MEDICAL DEVICES

.....THE NEXT BIG ATMANIRBHARTA STORY AFTER IT & PHARMA ?

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JULY 2023

AiMeD

Association of Indian Medical Industry

OBJECTIVE 1

Encourage Responsible Manufacturing

400 Primary Members
+
200 Associate Members

OBJECTIVE 2

Promote Make in India

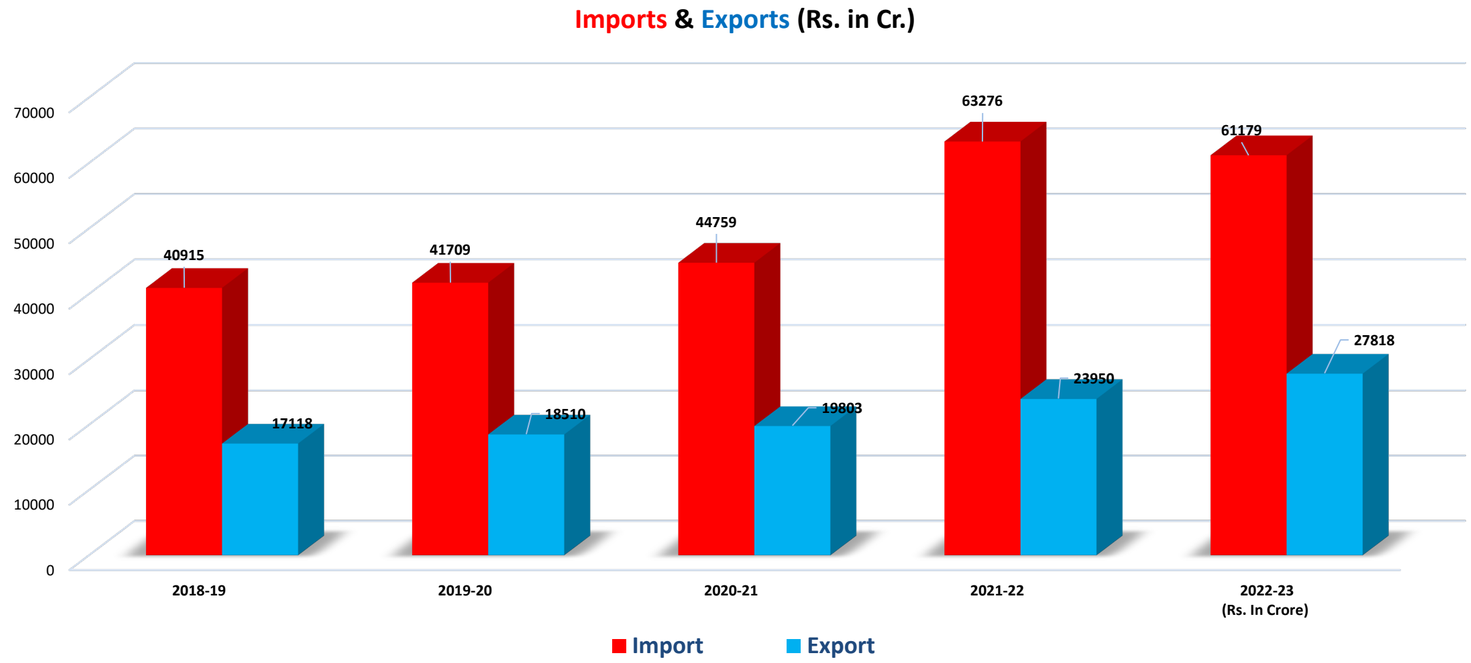
Safeguard Interest of 1500 Medical Devices Manufacturers

OBJECTIVE 3

Facilitation & Coordination

Bridge Between Govt. Dept Manufacturers, Academia, Users & Stakeholders

	2018-19	2019-20	2020-21	2021-22	2022-23 (Rs. In Crore)
Import	40915	41709	44759	63276	61179
Export	17118	18510	19803	23950	27818



National Health Policy 2017

14 - Regulatory Framework for Medical Devices

14.5 - Medical Devices Regulation:

- strengthening regulation of medical devices
- establishing a regulatory body for medical devices
- unleash innovation and entrepreneurial spirit for manufacture of medical device in India.
- supports harmonization of domestic regulatory standards with international standards.
- Building capacities in line with international practices in our regulatory personnel and institutions, would have the highest priority.
- Post market surveillance program shall be strengthened to ensure high degree of reliability
- Prevent adverse outcomes due to low quality and/or refurbished devices.

