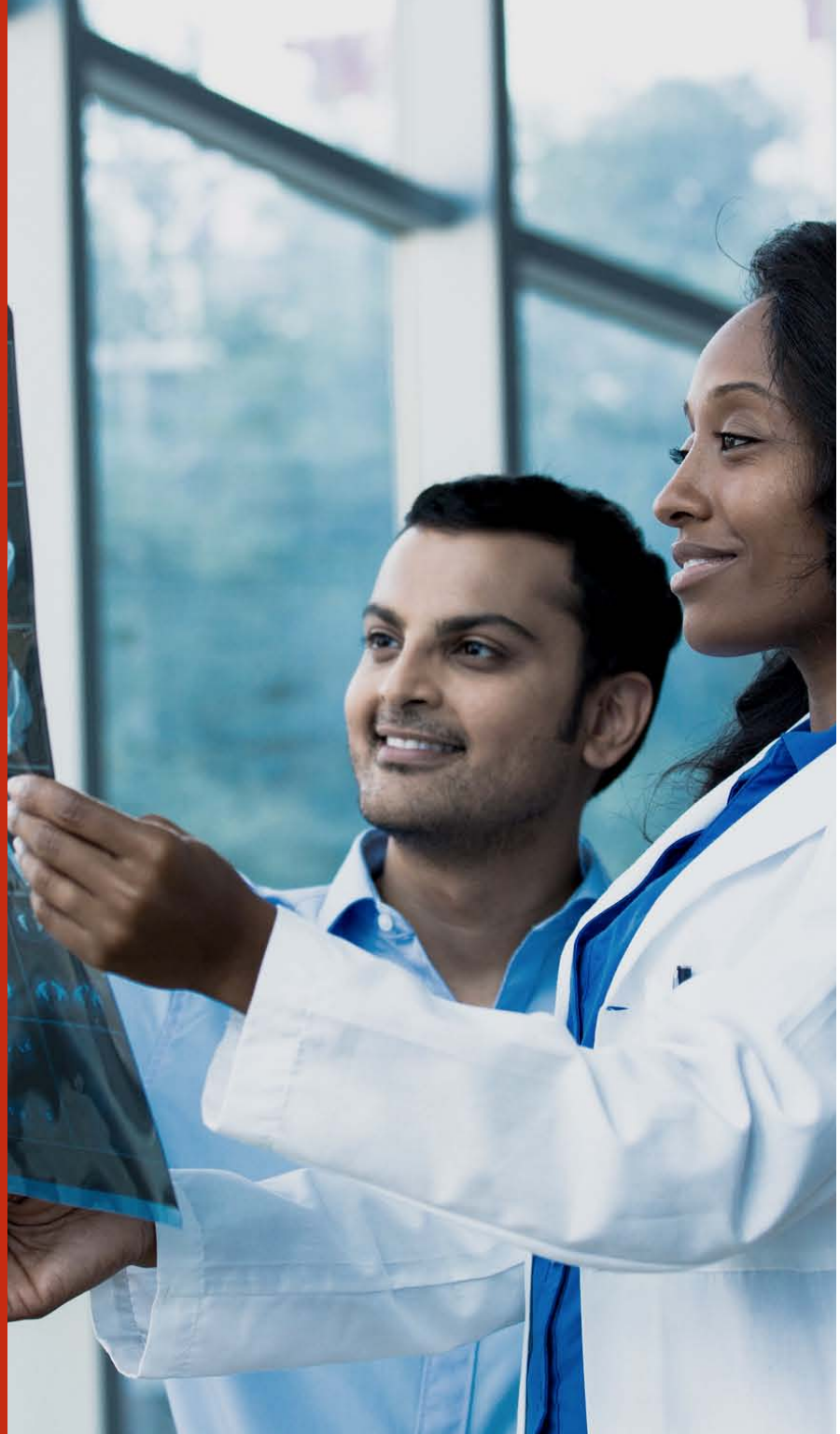
ASSOCIATION OF INDIAN MEDICAL DEVICES INDUSTRY

AiMED

ENCOURAGING RESPONSIBLE MANUFACTURING

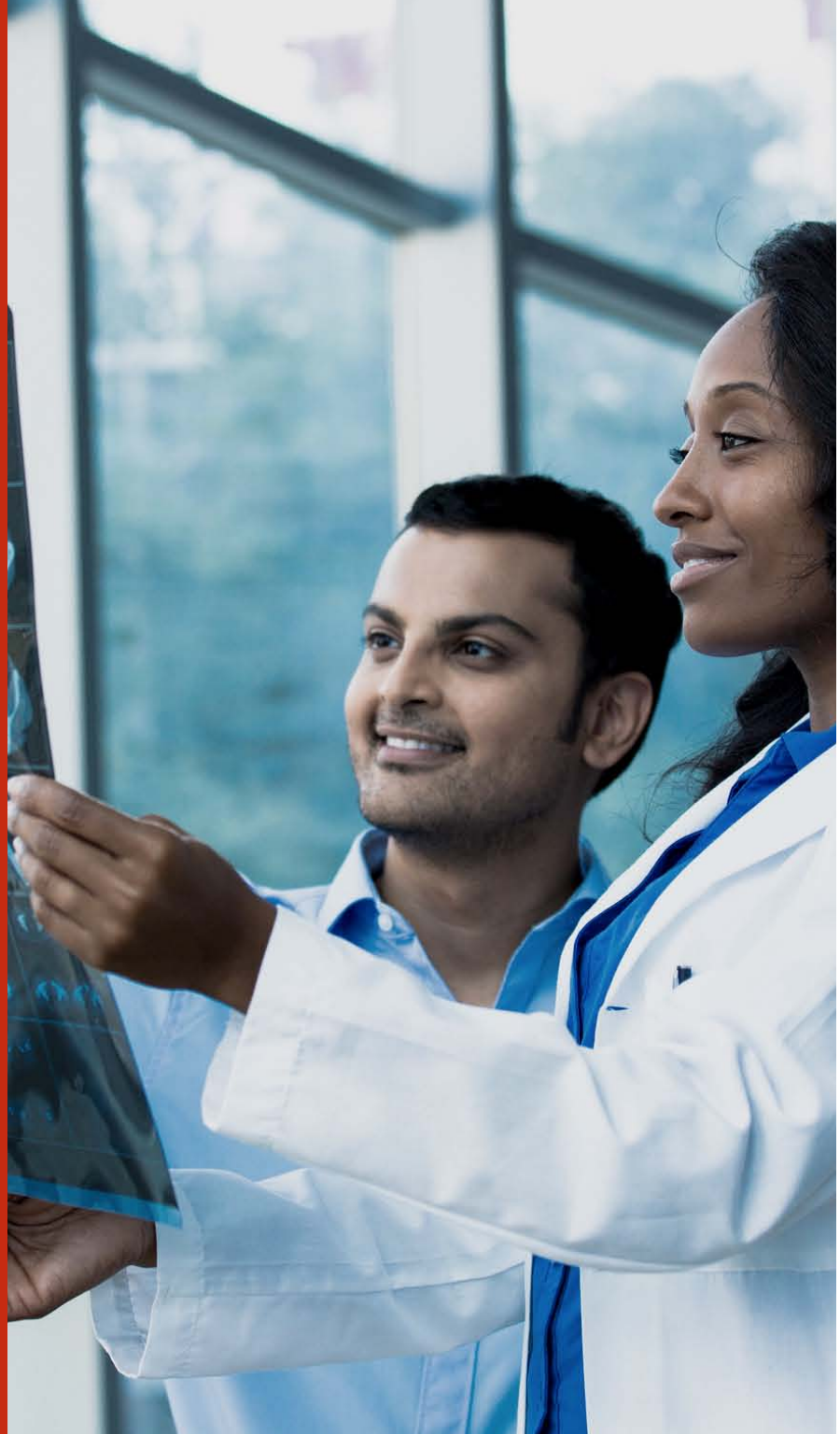
Ai-MeD an Umbrella Association of Indian Manufacturers of Medical Devices covers all types of Medical Devices including consumables, disposables, electronics, equipments , implants, instruments & diagnostic reagents representing the interest of over 800 Manufacturers of Medical Devices and address their problems.

The aim behind Ai-MeD - allow the Government to access a single point of contact and provide various services to the manufacturers like Advocacy on policy issues, Guidance for Quality Certification (ISO, CE, GMP), improve clinician and patient access to the modern, innovative and reliable medical device technologies through organizing Exhibitions, Seminars etc.



VISION

INDIA to be in the Top5 manufacturing global hubs of medical devices



VISION

Indian Medical Devices Regulatory Authority

- A Centre for Excellence.

- As a Gardner, assisting Industry to produce with adequate & appropriate controls & systems for ensuring patient safety

AIMED

NO REGULATIONS!

INDIAN TRAFFIC

CHAOTIC

SLOWS YOU DOWN

AIMED

