Pakistan's Regulatory Update on Medical Devices

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Pakistan at a glimpse



Geography / Demographics

Islamic Republics of Pakistan,

- **Area:** 796,095 km²
- *** Population:** 180 Million
- *** Capital:** Islamabad
- *** Population Gr.:** 1.551%
- *** Life Expectancy:** 66.35 years
- *** Religion:** 95% Mus. 5%Other

*Source Central Intelligence Authority USA 2012

Overview of Medical device Industry Pakistan:

Medical Device Market is dominated by Import

Imports of MDs have continued to grow very strongly over the last few years, albeit from a small base.

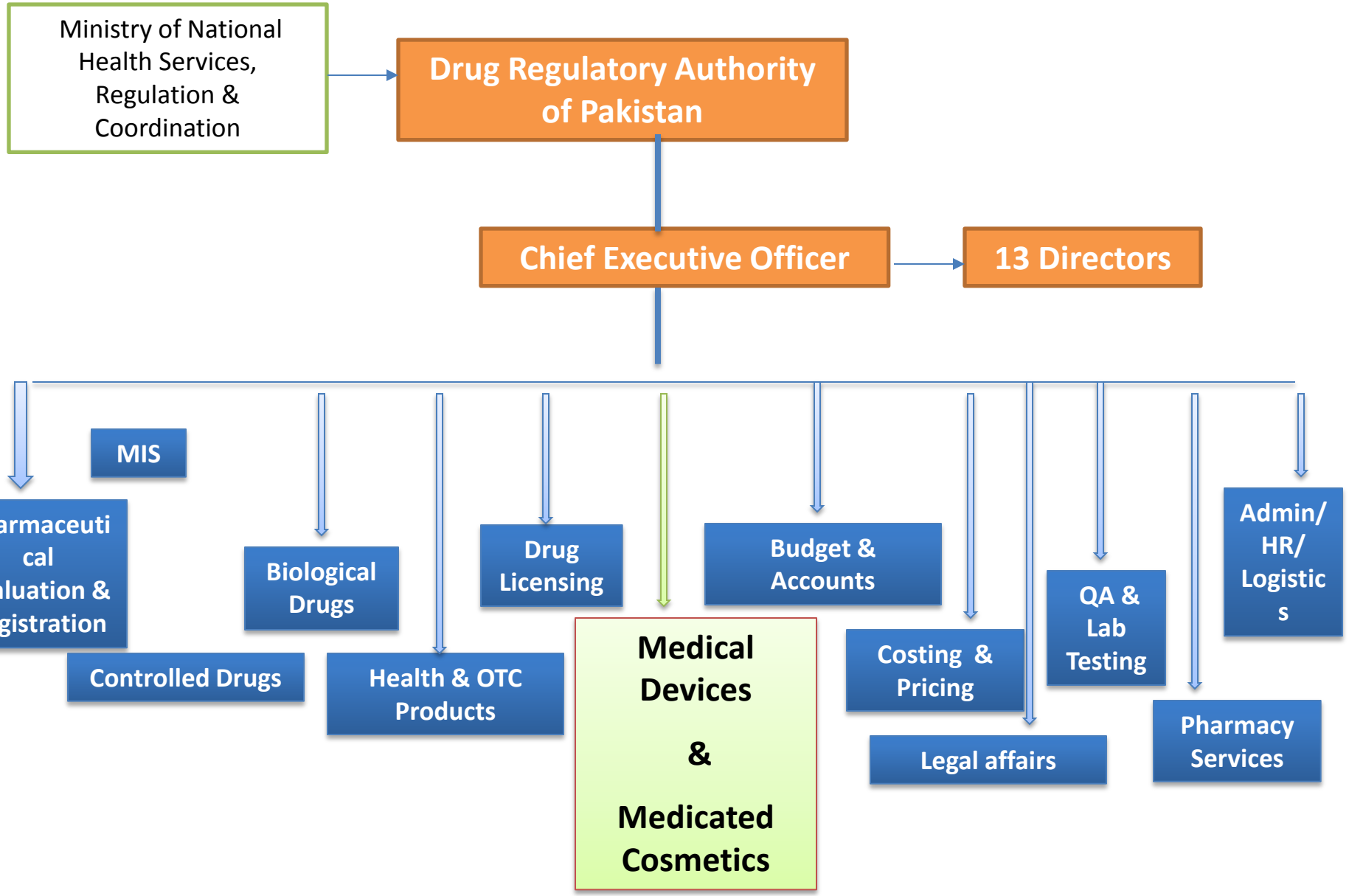
Market is expected to grow at a reasonable rate, with a growth rate of 13.1% forecast for the 2013-2018 period.

