MEDICAL DEVICES
REGULATORY FRAMEWORK
CURRENT REGULATORY STATUS

- “Medical Devices” regulated as “Drugs” under subclause (iv) of section 3(b) of D&C Act, 1940
- 15 categories of Medical Devices notified as Drugs
- Regulations for Import, Manufacturing, Sales and Clinical Trials
- 8 Devices regulated as “substances” under subclause (ii) of section 3(b) of D&C Act, 1940
### 15 Notified Medical Devices

<table>
<thead>
<tr>
<th>S.No</th>
<th>Name of the device</th>
<th>Notification Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disposable Hypodermic Syringes</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>2</td>
<td>Disposable Hypodermic Needles</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>3</td>
<td>Disposable Perfusion Sets</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>4</td>
<td><strong>In vitro Diagnostic Devices for HIV, HbsAg and HCV</strong></td>
<td>01-09-2002</td>
</tr>
<tr>
<td>5</td>
<td>Cardiac Stents</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>6</td>
<td>Drug Eluting Stents</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>7</td>
<td>Catheters</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>8</td>
<td>Intra Ocular Lenses</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>9</td>
<td>I.V. Cannulae</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>10</td>
<td>Bone Cements</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>11</td>
<td>Heart Valves</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>12</td>
<td>Scalp Vein Set</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>13</td>
<td>Orthopedic Implants</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>14</td>
<td>Internal Prosthetic Replacements</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>15</td>
<td>Ablation Devices</td>
<td>25-01-2016</td>
</tr>
</tbody>
</table>
# 8 Devices Regulated as Substances

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of the device</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Blood Grouping Sera</td>
</tr>
<tr>
<td>2</td>
<td>Ligatures, Sutures and Staplers</td>
</tr>
<tr>
<td>3</td>
<td>Intra Uterine Devices (Cu-T)</td>
</tr>
<tr>
<td>4</td>
<td>Tubal Rings</td>
</tr>
<tr>
<td>5</td>
<td>Surgical Dressings</td>
</tr>
<tr>
<td>6</td>
<td>Umbilical Tapes</td>
</tr>
<tr>
<td>7</td>
<td>Blood / Blood Component Bags</td>
</tr>
<tr>
<td>8</td>
<td>Condoms</td>
</tr>
</tbody>
</table>
SALIENT FEATURES OF PROPOSED REGULATION FOR INDIA

1. Separate set of Rules for medical devices for Import, Manufacture, Clinical Investigation and Sale
2. Risk Based classification
3. Notification of additional medical devices
4. Authorities to regulate medical devices
5. Standards for medical devices
6. No renewal of licence
7. Essential Principles of Safety and Performance of Medical Devices
8. Registration & Regulation of Notified Bodies
9. Use of IT enabled services
## Classification in Other Countries

<table>
<thead>
<tr>
<th>Risk Criteria</th>
<th>India (Proposed)</th>
<th>USFDA</th>
<th>EU</th>
<th>Japan</th>
<th>Singapore</th>
<th>IMDRF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Class A</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Low-Moderate</td>
<td>Class B</td>
<td>II</td>
<td>IIa</td>
<td>II</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>Moderate-High</td>
<td>Class C</td>
<td>III</td>
<td>IIb</td>
<td>III</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>High</td>
<td>Class D</td>
<td>III</td>
<td>IV</td>
<td></td>
<td>D</td>
<td>D</td>
</tr>
</tbody>
</table>
## PROPOSED CLASSIFICATION

<table>
<thead>
<tr>
<th>Risk Criteria</th>
<th>India (Proposed)</th>
<th>IMDRF</th>
<th>Regulatory Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Class A</td>
<td>Class A</td>
<td>Notified Body*</td>
</tr>
<tr>
<td>Low-Moderate</td>
<td>Class B</td>
<td>Class B</td>
<td>Notified Body*</td>
</tr>
<tr>
<td>Moderate-High</td>
<td>Class C</td>
<td>Class C</td>
<td>CDSCO</td>
</tr>
<tr>
<td>High</td>
<td>Class D</td>
<td>Class D</td>
<td>CDSCO</td>
</tr>
</tbody>
</table>

* Electronic online system – Random Selection
Online application to CDSCO for registration of site and product

Automatic transmission to a randomly selected Notified Body in case of domestic manufacturer and in case of imports CDSCO to take a call about in-house or external assessment.

Compliance with QMS (Schedule M-III) to be verified by Notified Body within 30 days

Non conformance- rectification by manufacturer

Re-assessment by Notified Body

Automatic registration of Manufacturing site/product by CDSCO where recommended by Notified body.