REGULATIONS THE GERMAN WAY

BRINGS IN DISCIPLINE

You Can Speeden Up

Clear Expectations of Role & Responsibilty

AIMED

BACKGROUND

- 70% Import Dependency
- 40% from USA
- Lack of Trust in Indian Devices
- Incomplete & Incorrect Regulations
- Reliance on 3rd country Certification
- Incorrect Regulations discourage Investments
- Need for Voluntary Certification
- Respect for Indian Medical Devices

INDIAN CERTIFICATION FOR MEDICAL DEVICES CERTIFICATION SCHEME

- AiMeD & QCI led Initiative
- ICMED 9000
- ICMED 13485
- ICMED 13485 Plus

Technical Criteria

IS/ISO:13485(2003) 184 + 23

+13 Essential Requirements for safety

+16 labelling requirements

IS/ISO:9001(2008),126+36


You can trust
ICMED certified
companies to
meet patient
safety needs.

INDIAN MEDICAL DEVICE RULES

Risk Proportionate Controls

Class A Self Certified

Class B Register with SLA

Class C & D Licensed by CLA

3rd Party Certification

NABCB Accredted Notified

Cerification Bodies will audit Class

A & B manufacturers

QMS Compliance

ISO13485.

Essential Requirements

for Patient Safety

Labelling Requirements

Regulatory Elements

Clinical Investigation for

Class C & D

Design Dossier for Class D

NEXT - REGULATORY ADD ONS.....