Major players ,

JNJ , Abbott ,Phillips , B Braun , Boston Scientific Medtronic , Covidien , 3M, LG, Siemens, BD, Otsuka , GE , Roche ,SMI, Zimmer,

Ref: http://www.espicom.com/pakistan-medical-device-market

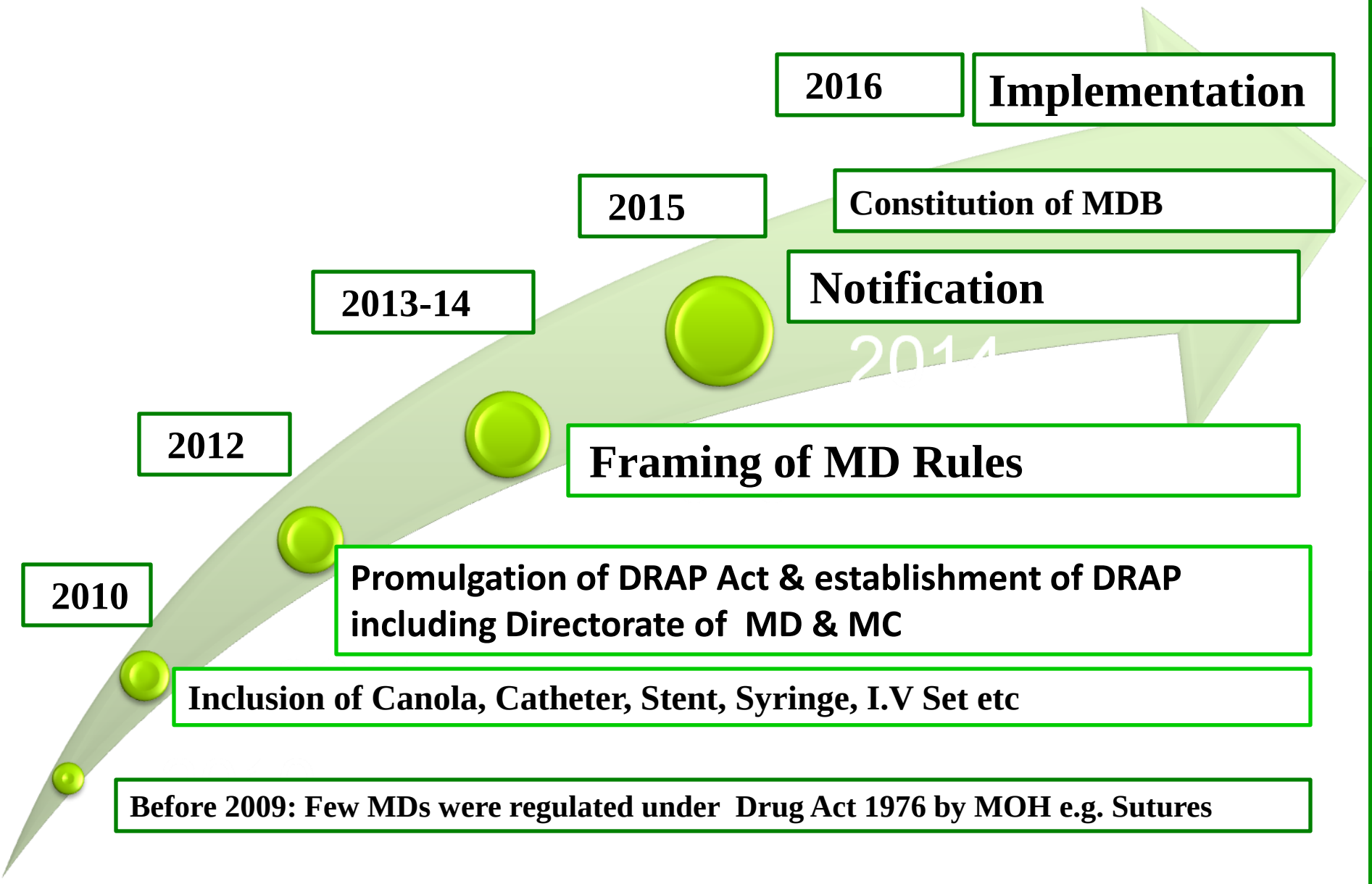
DRAP


Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
Chief Executive Officer
13 Directors
MIS
Pharmaceutical Evaluation & Registration
Biological Drugs
Drug Licensing
Budget & Accounts
Admin/ HR/ Logistics
QA & Lab Testing
Costing & Pricing
Controlled Drugs
Health & OTC Products
Medical Devices & Medicated Cosmetics
Legal affairs
Pharmacy Services

