22nd Asian Harmonization Working Party Meeting,
4-8 December 2017, New Delhi, India

Access to Medical Devices for Universal Health Coverage and achievement of SDGs: Medical Devices Landscape in India

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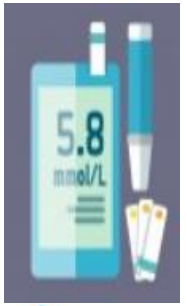
SUSTAINABLE DEVELOPMENT GOAL 3

Ensure healthy lives and promote well-being for all at all ages

The SDG3 emphasises the promotion of health throughout the life course and universal health coverage (UHC).

- Expand access to quality assured medicines and health products
- Ensure that quality essential medicines and health products are available in sufficient quantities and affordable to the population through functioning regulatory and procurement systems
- Focus on research and development efforts on diseases that disproportionate affect developing countries



World Health Organization India

“Towards Access 2030”

To Increase Access to Essential, High-Quality, Safe, Effective and Affordable Medical Products

Two strategic roles of EMP department

Facilitator

Supporting needs-based innovation and reinforcing health product selection, use, procurement and supply systems to increase access

Guardian

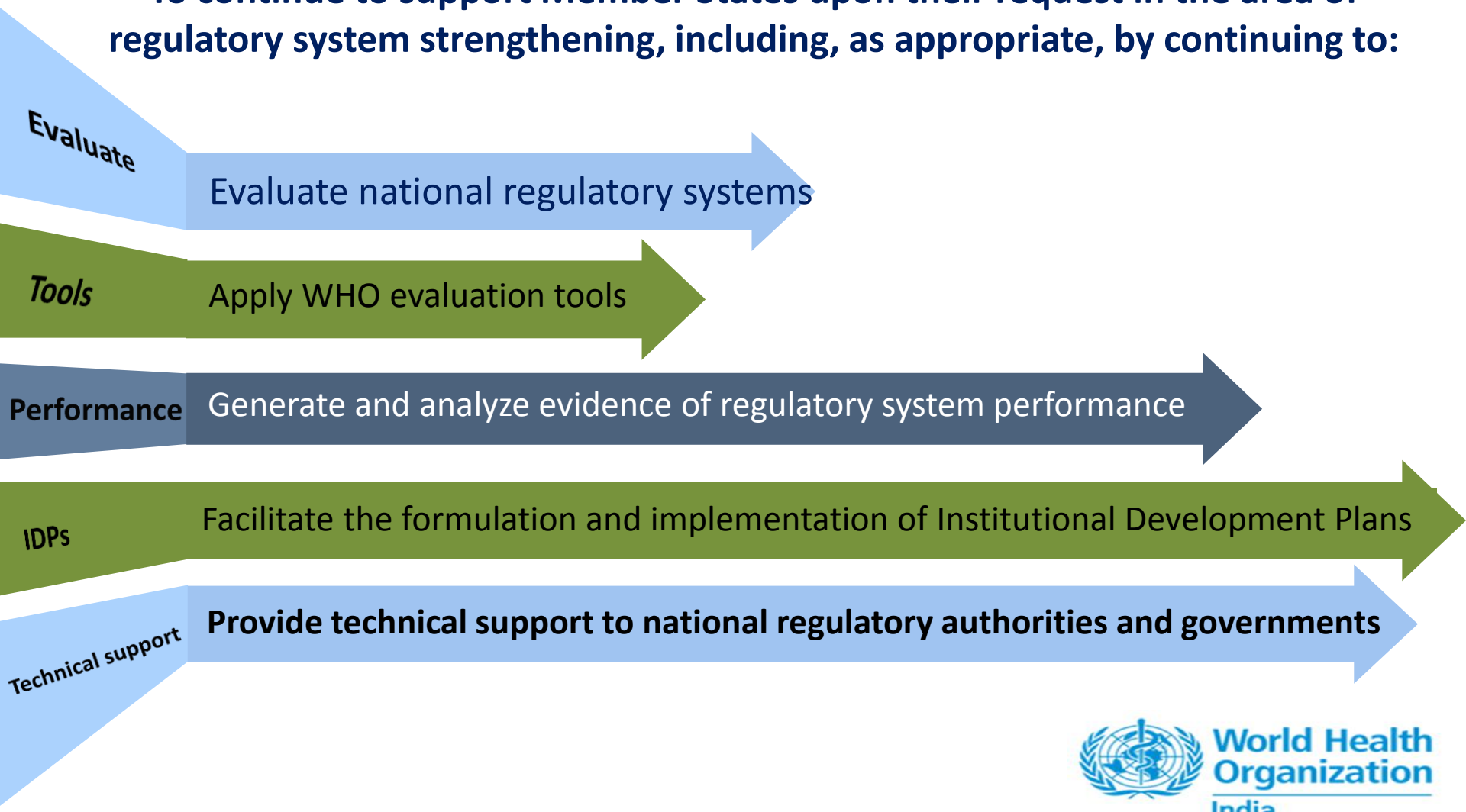
Strengthening regulatory capacity and practices to ensure the quality, safety and efficacy of products and improve the efficiency of regulatory system to secure health gains

World Health Organization India

Regulatory Systems Strengthening:

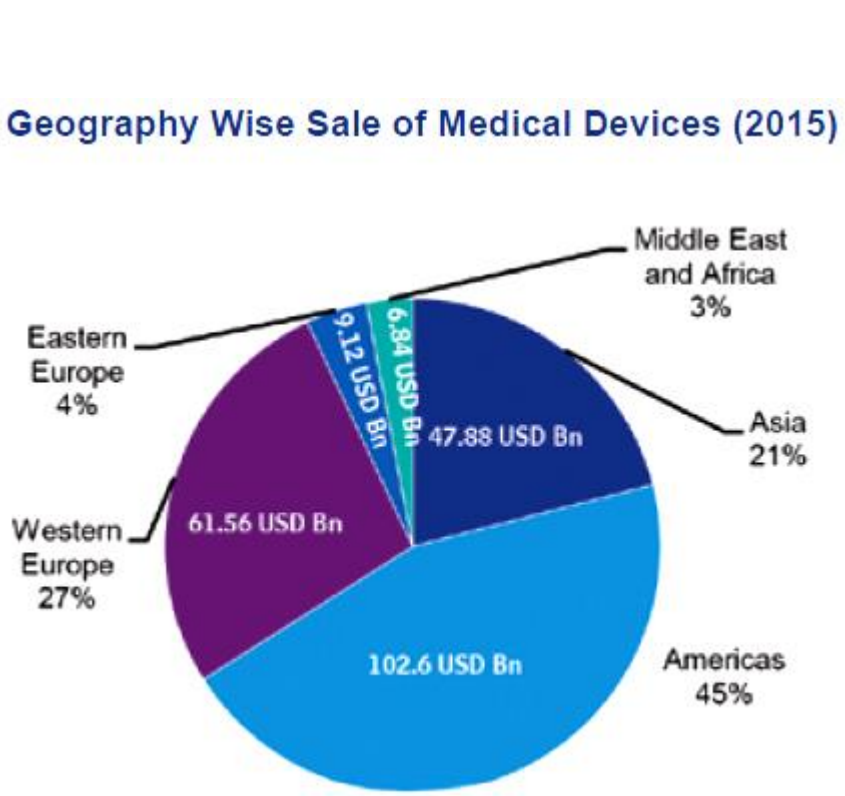
WHA Resolution 67.20: What WHO should do

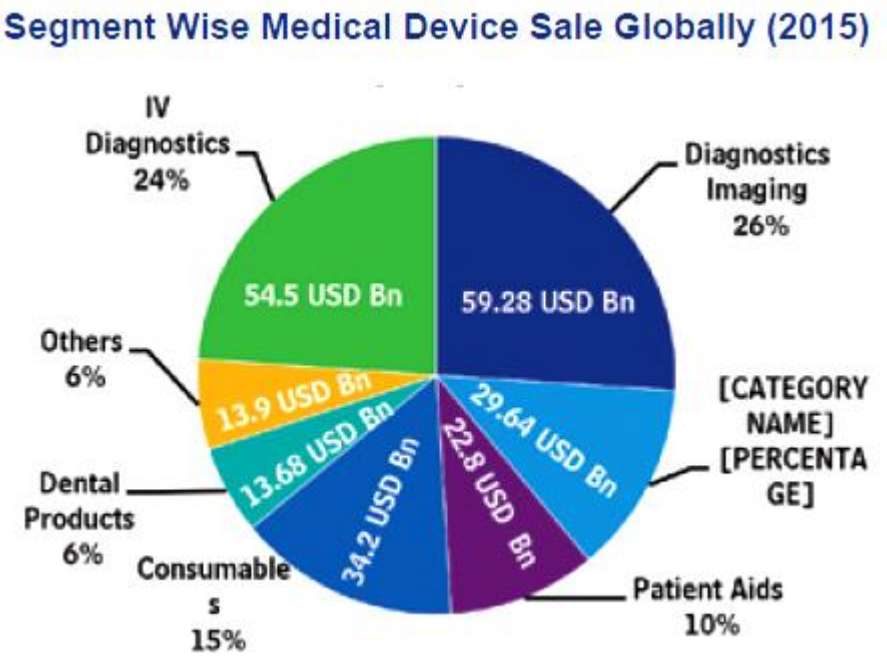
To continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:



World Health Organization India

Global Medical Device Market

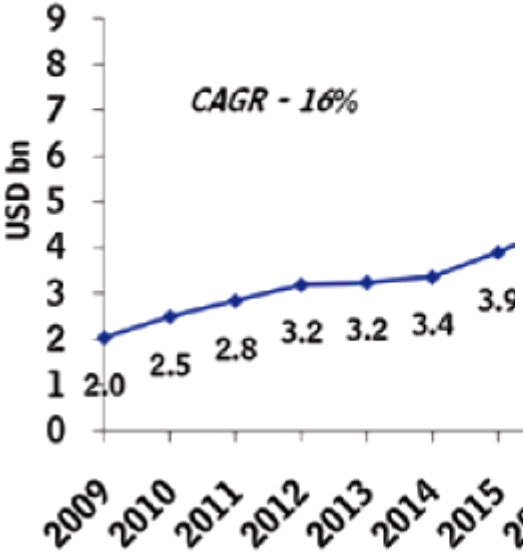


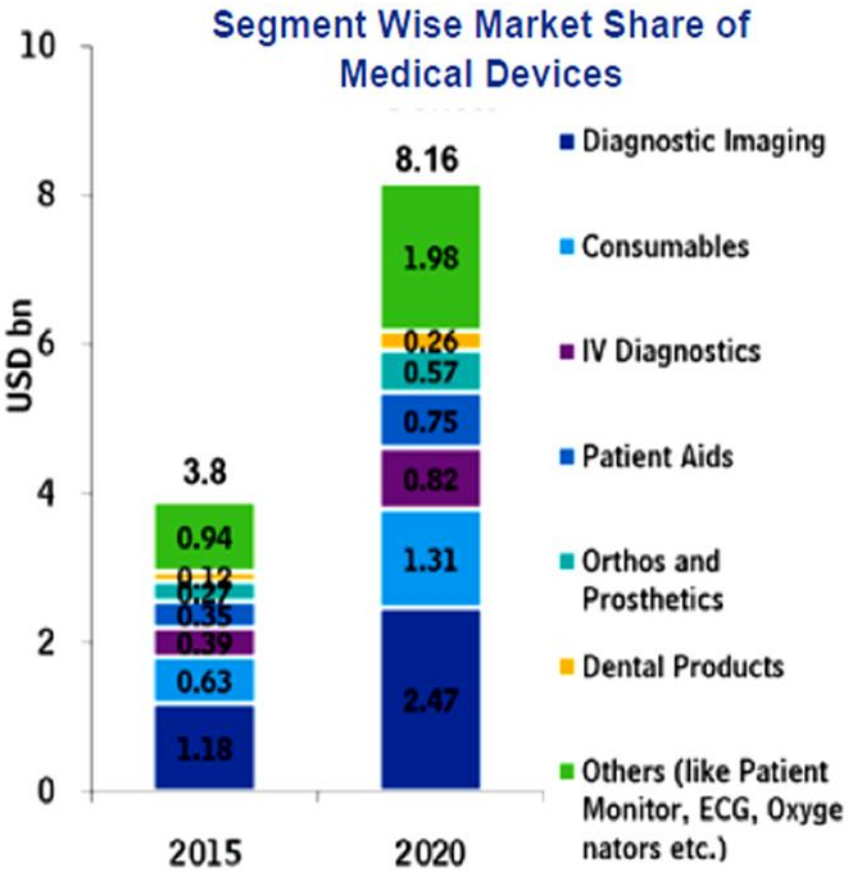


World Health Organization India

Indian Medical Device Market

India is one of the to
medical device mark
largest medical devi
Asia.





device sector is worth
D 5.5 Billion and is
GR.