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Parliament Health Committee Report

2.9 Strongly recommends that instead of drafting a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should appreciate the potential of the Medical Device industry and formulate a separate legislation for Medical Devices.

2.10 Recommends

- Instead of Panel have a National Commission on Medical Devices
- Bring forth a comprehensive law supported by a holistic policy and institutional infrastructure for the purpose.
- This Commission should study centralizing the Medical Device licensing with the Central regulator to make the approval process easy.
- The Ministry should also focus on guaranteeing transparency by designing this legislation so that the citizens/ experts get a right to participate in decision making process & register their objections.

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Concerns on Pre-Legislative Process on Bill to Regulate Medical Devices

- Conflict of interest to empower Regulators by a Bill drafted by Regulators
- No meeting or inputs from MDTAG (Medical Device Technical Advisory Group)
- No Meetings with AiMeD as largest representative body for Devices
- Need for Devices to have Separate Regulations from Drugs (as FSSAI is for food)
- Separate Law for Medical Devices EU, Canada, Japan, Brazil etc. and Saudi Arabia
- Niti Aayog drafted a Visionary Separate Bill for Medical Devices –
- 'The Medical Device (Safety, Effectiveness and Innovation) Bill 2019'
  - intention was a Separate Law and
  - Separate Regulatory Body that would grow out of current CDSCO but with Science & Engineering lead Regulators
  - The Law would be mostly with Risk Proportionate decriminalized provisions to encourage Innovations

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Concerns on Pre-Legislative Process on Bill to Regulate Medical Devices

- A mandatory **Pre-Legislative Consultative Policy** that lays mandatory conditions to be complied with before any legislative proposal is submitted to the Cabinet for its consideration and approval
- Without considering and appropriately addressing the raised concerns the Bill could possibly lead to a dangerous piece of legislation that would further jeopardize the struggling Indian Medical Device Industry and would cause a great loss to the public at large if affordable access to safe homegrown Medical Devices is not possible.
- The policy mandates that have not been complied are under Point 6. "*The summary of feedback/comments received from the public/other stakeholders should also be placed on the website of the Department/Ministry concerned.*"
- Failure in adhering to this mandatory provision is evident from the fact that contents of AiMeD's concerns in representative capacity of the industry are not shared online.

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National Medical Devices Policy

- For Encouraging Manufacturing , AiMeD seeks

In STRATEGY for STREAMLINING REGULATIONS

- Separate Law & Regulatory Framework than Drugs

In STRATEGY for ATTRACTING INVESTMENTS

- Predictable & Consistent Decriminalized Regulations

In STRATEGY for R&D AND INNOVATION

- Decriminalized Law
- Standardize Regulatory Pathways

In STRATEGY for HUMAN RESOURCE DEVELOPMENT

- Trained & Certified Competent Auditors as Regulators

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Concerns with Initial & final Draft

- No Risk Proportionate Regulations
- No Country Uses Threat of Imprisonment excessively like India to enforce Law
- Progressive Countries seek 3rd Party Certification Compliance & Administrative measures effectively
- Regulations don’t address Patient safety over complete lifecycle of product
- Regulations don’t cover responsibility of other stakeholders like Users, Regulators,Hospitals
- Concept of Audit and seeking improvements instead of search and seizure needed
- Pseudo manufacturing being legalised
- No sharing of Responsibilities between Centre , State and 3rd Party Regulators
- Pharmacists and not Scientists or Engineers are Regulators – Medical Device Officers
- Concept of Pharma type Central Testing Labs is antiquated
- Pharma Concept of Misbranded, Spurious, Adulterated misplaced for Engineering equipment

Threat of Jail will Scare Away Investors

- Limit criminal judicial action to Non - Licensed manufacturing facility of Medical Devices

- Delete provision of imprisonment & make appropriate administrative/penalty provisions
  Imprisonment up to :
  a) 1 year for obstructing a Medical Device Officer
  b) 1 year for failure to provide Medical Management and Compensation
  c) 7 years for import or manufacture of adulterated or spurious
  d) 3 years for import or manufacture of device not of a standard quality
  e) 2 Years for submission of misleading or wrong information Progressive