WHY TO REGULATE Medical Device

- To protect the public health by providing safe & effective devices.
- To ensure that new technology is made available in a timely manner
- To prevent alarming increase in deadly blood born infectious diseases
- To prevent the reuse of disposable devices.
- To prevent the unsafe, non-functional, counterfeit and sub-standard devices.

MD REGULATION HISTORY IN PAKISTAN



REGULATION OF MEDICAL DEVICES

DRAP ACT, 2012

(MEDICAL DEVICES RULES, 2015)

Definition and Key Concept

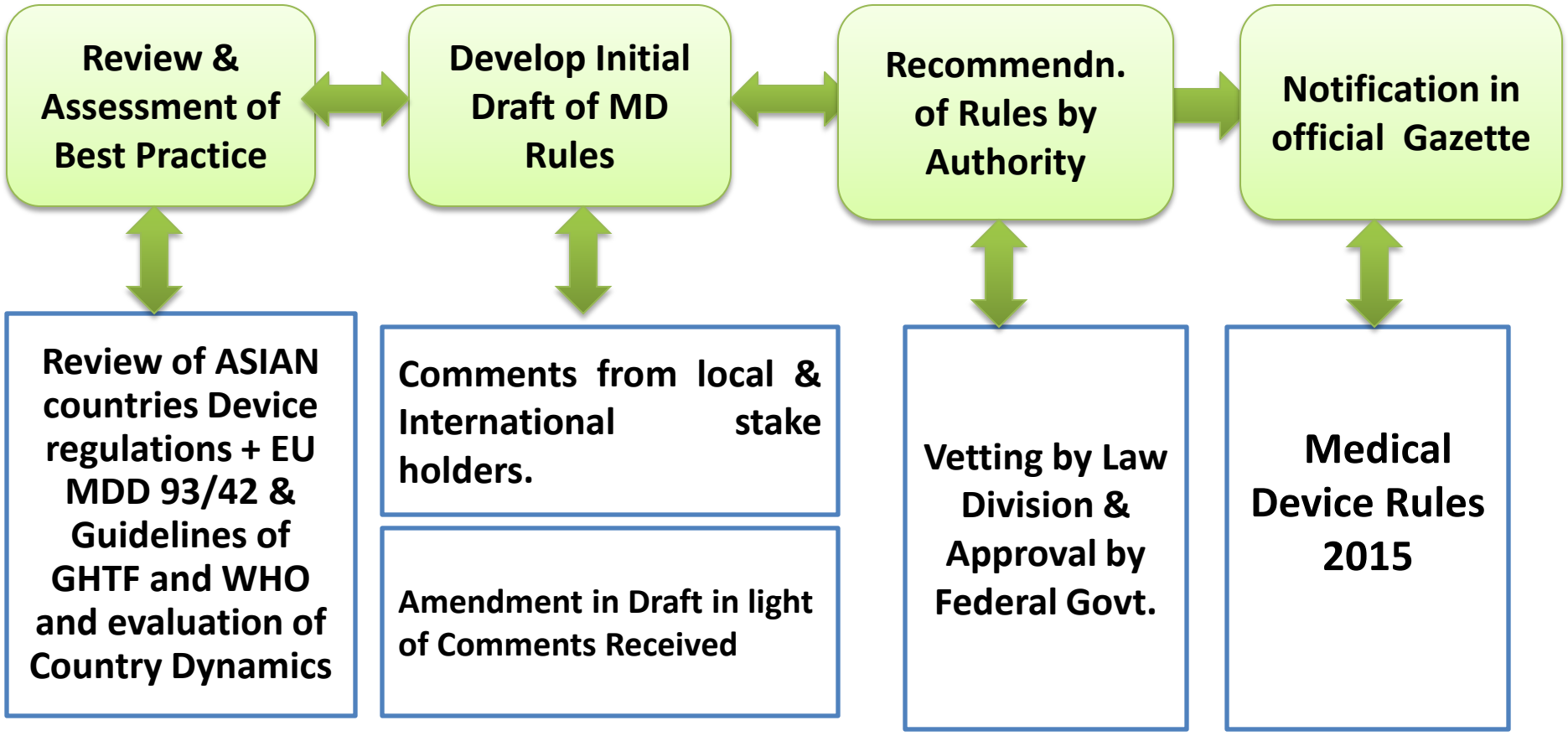
- ***Aligned with GHTF & AHWP Guidance Documents.***
  - Scope includes General Medical Devices , IVDs & Combination Products.
  - Covers both Human & Veterinary areas.
  - Does not include Border Line Devices at this stage.
  - The Federal Govt. may declare any item as a medical device to ensure Patient safety.