Electronic generation of Registration Certificate

Post market surveillance.

Existing manufacturer to be registered within one year from date of enactment of these rules.

Clinical Trial/investigation, Animal testing, and Biocompatibility data not required.
Online application to CDSCO for registration of site and product
Automatic transmission to a randomly selected Notified Body in case of domestic manufacturer and in case of imports CDSCO to take a call about in-house or external assessment.

Class B devices to comply with:
- QMS
- Data requirements at the time of electronic submission of application
  - Performance standards for functional conformance
  - Biocompatibility
  - Animal study (if any)
  - Device Master File including essential requirements
- Labelling requirements
- Post Marketing Surveillance
- No Clinical Trial/investigation data required
Online application to CDSCO for registration of site and product

Class C & D devices to comply with:
- QMS
- Functional conformance
- Biocompatibility
- Animal study (if any)
- Device Master File including essential requirements
- Labelling requirements
- Clinical investigation data
- Post Marketing Surveillance
- Sample of the device
- Device having predicate device exempted from clinical investigation data.
## Requirements for Approval of Product

<table>
<thead>
<tr>
<th>Regulatory Compliance</th>
<th>Class A</th>
<th>Class B</th>
<th>Class C</th>
<th>Class D</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMS</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Electrical Safety/EMI/EMC testing data</td>
<td>✓*</td>
<td>✓*</td>
<td>✓*</td>
<td>✓*</td>
</tr>
<tr>
<td>Risk Analysis Report</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Device Master File</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Biocompatibility data</td>
<td>✓**</td>
<td>✓**</td>
<td>✓**</td>
<td></td>
</tr>
<tr>
<td>Animal Testing</td>
<td>✓**</td>
<td>✓**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Data</td>
<td>✓***</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Only for Electrical supply based devices  
**Only for invasive or implantable devices  
***Only for Investigational devices
REGULATIONS FOR IMPORT

- In case of products approved by any one of the GHTF countries, FSC/CFG from GHTF countries is to be insisted upon. [Class A, B, C, D]
- In case of others the Certifying Bodies should be accredited by International accreditation forum or by NABCB with FSC.
- Others in accordance with the system to be put in place by CDSCO.
<table>
<thead>
<tr>
<th>Scope of Regulation</th>
<th>Reviewer / Auditors</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Investigation and approval</td>
<td>Medical Device Officer (MDO)/ Drugs</td>
<td>CDSCO</td>
</tr>
<tr>
<td>of investigational medical devices</td>
<td>Inspector (DIs)/ External subject experts</td>
<td></td>
</tr>
<tr>
<td>Import</td>
<td>All Class</td>
<td>CDSCO issue licence/certificate</td>
</tr>
<tr>
<td>Manufacture</td>
<td>Class A&amp;B/Class C&amp;D</td>
<td>CDSCO</td>
</tr>
<tr>
<td>Sales</td>
<td>MDO/ DI (State officers)</td>
<td>State Licensing Authority</td>
</tr>
</tbody>
</table>
Devices to be notified along with its respective risk class by Central Government
A committee of experts to be constituted to lay down criteria for classification and identification of devices to be notified
International classification to be taken as the broad basis for classification
CDSCO to place recommendations before DTAB with experts in relevant fields
Phased notification of devices based on preparedness of regulatory structures
Transition time to be provided
A registration certificate or import licence shall remain valid, till it is suspended or cancelled from its date of issue.

Provided the applicant pays a certificate/licence retention fee on annual basis in the month of December.

Provision for payment with late fee upto a maximum period of two months. After 2 months licence will be deemed to have been cancelled.

Manufacturer shall be audited on annual basis.

Submission to CLA on changes in respect of site or significant changes in product, reportable complaints, recall etc.
QMS/ISO 13485

Standards to be adopted for demonstrating compliance in respect of:

4. Labelling

Manufacturer to comply with:

- BIS standards, if available, or
- ISO/IEC standards, or
- Manufacturer’s validated methods,
**ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE**

- General Requirements (Risk assessment, qualification of personnel etc.)
- Design and Manufacturing Requirements (material selection, verification and validation etc.)
- Requirements for medical devices connected to or equipped with an energy source
- Requirements for devices with a diagnostic or measuring function
- Protection against radiation
- Protection against mechanical risks
- Protection against risks posed to the patient by devices for self-testing or self-administration
- Clinical Evaluation
HUMAN RESOURCES