Device market
f the Indian healthcare
gged at USD 96.7 bn
es), in 2015.

te suggests that the
ce market will grow to
3,053 crore) in 2020 at

World Health Organization India

Medical Device Clusters in India

Haryana

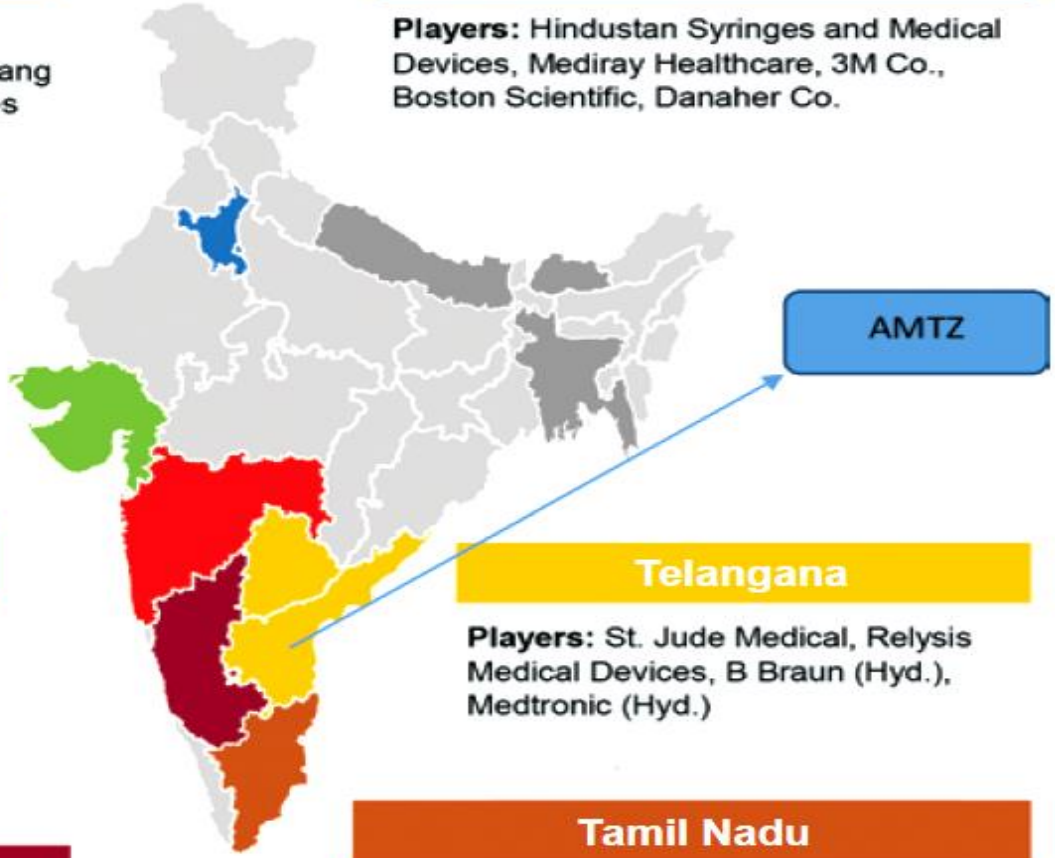
Players: Boston Scientific Corp., Becton Dickinson India, Hindustan Syringes, Narang Medicals, Poly Medicure, BL Life Sciences

Delhi (NCR)

Players: Hindustan Syringes and Medical Devices, Mediray Healthcare, 3M Co., Boston Scientific, Danaher Co.

Gujarat

Players: 3M Co., Bayer AG, Meril Life Sciences, Envision Scientific, Invent Bio-Med, Sahjanand Medical Technologies



Maharashtra

Players: Johnson & Johnson, Smith & Nephew, Philips Healthcare, Siemens, Nipro Corp., Danaher Corp, Trivitron Healthcare, Remi Laboratories

Telangana

Players: St. Jude Medical, Relysis Medical Devices, B Braun (Hyd.), Medtronic (Hyd.)

Karnataka

Players: GE Healthcare, Biocon, Medived, Skanray, Bigtec Labs, Skanray Technologies, Prognosys Medical, Opto Circuits, Biorad Medisys, Vascular Concepts, Confident Dental Equipments

Tamil Nadu

Players: Roche, Trivitron Healthcare, Opto Circuits, Perfint Healthcare, Cura Healthcare, Appaswami Associates, Phoenix Medical Systems, Schiller

NATIONAL HEALTH POLI

20

13.11 **Make in India:** Towards furthering "Make in India", the private domestic manufacturing firms/ industry could be engaged to provide customized indigenous medical devices to the health sector

14. **Regulatory Framework:** The regulatory role of the Ministry of Health and Family Welfare- which includes regulation of clinical establishments, professional and technical education, food safety, medical

14.5 **Medical Devices Regulation:** The policy recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India. The policy supports harmonization of domestic

14.7 **Pricing- Drugs, Medical Devices and Equipment:** The regulatory environment around pricing requires a balance between the patients concern for affordability and industry's concern for adequate

18. **Availability of Drugs and Medical Devices:** The policy accords special focus on production of Active Pharmaceutical Ingredient (API) which is the back-bone of the generic formulations industry. Recognizing that over 70% of the medical devices and equipments are imported in India, the policy

19. **Aligning other policies for medical devices and equipment with public health goals:** For medical devices and equipment, the policy recommends and prioritises establishing sufficient labeling and packaging requirements on part of industry, adequate medical devices testing facility and effective port -

16 **Medical Technologies:** India is known as the pharmacy of the developing world. However, its role in new drug discovery and drug innovations including bio-pharmaceuticals and bio-similars for its own health priorities is limited. This needs to be addressed in the context of progress towards universal health care. Making available good quality, free essential and generic drugs and diagnostics, at public

22. **Health Technology Assessment:** Health Technology assessment is required to ensure that technology choice is participatory and is guided by considerations of scientific evidence, safety, consideration on cost effectiveness and social values. The National Health Policy commits to the development of institutional framework and capacity for Health Technology Assessment and adoption.