Rules For -

i) Restricting Reuse of Single Use

ii) Restricting import of Preowned Equipment

iii) Advertisement & claiming performance

iv) Responsibilty of BIS & NABL

v) Responsiblity of User

Regulatory Framework

Separate Law Book

Traders not be permitted to be called as Manufacturers

Who Regulates Whom?

THE NATIONAL REGULATOR

- The Manufacturing Site
- The Market Access Holder (MAAH)
  -Importer/Agent/Mfr./Marketer

THE STATE REGULATOR

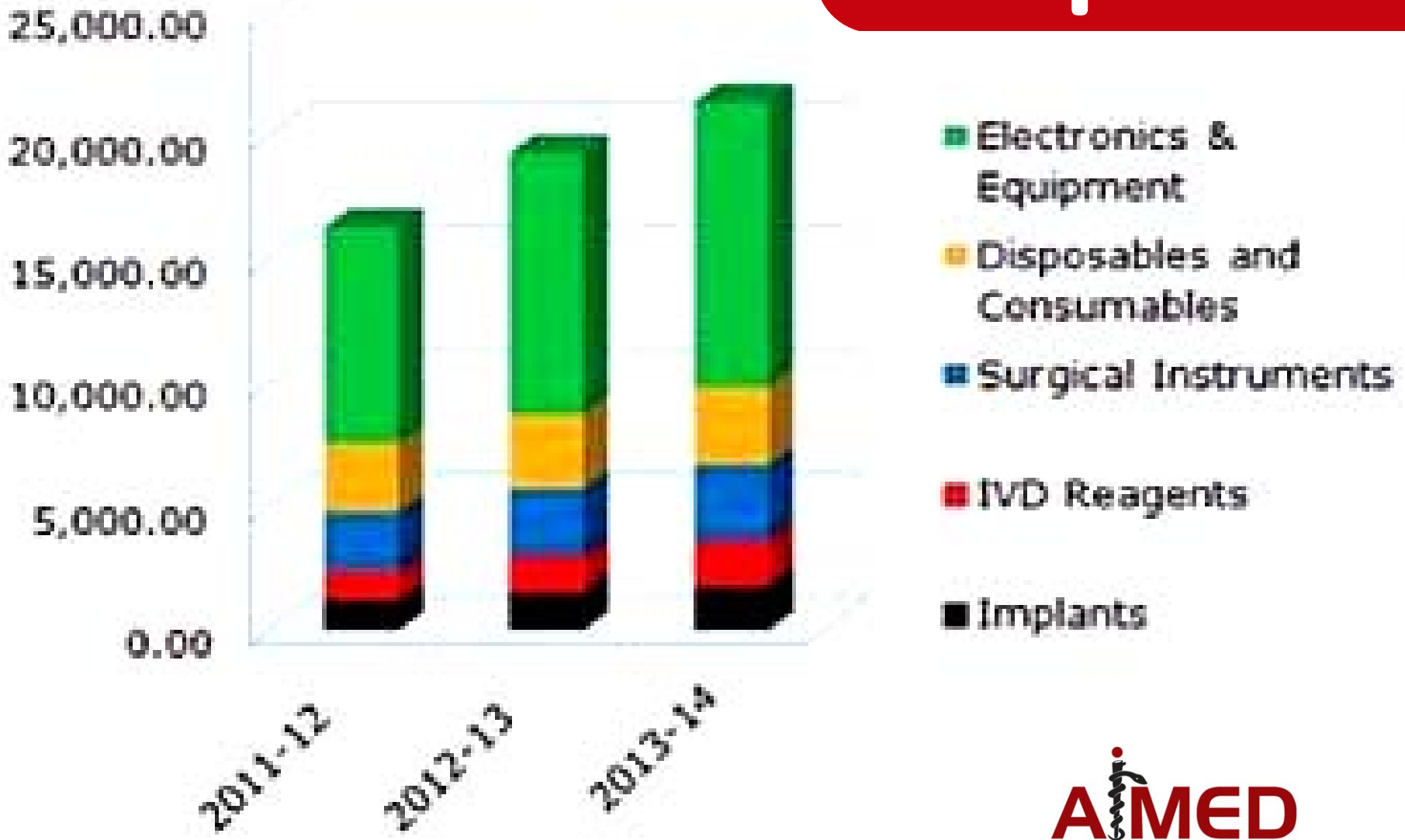
-The Domestic Reseller

-The WholesaleDealer

-The Retailer

-The Healthcare Provider

Imports



source:Dept. of pharma