Classification

Harmonized with International and Regional Regulatory Frameworks

Risk Level	***Pakistan Classification***	***EU***	***Health Canada***
High	D	Class III	IV
Moderate –High	C	Class IIb	III
Low-Moderate	B	Class IIa	II
Low	A	Class I	I

Road Map to Frame the Medical Device Rules



Spirit-Conformity Assessment

Elements of CA:

a) QMS:

- Good management of manufacturing processes

b) PMS:

- Continued conformity to EPSP throughout the post-market stage.

c) Technical documentation:

- Common Submission Dossier Template (CSDT).

d) DoC:

- Declaration by manufacturer.

Requirements for Quality Management System

TYPE OF ESTABLISHMENT	QMS
I. Manufacturer	ISO-13485
I. Importer / II. authorized representative/ III. Distributors	GDPMD

SALIENT POINTS OF THE RULES

- Definition of technical terms.
- Role of conformity assessment body.
- Procedures for grant of registration of CABs.
- Licensing for establishments including manufacturers and importers
- Essential Principles for Safety and Performance
- Rules for classification of medical devices
- Rules for Grouping of medical devices into single, system, *in vitro* test kit etc

SALIENT POINTS OF THE RULES

- Procedure for **export** of medical devices for commercial, personal and investigational purposes.
- **Labeling** requirements
- **Responsibilities and obligations** of licensees and registration holders.
- **Post market surveillance** and vigilance system
- **Exemptions,** prohibitions etc
- **Usage**, operation and maintenance.
- Maintenance of the **Medical Device Register** of Pakistan, containing information of all the registered medical devices, licensed establishments and CABs

Constitution of Medical Device Board

- Inclusion of the ***technical experts*** like biomedical, software and electromechanical engineers, cardiac, general and orthopedic surgeons, urologists, radiologists, pathologists, pharmacists and medical administrators in MDB.
- ***Responsibilities:***
  - Establishment Licensing;
  - Registration of CABs;
  - Device Registration ;
  - Post Marketing Surveillance ; and
  - Functions ancillary thereto .

Scope & Flow of Regulatory Obligations

Obligations	Activities
Establishment license	1. License for Local Manufacturing 2. **License for Import** (Authorized Representative) / **GDPMD Certificate**
Device Registration	Rules of Classification / Essential Principals / DOC/ CSDT / Labeling
Good Distribution	***GDPMD*** obligations for Distributor
Sales Obligations	Sales will be regulated by Provincial Govts.
PM Surveillance & Vigilance	Record maintenance for complaint handling system, mandatory problem reporting, including investigation of problem or incident , field corrective action & Recall Procedure.
HCP Obligations	Medical Device Register / Controls on usage operations maintenance

Enforcement Timeline / Grace Period

S.No	Class of medical device, establishment or conformity assessment body	Exemption period
(1)	(2)	(3)
1.	Class D medical devices and establishments manufacturing or importing Class D medical devices.	*March 2016*
2.	Class C medical devices and establishments manufacturing or importing Class C medical devices.	*September 2016*
3.	Class A (active, sterile or having measuring function) or Class B medical devices and establishments manufacturing or importing Class A (active, sterile or having measuring function) or B medical devices.	*March 2017*
4.	**Class A Medical Devices other than those having Measuring function , Active Or Sterile shall be enblisted Only.**	***Rules To be Formulated***

Challenges :

Transition Plan for MDs declared as Drug.