25.4 **Research Collaboration:** The policy on international health and health diplomacy should leverage India's strength in cost effective innovations in the areas of pharmaceuticals, medical devices, health care delivery and information technology. Additionally leveraging international cooperation, especially

diagnostics for chronic ts and out- subsidized

d Health anization India

Assessment of the **National Regulatory Authority (NRA) of India**

Ensuring quality, safety and efficacy of vaccines

"Pharmacovigilance" is one of the core functions in the WHO global NRA benchmarking tool

The **WHO NRA re-benchmarking exercise, from 13-17 February 2017**, was aimed at assessing the status of the India vaccine regulatory system

Press Information Bureau
Government of India
Ministry of Health and Family Welfare

17-February-2017 19:22

Maximum Possible Marks to Indian NRA in WHO Assessment

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Government of India
Ministry of Health and Family Welfare

21-February-2017 1

WHO congratulates India on successful assessment of India's National Regulatory Authority

Big boost to Government's efforts towards quality healthcare: J P Nadda

"The successful outcome of the WHO conducted assessment of the National Regulatory Authority (NI India is a big boost to the Government's efforts towards quality healthcare, for which the Governm committed to". This was stated by Union Minister for Health & Family Welfare Shri J P Nadda, here to WHO congratulated him and the Ministry for successful assessment of the country's National Regu Authority (NRA). He stated that the Ministry under the dynamic guidance and leadership of the Hon. Minister Shri Narendra Modiji is poised for more such laurels in the healthcare sector.

Regulatory Landscape: Government Support & Initiatives for Medical Devices Sector

Regulatory Landscape Strenghtening

- Materio-vigilance Programme of India
- Delinking of Schedule M-III
- Significant experience for Manufacturing Supervisor
- Presription of Shelf-life for medical devices
- Exemption for Custom Made Medical Devices
- Clarification of Standards for medical devices
- Drugs and Cosmetic (Amendment) Bill, draft for stakeholder views
- Draft National Medical Device Policy, 2015

Tax/ Duty Modifications

- Subsidies and exemptions to MSMEs
- Corrections in the Inverted Duty Structure to boost domestic manufacturing of medical devices
- Budget initiatives

Infrastructure Boost

- 'Make In India' Campaign to boost domestic manufacturing
- Setting up of Medical Device Parks in three states
- Setting up of Medical Device Testing Labs in two states

Other Favourable Initiatives

- Exemption from Phase I clinical trials for medical devices
- Development of ICMED scheme for certification of medical devices

India

Make in India campaign: launched with focus on 25 sectors including medical devices

100 per cent FDI allowed: The medical device sector was carved out from the pharmaceutical sector thereby allowing 100 per cent FDI under the automatic route, for brownfield as well as greenfield set-ups.

Draft National Medical Device Policy, 2015 rel
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The Ministry of Health and Family Welfare has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and WHO Guidelines to comply with best international practices

Sept 2014 → **Oct 2014** → **Dec 2014** → **Jan 2015** → **Apr 2015** → **Jun 2016** → **Jan 2017**

Formation of Task Force: The DoP constituted a task force to identify issues relating to the promotion of domestic production of high end medical devices.

Draft Drugs & Cosmetics (Amendment) Bill, 2015 released: The bill proposes to expand the scope of the Act to cover new areas and will "regulate the import, manufacture, distribution and sale of drugs, cosmetics, medical devices". The amendment is likely to be approved soon.

Funding approval to AMTZ:
AMTZ receives approval for funding by the state cabinet on 1st June, 2016 for setting
up Asia's first dedicated medical device park at Visakhapatnam.

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Organization
India

Honourable Finance Minister Budget Speech

We propose to amend the Drugs

Press Information Bureau
Government of India
Ministry of Chemicals and Fertilizers

28-January-2017 14:38 IST

'India Pharma 2017' & 'India Medical Device 2017': for responsible Healthcare

Aim to Project India as an Attractive Investment Destination and Global Hub for Pharma and Medical Devices Sector: Shri Ananth Kumar

Online Media Regist

The Department of Pharmaceuticals (DoP), Minist
Chambers of Commerce & Industry (FICCI), is organi
- '*For Responsible Healthcare*', the 2nd Internation
sector from 11th-13thFebruary, 2017 in Bengaluru.

Addressing the media during the **Curtain Raiser fo**
Fertilizers and Parliamentary Affairs, Shri Ananth Ku
platform to tap global potential for the Indian
opportunity to **project India as an attractive investm**
areas such as Research & Developments, Clinical Tr
bringing in best practices in the sector from around the

Further, the Minister informed that this year the 'Ind
Themes: Medical Devices- *'Shaping the Future-Ma*
Pharma'. This initiative will be a platform to give a
globally competitive. It would play the role of a me
Investors and CEOs from the Global Pharma & M
participating stakeholders to network and learn amor
highlight would be the International Drug Regulators

Press Information Bureau
Government of India
Ministry of Health and Family Welfare

02-February-2017 18:19 IST

Health Ministry Notifies Medical Devices Rules, 2017

The Ministry of Health and Family Welfare has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and conform to best international practices. Only 15 categories of medical devices are, at present, regulated as drugs and to that extent, the current regulatory practices in India were not fully geared to meet the requirements of medical devices sector in the country. The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.

Medical devices will, under the new Rules, be classified as per GHTF practice, based on associated risks, into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.

Medical Device Rules, 2017

- Ministry of Health & Family Welfare, ***notified Medical Devices Rules, 2017 on 31.01.2017***

- There will be ***no requirement of periodic renewal of licences***.
- Accordingly, manufacturing and import licences will remain valid till these are suspended or cancelled or surrendered.
- Further, ***the entire process starting from submission of application to grant of permission/licence will be processed through online electronic platform.***
- ***Timelines have been defined*** for most activities at the regulators end.
- These Rules envisage creation of a **robust eco-system for all stakeholders** including innovators, manufacturers, providers, consumers, buyers and regulators.
- The Rules will provide a ***conducive environment for fostering India specific innovation and improving accessibility and affordability of medical devices across the globe*** by leveraging comparative cost advantage of manufacturing in India.
- The ***objective, transparent and predictable regulatory framework will boost the confidence of investors*** and, as a consequence, the ***quality and range of products and services will improve and business burdens will be reduced***.