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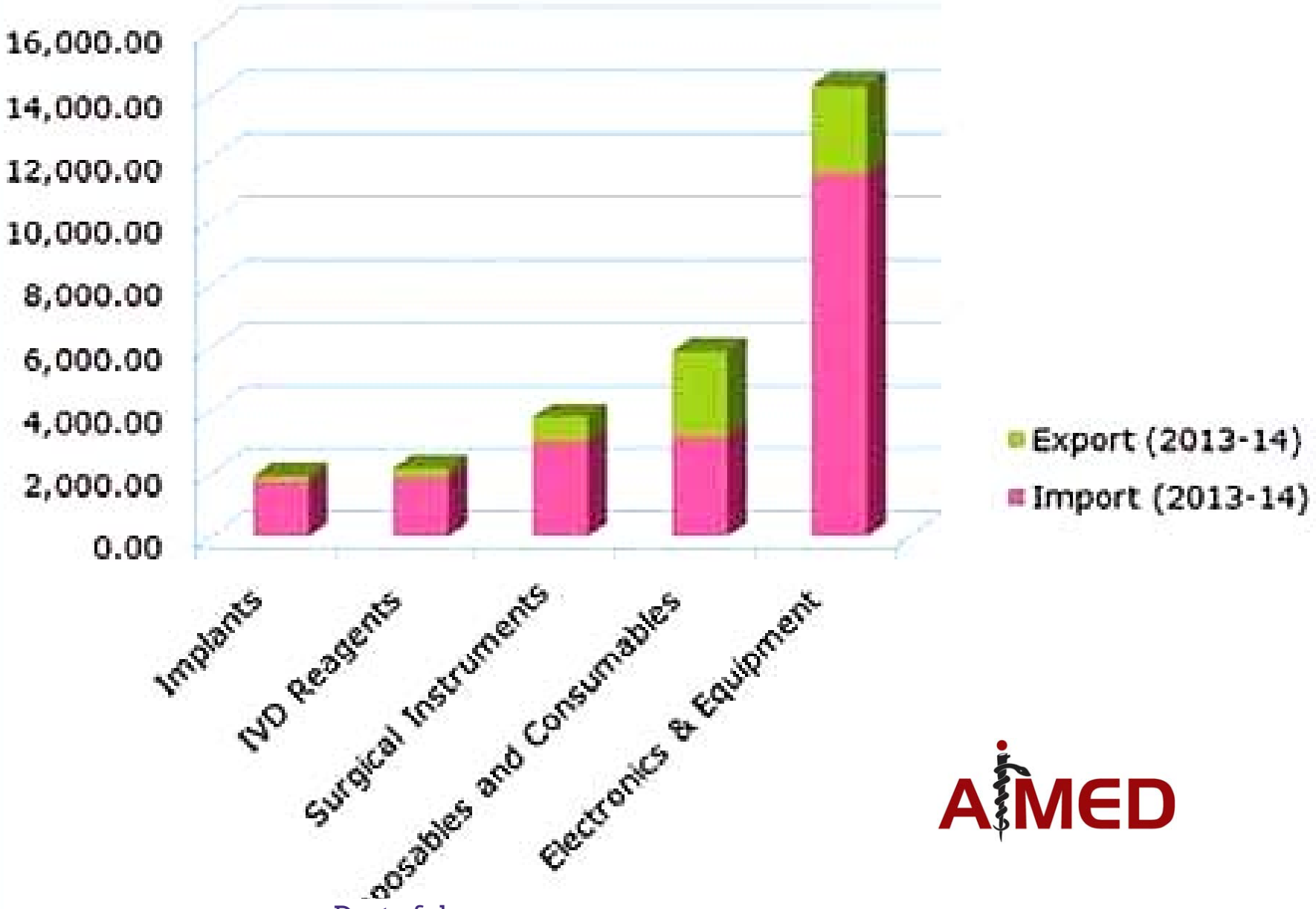

source:Dept.ofpharma


Make in India

INVESTMENT ENABLERS

i) Corrrection of inverted Duty structure on 19 Jan 2016 on 78 Medical Devices.

ii) Launch of ICMED Certification on 15 March 2016

iii) Medical Devices Regulatory Framework Separate from Pharmaceuticals being created - New MD Rules on 31 January 2017 - Effective 1st January 2018

iv) Central Govt. & State Govt. creating Medical Devices Parks with Common Mfg. Facility + incentives to create conducive and cost effective clusters.

v) Preferential Market Access policy based on Domestic Content under consideration

AIMED

THANK YOU!