- A separate vertical with dedicated staff for medical devices
- Medical Device officers (MDO) in place of Drugs Inspectors
- Qualification of MDO
  - Biomedical Engineers
  - Electrical & Electronic Engineers
  - Plastics Engineers
  - Mechanical Engineers
  - Pharmacy
- External Subject Experts
- Contractual technical staff
- Training
- Accredited Notified Bodies (Class A & Class B)
- State Drug Regulators (for sales)
SCOPE OF NOTIFIED BODIES

- Only Class A and Class B medical Devices
- To verify QMS conformance at manufacturing site where necessary by inspection
- Verification of Essential Requirements
- Verifying validation of manufacturing process through objective evidence
- Conformity of material with defined specifications
- Responsibility for ensuring conformance to QMS and conditions of license/registration
- CDSCO to audit notified bodies and test audit 5% of the licenses/registrations issued on the recommendation of each Notified Body
Only NABCB accredited Notified bodies to be registered with CDSCO

Weightage to be given to accreditation by International bodies, but accreditation by NABCB will be mandatory

ISO standards to be laid down in schedules to apply for accreditation/recognition

System of Audit/inspection/unannounced Audits of Notified Bodies by CDSCO

Schedule of fee to be charged by notified bodies to be prepared with provision for automatic upward revision based on WPI

Refundable security deposit and revenue sharing model

Duties, functions and obligations of notified bodies including penal provisions to be specified
WORLD CLASS REGULATORY FRAMEWORK - A COMMITMENT

- Leverage:
  - Japanese Technology
  - Indian demographic dividend, enterprise, scale and cost competitiveness
  - Indo Japanese qualities head and heart
  - Knowledge from across the world

- Build a hub for meeting world requirements of quality medical devices at affordable cost
THE JOURNEY

- Draft Rules prepared/discussed with stakeholders
- Final round on 24th May 2016
- Placing in Public domain
- DTAB consultation
- Expert committee for finalising classification and inclusion of devices
REACHING DESTINATION

- Survey undertaken
- Stake holders to suggest:
  - What it requires to do business with ease and integrity
  - Ensuring quality, safety, performance and affordability
- Jointly build the highway
- Government to concretise the highway
- Zoom on the highway at the speed you choose
Keynote Speech II

Latest trend of medical device regulations in Japan

1st India-Japan Medical Products Regulation Symposium
19th May 2016

Toshiyoshi Tominaga, Ph.D.
Associate Executive Director for International Programs,
Pharmaceuticals and Medical Devices Agency (PMDA)
JAPAN
Overview of Medical Device Regulations in Japan
Medical Device has been regulated since 1948 in Japan. Regulations under current Act started in 1960 and there have been 2 big amendments for the regulations recently;

1. Amendment in 2005
   ① Introduction of Marketing Authorization Holder system
   ② Introduction of Third Party Certification system
   ③ Introduction of medical device classification based on the GHTF Classification Rule
   ④ Introduction of STED and Essential Principles
   ⑤ Introduction of GCP as a ministerial ordinance
   ⑥ Introduction of QMS, instead of GMP
Medical Device has been regulated since 1948 in Japan. Regulations under current Act started in 1960 and there have been 2 big amendments for the regulations recently;

2. Amendment in 2014
   ① Amendment of Third Party Certification system, including expansion of scope
   ② Improvement of regulations on manufacturer
   ③ Improvement of QMS inspection
   ④ Application of medical device regulations on SaMD (Software as a Medical Device)
   ⑤ Establishment of a new category, Regenerative Medicine Product
### Medical Device Regulations

<table>
<thead>
<tr>
<th>EU</th>
<th>Japan</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-market review</strong></td>
<td><strong>Class III, IV: Minister’s approval</strong></td>
<td><strong>Class III: PMA Approval</strong></td>
</tr>
<tr>
<td><strong>Notified body certification</strong>&lt;br&gt;(requirements depend on device classification)</td>
<td><strong>Class II and a few Class III: Third Party Certification by Registered Certification Body</strong></td>
<td><strong>Class II: 510(k) clearance,</strong>&lt;br&gt;<strong>Class I: Listing</strong></td>
</tr>
<tr>
<td><strong>Class I: Marketing Notification</strong></td>
<td></td>
<td><strong>Class I: Listing</strong></td>
</tr>
</tbody>
</table>

Governmental approval/license<br>Notified body review/certification<br>Self declaration/exemption
Legal structure for medical device/IVD regulations

- **Act**
  - Pharmaceutical and Medical Device Act (PMD Act), 1960

- **Cabinet Ordinance**
  - Cabinet Ordinance on PMD Act, 1961

- **Ministerial Ordinance**
  - Ministerial Ordinance on PMD Act, 1961
  - GCP for medical device, 2005
  - Good Vigilance Practice (GVP)
  - Quality Management System (QMS) etc.