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- ***Separate provisions for regulation of Clinical investigation (clinical trials) of investigational medical devices (i.e. new devices***) have also been made at par with international practices and, like clinical trials, ***these will be regulated by CDSCO.***

Initiatives for Promotion of Medical Device Industry

Scheme for Financing Common Facility Centres (CFCs) at Medical Device Parks:

- Proposal for scheme for "*Development of Common Facilitation Centres for Medical Devices"* in medical device parks under the Umbrella scheme for "Development of Pharmaceuticals Industry" thus creating an ***Eco System for High End Medical Device Manufacturing and Import Substitution with an eye for Export Market***
- This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs 250 crores

Corrections in the Inverted Duty Structure:

a. **Raised import duty** on 67 ITC Categories of Medical to 7.5 per cent

Medical Device Promotion Council:

- **P**roposal under consideration for establishment in co-operation with Andhra Pradesh MedTech Zone Ltd. (AMTZ) at

Preferential Market Access:

- **P**roposal under consideration for giving ***preference to domestic industry in purchase of medical devices by all government agencies.***

Uniform Code For Medical Device Marketing Practices (UCMDMP):

- Draft Uniform Code for Medical Device Marketing Practices (UCMDMP) was prepared.
- It was decided to consult UCMDMP with the stakeholders.
- Two meetings in this regard were held with the stakeholders for incorporating their suggestions and further course of action in the matter.

– xi. Other facilities commonly required in manufacturing of medical devices

World Health Organization India

India: CDSCO can play a key role

With time WHO would like to rely on CDSCO ….

- India is a global supplier of IVDs, Medicines & Vaccines
- The First Critical Steps for the regulations of Medical Devices, including IVDs have been taken, followed by a steady continuation.
  - Avoid the mistakes made by others
  - Harmonize with internationall y accepted requirements
  - Do not duplicate that has been well done _ reliance
  - Seek opportunities for collaboration
- Effects on IVD manufacturers are already visible
- India is among the largest of WHO Member States

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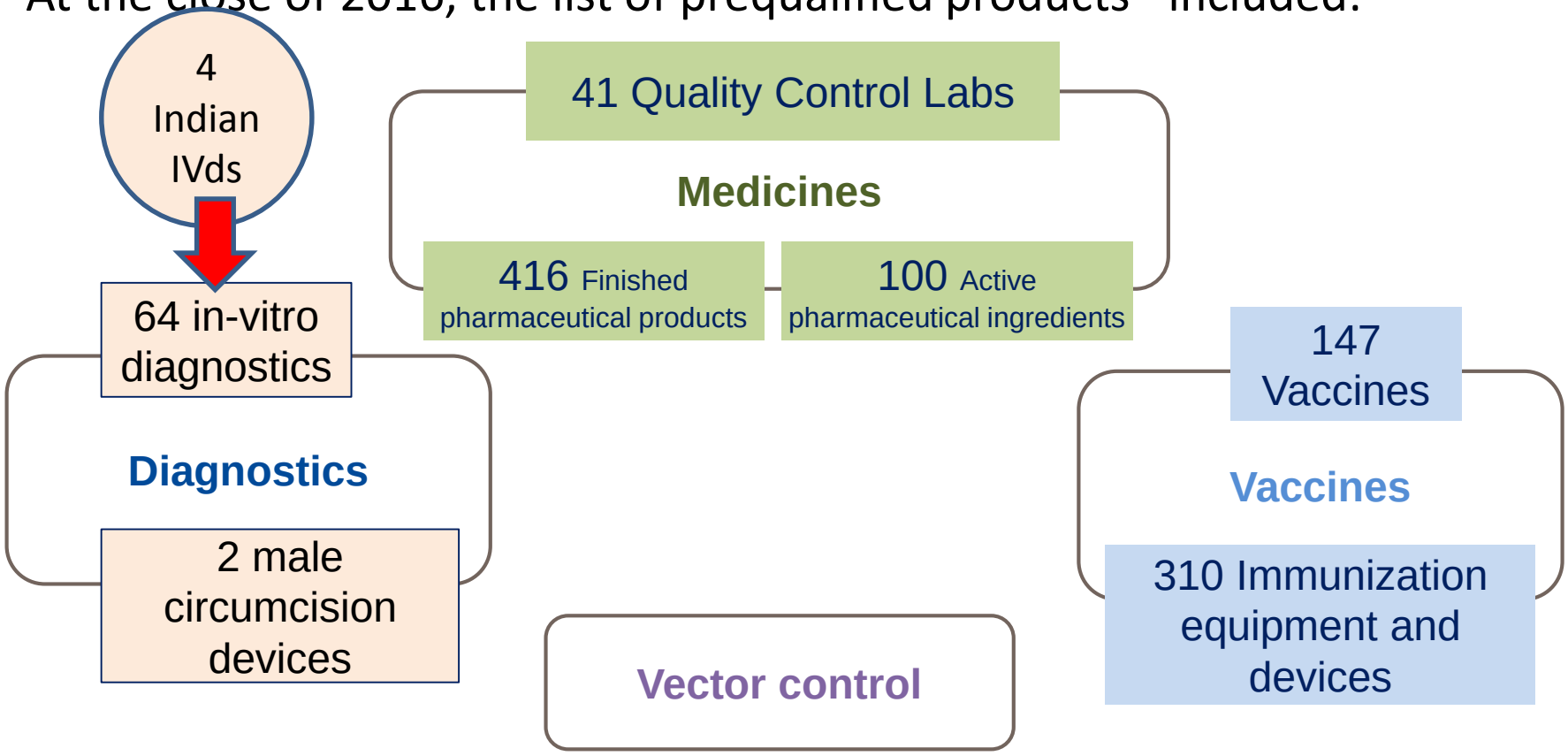
Prequalification by numbers:

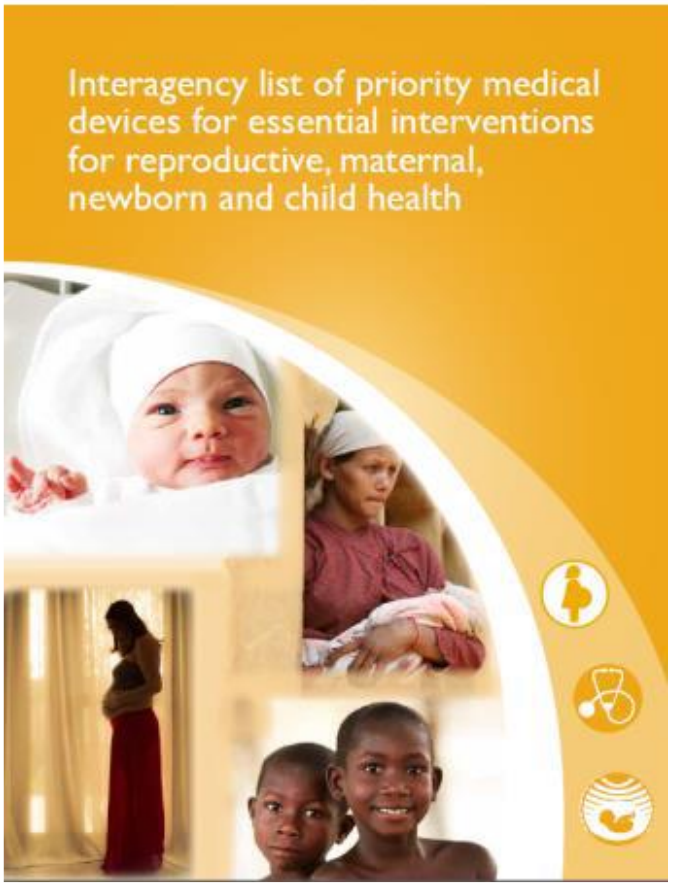
At the close of 2016, the list of prequalified products* included:

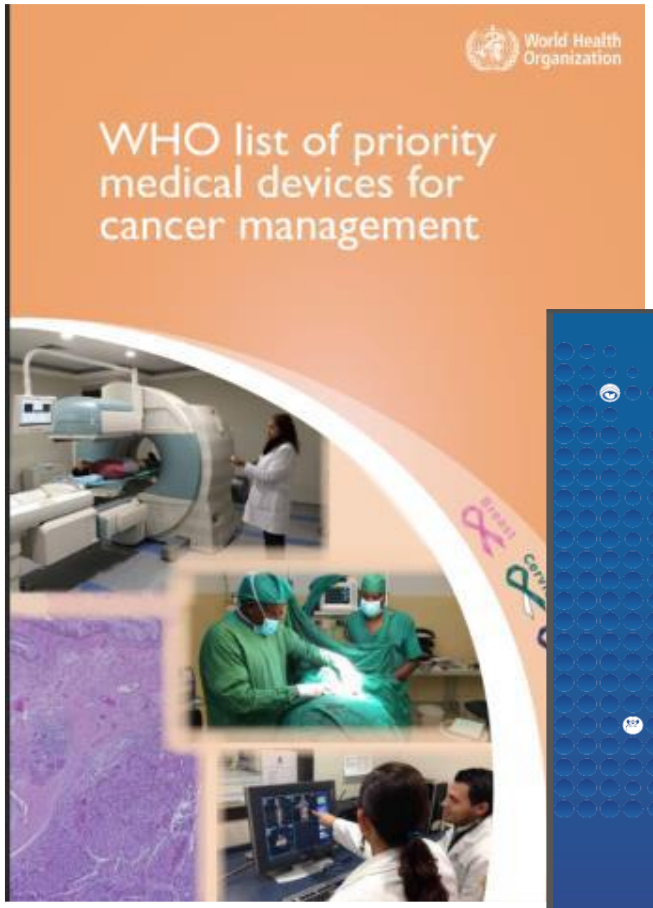


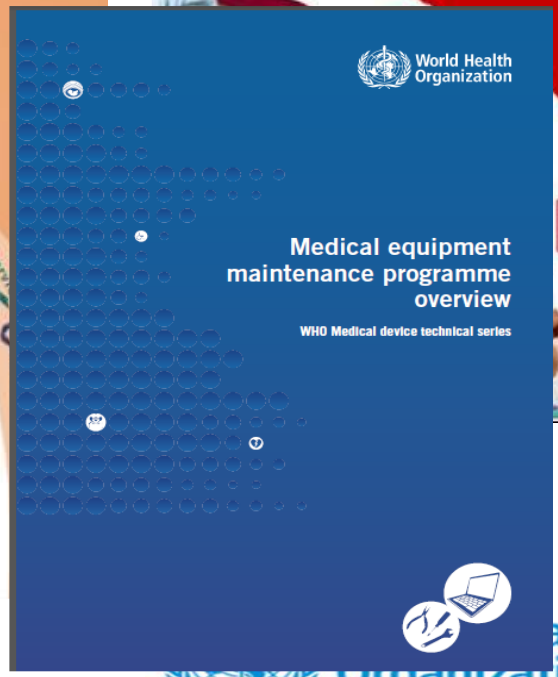
* Numbers are not the cumulative PQed products since their inceptions

World Health Organization India

Defining, Guidelines, Interventions, and medical devices by levels of care. Work on priority medical devices 2014- 2016