Lets Make in India

Rajiv Nath
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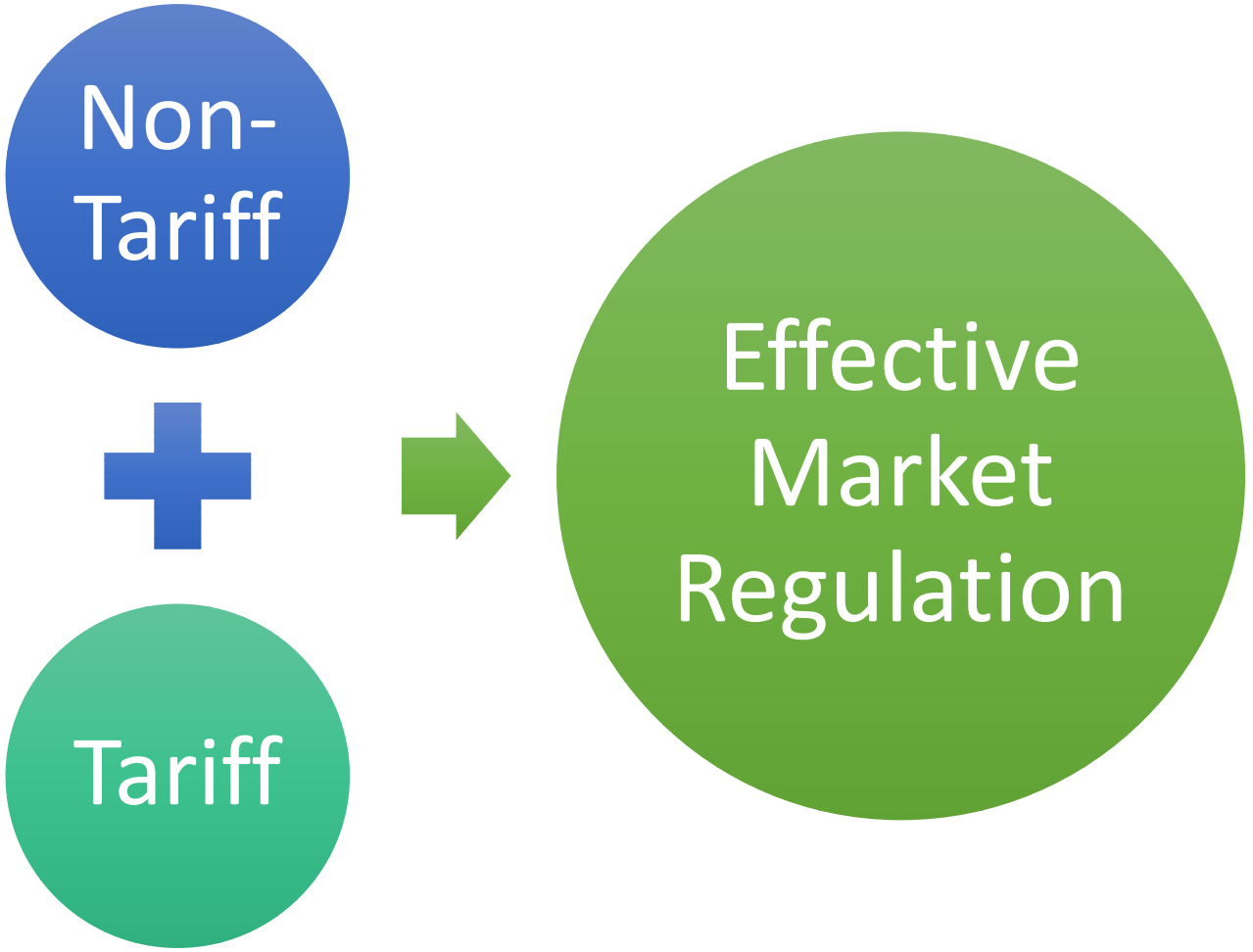
Regulation for facilitating

Industry Promotion

Dr. Jitendar Sharma

Director & CEO, Andhra Pradesh MedTech Zone

Regulation- an Industry Promotion Perspective



Non-Tariff regulation

- ✓Regulation of Safety & Risk profile –CDSCO(MoHFW)
- ✓Regulation of Market Authorization & Licensing – CDSCO(MoHFW)/States
- ✓Regulation of Standards & Certifications Systems – CDSCO(MoHFW)/QCI/NABL/BIS/AICTE
- ✓Regulation of Complaints-MoHFW/Dept. of Pharma/DIPP
- ✓Regulation of Marketing Practices – Dept. of Pharma
- ✓Regulation of Import/Export policies- DGFT
- ✓Regulation of Research - ICMR (MoHFW)/DBT/DST

Tariff Regulations

- ✓Regulation of Customs Duty Structure- Tariff commission/Dept. of Revenue
- ✓Regulation of Preferential Market Access- Dept. of Electronics & IT/Ministry of Finance
- ✓Regulation of Procurement- DG(S&D)-Ministry of Commerce/MoHFW
- ✓Regulation of Enterprise scale specific benefits – Ministry of MSME
- ✓Rarely used- Regulation of Prices- NPPA

Bright spots in medical device policy landscape

- Medical Devices reform task force- 2014/15
- Inverted Duty Correction for spares/components -2016
- Medical Devices Rules, 2017
- Preferential Procurement of domestically manufactured good, GFR-2017
- Medical Devices R & D priority & market access think tank- 2017
- Code for Marketing Practices- under final stages of formulation
- Medical Devices Promotion Council- Advance stages of planning
- Promotion of organized infrastructure support- AMTZ 2016-17 onwards