- **Ministerial Notification**
  - Essential Principles
  - Certification standards for class II/III devices
  - Classification of medical devices
  - List of orphan designation etc.

- **Notification**
  - Information on application procedures
  - Guidelines for clinical evaluation etc.
Scope of regulations on medical device/IVD marketing in Japan under PMD Act

- **Product**: Minister’s Approval for marketing or, Certification by a Registered Certification Body or, Marketing Notification
- **Company**: License of Marketing Authorization Holder (MAH)
- **Plant**: Registration as a Manufacturer
# Device classification

<table>
<thead>
<tr>
<th>GHTF Classification</th>
<th>PAD Act classification</th>
<th>Japanese MD Nomenclature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class A</strong>&lt;br&gt;Extremely low risk&lt;br&gt;e.g., X-ray film</td>
<td>General MDs (Class I)&lt;br&gt;Self declaration&lt;br&gt;Approval of the product is not required, but marketing notification is necessary.</td>
<td>1,195</td>
</tr>
<tr>
<td><strong>Class B</strong>&lt;br&gt;Low risk&lt;br&gt;e.g., MRI, digestive catheters</td>
<td>Controlled MDs (class II)&lt;br&gt;Third party Certification&lt;br&gt;Certification by a registered certification body is required.&lt;br&gt;• Certification standard&lt;br&gt;Certification&lt;br&gt;Minister's Approval&lt;br&gt;(Review by PMDA)</td>
<td>1,972&lt;br&gt;(1,519 for 3rd Party)</td>
</tr>
<tr>
<td><strong>Class C</strong>&lt;br&gt;Medium risk&lt;br&gt;e.g., dialyzer</td>
<td>Specially Controlled MDs (class III &amp; IV)&lt;br&gt;The Minister's approval for the product is required.&lt;br&gt;• Approval standard&lt;br&gt;• Review guideline</td>
<td>771</td>
</tr>
<tr>
<td><strong>Class D</strong>&lt;br&gt;High risk&lt;br&gt;e.g., pacemaker</td>
<td></td>
<td>350</td>
</tr>
</tbody>
</table>
Overview of Medical Device Regulations in Japan

- Use result survey for designated MDs
- Adverse Event reporting
- QMS inspection

- Review
- QMS inspection
- Data integrity inspection
  - GCP inspection on clinical trial data
  - Integrity inspection on non-clinical safety data

- Clinical Trial Notification
- Registration of manufacturing site
- Consultations
### Number of approvals of Medical Devices

<table>
<thead>
<tr>
<th>Breakdown</th>
<th>FY2010</th>
<th>FY2011</th>
<th>FY2012</th>
<th>FY2013</th>
<th>FY2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices (total)</td>
<td>1,634</td>
<td>1,227</td>
<td>1,535</td>
<td>1,347</td>
<td>1,235</td>
</tr>
<tr>
<td>Priority review items (included in total)</td>
<td>3</td>
<td>6</td>
<td>5</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td><strong>Band-new MDs</strong></td>
<td>18</td>
<td>33</td>
<td>46</td>
<td>94</td>
<td>67</td>
</tr>
<tr>
<td><strong>Others (e.g. Improved MDs w/wo clinical data, Me-too MDs)</strong></td>
<td>1,616</td>
<td>1,194</td>
<td>1,489</td>
<td>1,253</td>
<td>1,168</td>
</tr>
</tbody>
</table>

### Number of certifications by registered certification bodies

| Certification (including partial change certification) | 2,298 | 2,369 | 2,350 | 2,417 | 2,276 |
MHLW/PMDA have been accepting foreign clinical data for years if it is good enough to evaluate a device’s clinical safety and efficacy on Japanese population under Japanese medical practice/environment.

Number of devices approved after review with clinical data

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign clinical data only</td>
<td>32</td>
<td>29</td>
<td>38</td>
<td>23</td>
<td>34</td>
<td>28</td>
</tr>
<tr>
<td>Both foreign and Japanese clinical data</td>
<td>6</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Japanese Clinical data only</td>
<td>14</td>
<td>19</td>
<td>14</td>
<td>23</td>
<td>24</td>
<td>11</td>
</tr>
</tbody>
</table>

(Source: PMDA Annual Report FY2014)
PMDA’s Consultation Menu

Very early stage

Market and Literature Surveys

Pre-development consultation

Non-Clinical

Stability Test

Biological Safety Test

Electrical Safety Test

Performance Test

Protocols or Results

Safety Confirmation Consultation

Quality Consultation

Consultation on Performance Test

CT required?