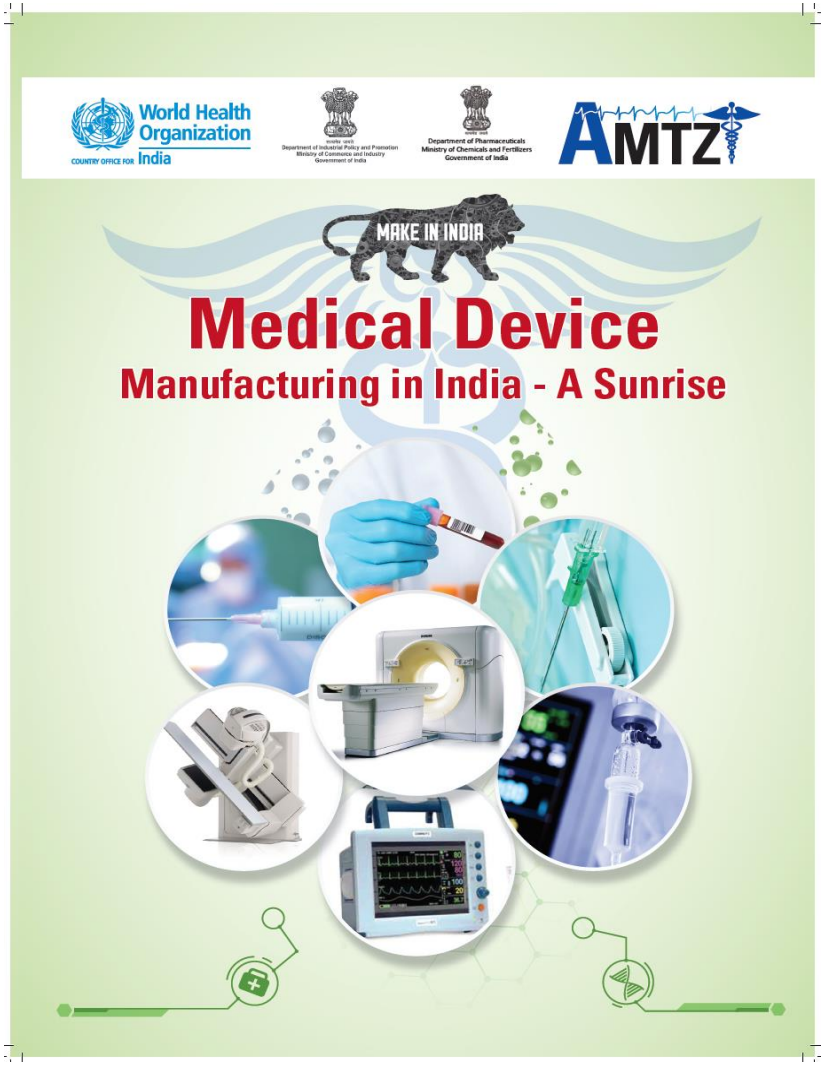






India

Launch of the Joint WHO-AMTZ-DoP-DIPP Medical Device Report



World Health Organization
India

Launch of WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services
at
National Coordination Centre- Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India

Health
ization
India

Launch of "National Strategic Plan for Scale up of Pharmacovigilance in India"

Launch of "Pharmacovigilance Guidelines for Stakeholders"

Ministry of Health & Family Welfare
Government of India

World Health Organization
India

1st World Conference on Access to Medical Products and International Laws for Trade and Health

in the context of the 2030 Agenda for Sustainable Development

21–23 November 2017 | New Delhi, India

1st World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development

21-23 November 2017,
The Taj Mahal Hotel
New Delhi, India

“India is deeply committed nationally and globally to achieving all public health goals and also focusing on developing India as a hub for affordable medical devices.” This was stated by HE Mr JP Nadda, Union Minister, Health & Family Welfare, Government of India.

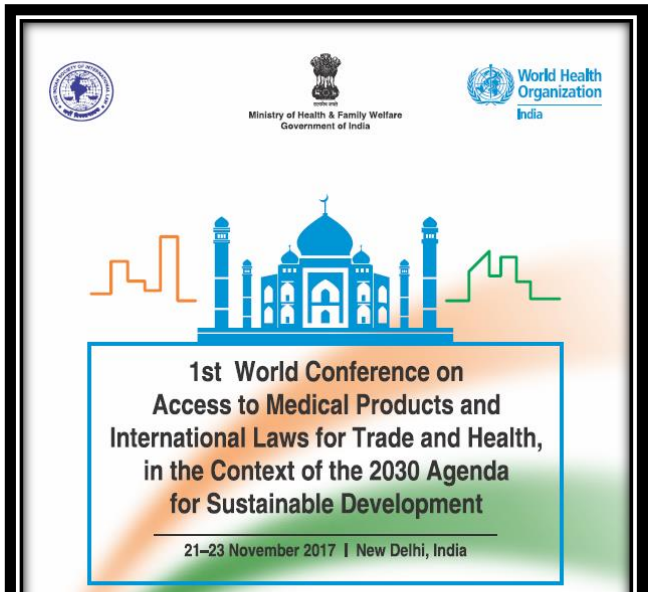
The Union Health Minister announced that the **second World Conference** on “Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development’’ would be **held in India** from **9-11 October 2018** and invited in advance all the participants.

World Health Organization India

Launch of Position Paper by HE Mr JP Nadda, Union Minister, Health & Family Welfare, Government of India and dignitaries on the dais

World Health Organization India

World Health Organization
India



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India

National Consultation – Outcomes of Survey of Indian Pharmaceutical Enterprises for Meeting National and Global Health Needs