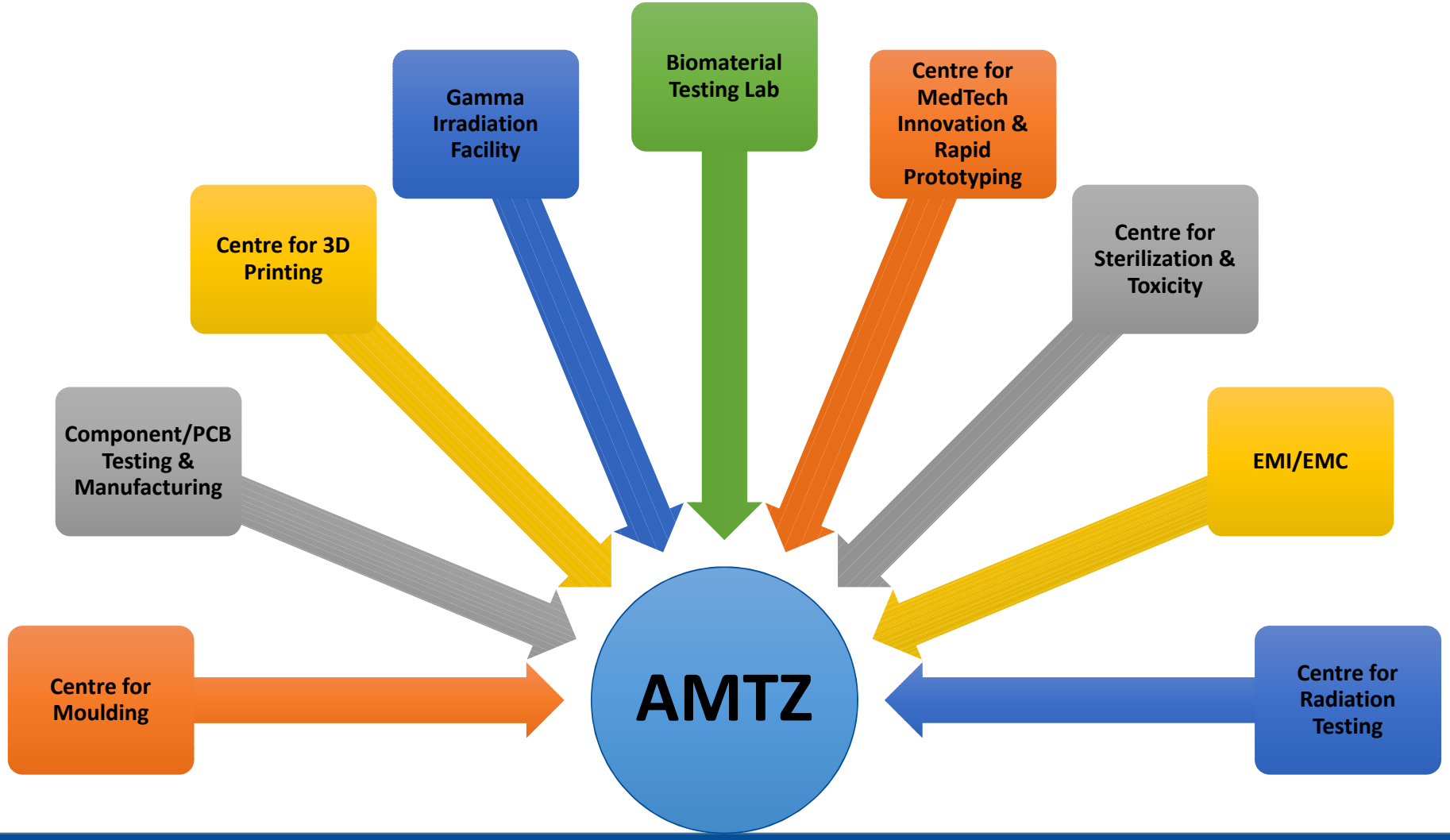
India's 1st Integrated Medical Devices Manufacturing Park