Consultation on Clinical Evaluation

CT

Exploratory Clinical Test

Clinical Test for Verification

Protocols or Results

Clinical Trial Consultation

Exploratory Clinical Trial Consultation

Pre-application

Development of Application Dossier

Application Procedural Consultation

Pharmaceutical Affairs Consultation on R&D Strategy

Prior Assessment Consultation
Collaboration among Stakeholders
Shortening of medical device review period
- Collaboration with Industry -

• Action Program for Acceleration of Medical Device Reviews (FY2009～FY2013)
• Collaboration Plan for Acceleration of Medical Device Review (FY2014～FY2018)
### 90% Tile Review Times for Medical Devices
(Total time in submission cohort)

<table>
<thead>
<tr>
<th>Category</th>
<th>FY</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td></td>
<td>100%</td>
<td>92.0%</td>
<td>95.2%</td>
<td>96.3%</td>
<td>46.9%</td>
</tr>
<tr>
<td>Improved (w clinical data)</td>
<td></td>
<td>100%</td>
<td>96.1%</td>
<td>96.0%</td>
<td>100%</td>
<td>75.0%</td>
</tr>
<tr>
<td>Improved (w/o clinical data)</td>
<td></td>
<td>100%</td>
<td>95.7%</td>
<td>94.2%</td>
<td>88.9%</td>
<td>44.8%</td>
</tr>
<tr>
<td>Generic (me-too)</td>
<td></td>
<td>98.4%</td>
<td>96.2%</td>
<td>97.2%</td>
<td>95.6%</td>
<td>63.9%</td>
</tr>
</tbody>
</table>

---

**Graph:**
- **Completion rate:**
  - 2009: 29.2, 20.4, 19.4
  - 2010: 26.8, 19.4, 14.6
  - 2011: 22.0, 18.4, 10.5
  - 2012: 23.8, 17.4, 8.7
  - 2013: 29.3, 10.5, 7.1

**Legend:**
- New: Red
- Improved (w clinical data): Green
- Improved (w/o clinical data): Gray
- Generic (me-too): Blue
Collaboration Plan for Acceleration of Medical Device Review (FY2014～FY2018)

New Performance Goal towards FY2018*

• New Medical Device
  - Standard items: 12 months
  - Priority items: 9 months

• Improved Medical Device
  - With clinical data: 9 months
  - Without clinical data: 7 months

• Generic Medical Device
  - New application: 5 months
  - Partial change application: 4 months

* In order to set higher target, 80 percentile figures are adopted instead of median
Pharmaceuticals and Medical Devices Agency

IMDRF - International Medical Device Regulators Forum

Management Committee member

Founding member of GHTF

Official Observer

World Health Organization

APEC LSIF RHSC

Affiliate Organization

Asian Harmonization Working Party

Pan American Health Organization

Brazil  Russia  China
Collaboration Among Stakeholders

Collaboration among Industry, Government and Academia
Thank you for your attention
1st India – Japan Medical Products Regulation Symposium

Probir Das
Chair – FICCI Medical Devices Forum
Our histories and cultures are intricately linked

4th largest FDI contributor to India; May 2015 agreement to double investment in 5 yr

Ministry of Commerce (DIPP) ‘Japan Plus’ fast track

Regulator to Regulator collaboration – great step forward
Need for collaboration

• Japanese Med Tech $30B & Pharma $97B

• 3rd Biggest medical device market

• GHTF founding nation; highly respected Regulators

• Cardiac, cancer, pain, regenerative med, self care ... best in world solutions

• Reasonably flat domestic market; interests high in hyper growth Indian healthcare
Young relationship, but scaling up

• Started in 2014 !!!

• Several G2G missions and interactions

• July 2015 onwards PMDA approval accepted independently

• Feb 2016 – Indian Regulator @ PMDA training

• In 2 years we have come a long way …
  But a long march ahead.
Industry commitment

- Support to the various engagement platforms
- Skill building partnerships
- “Make in India” commitment
- Beyond Regulatory / QMS ...
  Clinical best practices collaborations
Some requests

• Completely distinct treatment from Pharma

• Stitched “one policy” towards industrial interest to drive ‘Make In India’

• Increase healthcare spend & combine with global fiscal competitiveness

• Regulatory streamlining
  ❖ Logical timelines post new Act
  ❖ e-Sugam roll out should not delay pending registrations
  ❖ ‘Fast track’ provision