- Use 3rd Party Certification Compliance & Administrative measures more effectively

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For INDIA to be leading manufacturer

Medical Devices need their own House, don't Bind them

- Drugs are a chemical - a homogeneous lot of powder / compound / liquid/ formulation
- Medical devices are usually engineered and assembled products
- One can aspire for 6 sigma Quality- one in a million defect - very few achieve this !
- Zero defect ? Nice motivational target - elusive with the sincerest efforts & best of technology to back it as there's a human & skill element too .
- Seeking Pharma Results and then punishments as in pharma is a Non-Starter !
- As oil & water can't be mixed so is the need for Devices to have separate regulations.
- Most progressive countries EU, Canada, Japan, Brazil, Saudi Arabia etc have Separate Law
- Why India an aspiring nation should not seek to simplify laws and its compliance?

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The 1.6 lac Cr. Rs. Medtech Market

Don’t jeopardize the 80,000 Cr. Rs. Investment Opportunity

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VISION : TO BE TOP5 TO BE GLOBAL LEADER

AiMeD & Invest India Targeting:

1200 TECHNICAL COLLABORATIONS

@ 40Cr.Rs. for Indian investors for 48000Cr.Rs.

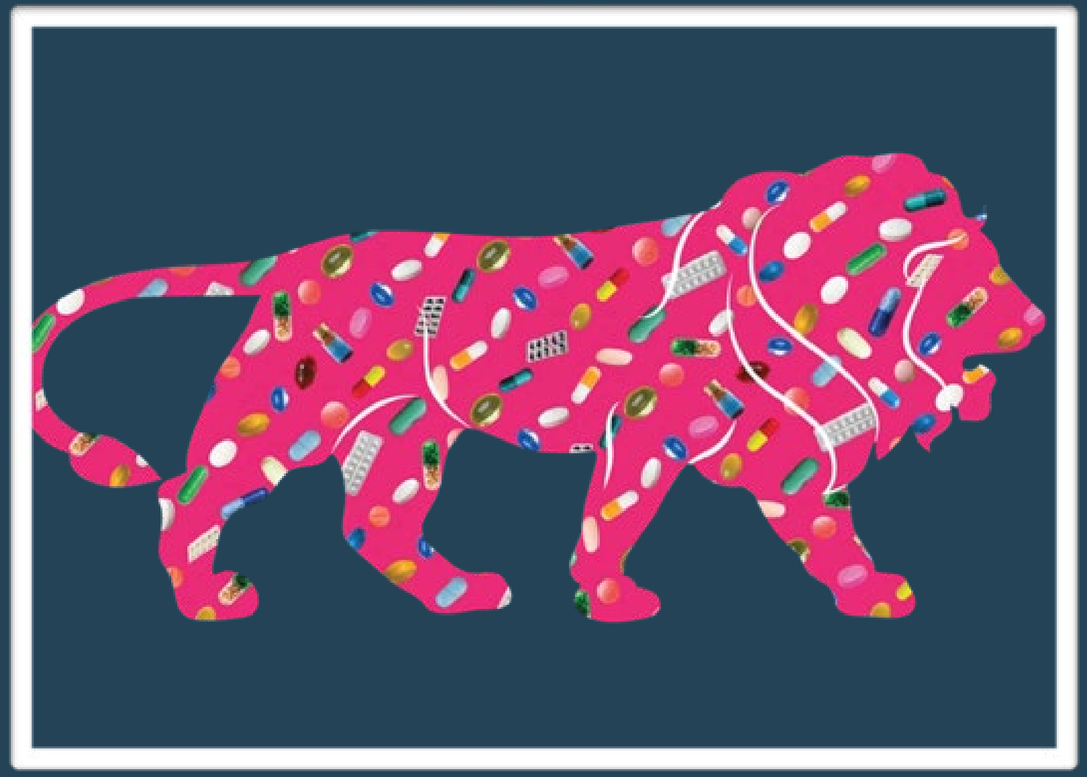
200 JOINT VENTURES

@ 80Cr Rs. for Indian investors for 96000Cr.Rs.

50 MNCS FDI

@ 320Cr Rs. for Overseas investors for 16000Cr.Rs.

MAKE IN INDIA



Covid Demonstrated

Mountains are Moved by Teamwork

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