24 November 2017, The Taj Mahal Hotel, New Delhi

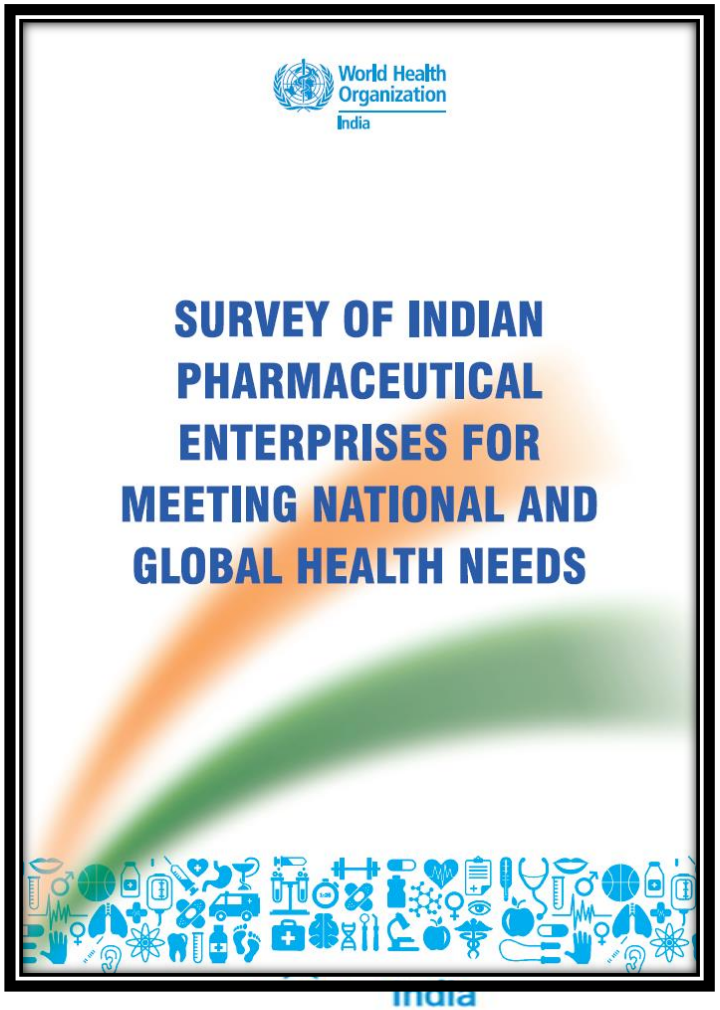
World Health Organization
India

Medical devices: The second section of the survey deals with information for enterprises engaged in the manufacturing of medical equipment, machinery and parts, etc., classified as Group IV inter-alia that comprises: X-ray films and plates, medical, surgical, laboratory and health fitness equipment, human safety articles and parts thereof

Specific suggestions for improving R&D in the medical device sector

Access to finance: According to the survey, 25.58% of respondents suggested easy access to finance for R&D activities, 16.28% for subsidy in R&D activities, 13.95% for tax incentives, 4.65% for building infrastructure, 2.33% for R&D cluster, and 2.33% for all kind of the assistance from government agencies to encourage R&D in the pharmaceutical sector.

Encourage national/foreign collaborations in R&D: There are suggestions for Government of India to encourage national/foreign collaborations for R&D, which are – technical know-how be sought from export industries, quick clearance of documentation and approval, single window clearance with minimized bureaucratic hurdles, support in technology transfer, and easy export policy with good incentive.



Launch of Support Cells for WHO PQS for IVDs in India

for providing guidance to the Indian manufacturers for the WHO Prequalification of *In Vitro* Diagnostics Programme in India

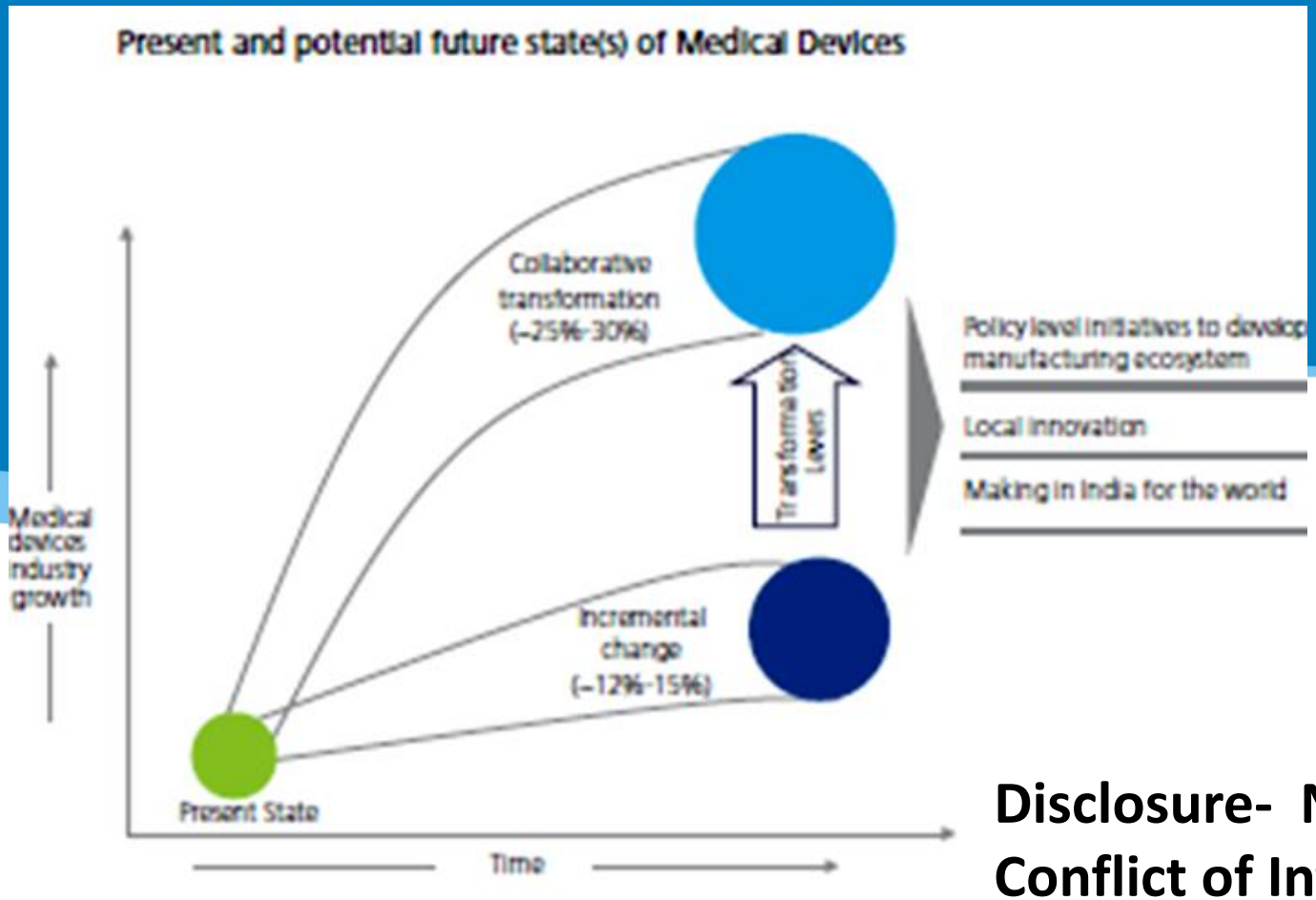
1) National Institute of Biologicals in North India
2) Andhra Med-tech Zone in south India

WHO would provide the required training to the support cell staff to guide the manufacturers about WHO Prequalification expectations

World Health Organization
India

World Health Organization
COUNTRY OFFICE FOR India

Thank you!



Disclosure- No Conflict of Interest