AMTZ - Manufacturing Units

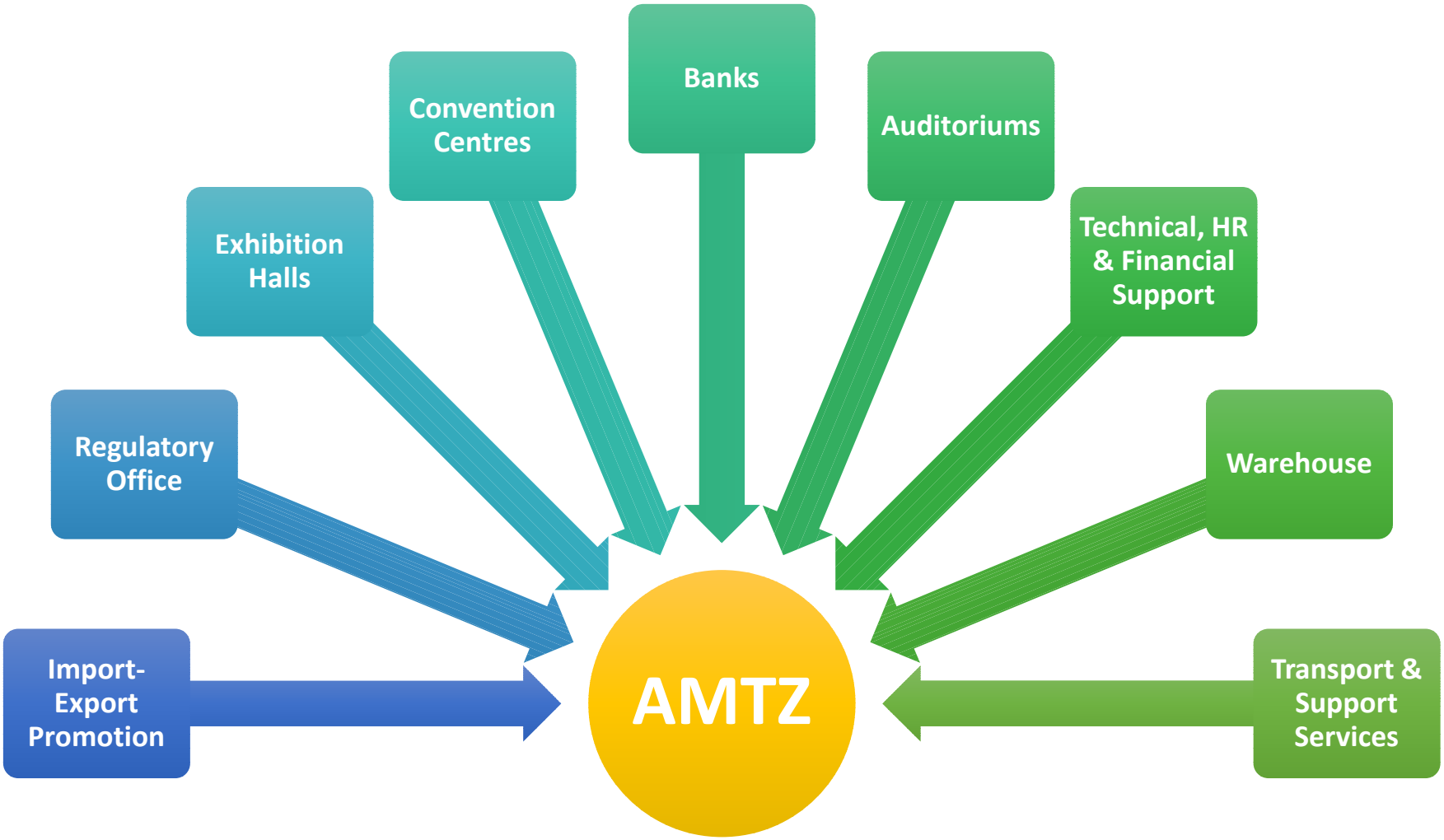
Size	10,000 sft	20,000 sft	40,000 sft
Booking fee (refundable) USD/$	100	200	400
Development fee (USD/$ once for 33 years)	37, 500	75, 000	150, 000 1 Cent/SFT/month
Monthly fees USD/$	600	1200	2400 0.45 Cents/SFT/Month