Capacity Building

- Human Resource
- Infrastructure database
- Technical Expertise
- Industry Readiness
- Political Patronage

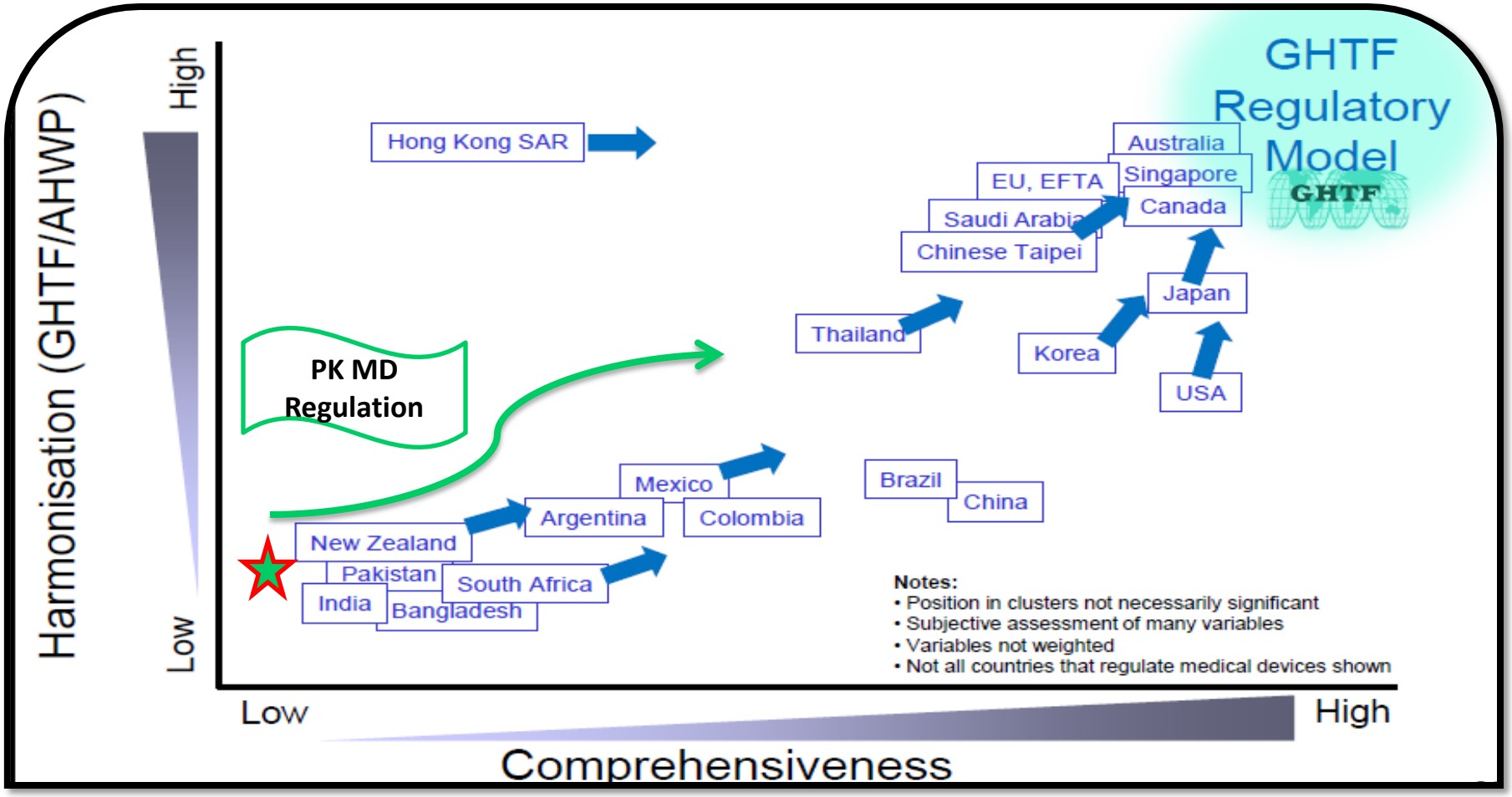
Capacity Building Providing the tools to optimally fulfill responsibilities

Types of Regulatory Activities

Volume / Distribution of regulatory activities

Expertise

Medical Device Regulation; Vision of Medical Device Directorate in A global Perspective



Thank You …….