Visakhapatnam- the port city

Un-Common Scientific Facilities



Business Promotion Facilities

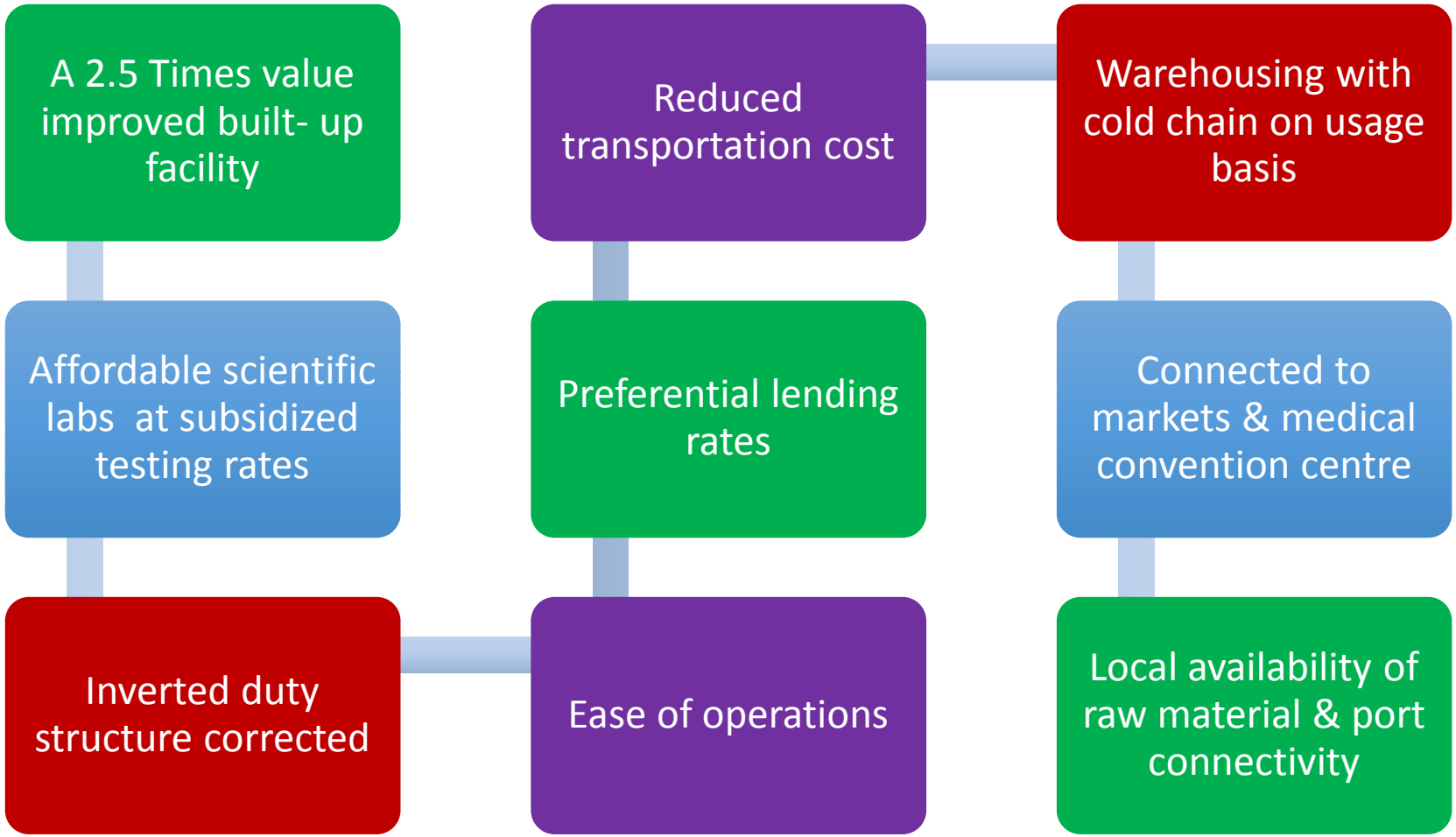


Benefits for Manufacturers

- Infra Development
- Lower Cost for Testing Services
- Lower CapEx for Manufacturers
- Regulators & Export Facilitation
- Finance & Technology Transfer Services
- Promotional activities through Expo & Convention Centre
- 20% space saving due to centralized Warehousing
- Preferential Market Access

The Grand Beginning…

Operational Efficiencies



Incentives & Positives

Quality Certification

50% subsidy on the expenses incurred for quality certification limited to Rs 4 Lakh / 6,400 USD (Conformity European (CE),

100% subsidy for IC-MED certification by Quality Council of India, supported by AMTZ

Green Production Measures

•25% subsidy on cleaner / greener production measures limited to Rs 10 Lakh / 16,000 USD

Skill Up-gradation & Training

•50% reimbursement of the cost incurred subject to a maximum of Rs.10,000 (USD150) per employee to the companies for providing skill gap trainings to the engineers of AP domicile

Micro, Small and Medium Scale Enterprises

20% Investment Subsidy limited to Rs 20 lakh / 32,000 USD for MSME and additional 5% investment subsidy for Women Entrepreneurs

Preferential Market Access

The policy of GoI on preferential market access for domestically manufactured electronics products/ other products

Incentives & Positives

Tax benefit & depreciation

Eligible for 15 per cent of higher additional depreciation making it 65% and 15 per cent of investment allowance on the cost of plant and machinery

Power Subsidy

50% to micro, 40% to small & 25% to medium & 10% to large-scale industry limited to Rs 50 lakh / 80,000 USD for a period of 5 years from the date of commencement of commercial operations.

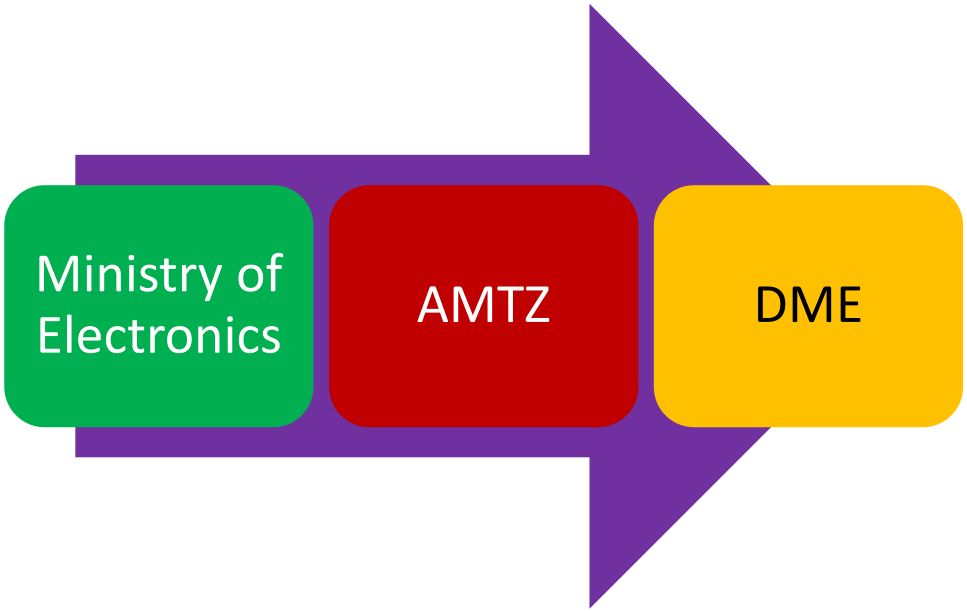
Exemption of Electricity Duty for new electronic hardware units, after coming into commercial operations entitled for 100% exemption on Electricity duty for a period of 5 years

Patent Filing Cost

The cost of filing patents will be reimbursed to the companies having their headquarters in Andhra Pradesh, subject to a limit of Rs 5 Lakh / 8,000 USD per domestic patent awarded and Rs 10 Lakh / 16,000 USD per international patent awarded

AVISHCAR

Advance Identification Of Scientific Technology & Commissioning Roadmap



Advance Purchase/use agreement for high value medical technology products with exclusivity

Ranked best Investment Destination in India by World Bank & DIPP, Govt. of India

India's 1st Integrated Medical Devices Manufacturing Park