China Updates

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Content

- Overall introduction
  - Industry briefing
  - General administrative framework
- Current Regulations
- Revision of Medical Device Regulations

Medical Device Industry in China

- 3rd Largest Medical Device Market in the world
  - Market size – 63.5billion USD
  - Manufacturing capability – 50billion USD
  - Import & export – 25billion USD
- No. of manufacturing company -15,000
- No. of sales company – 170,000

Administrative Framework

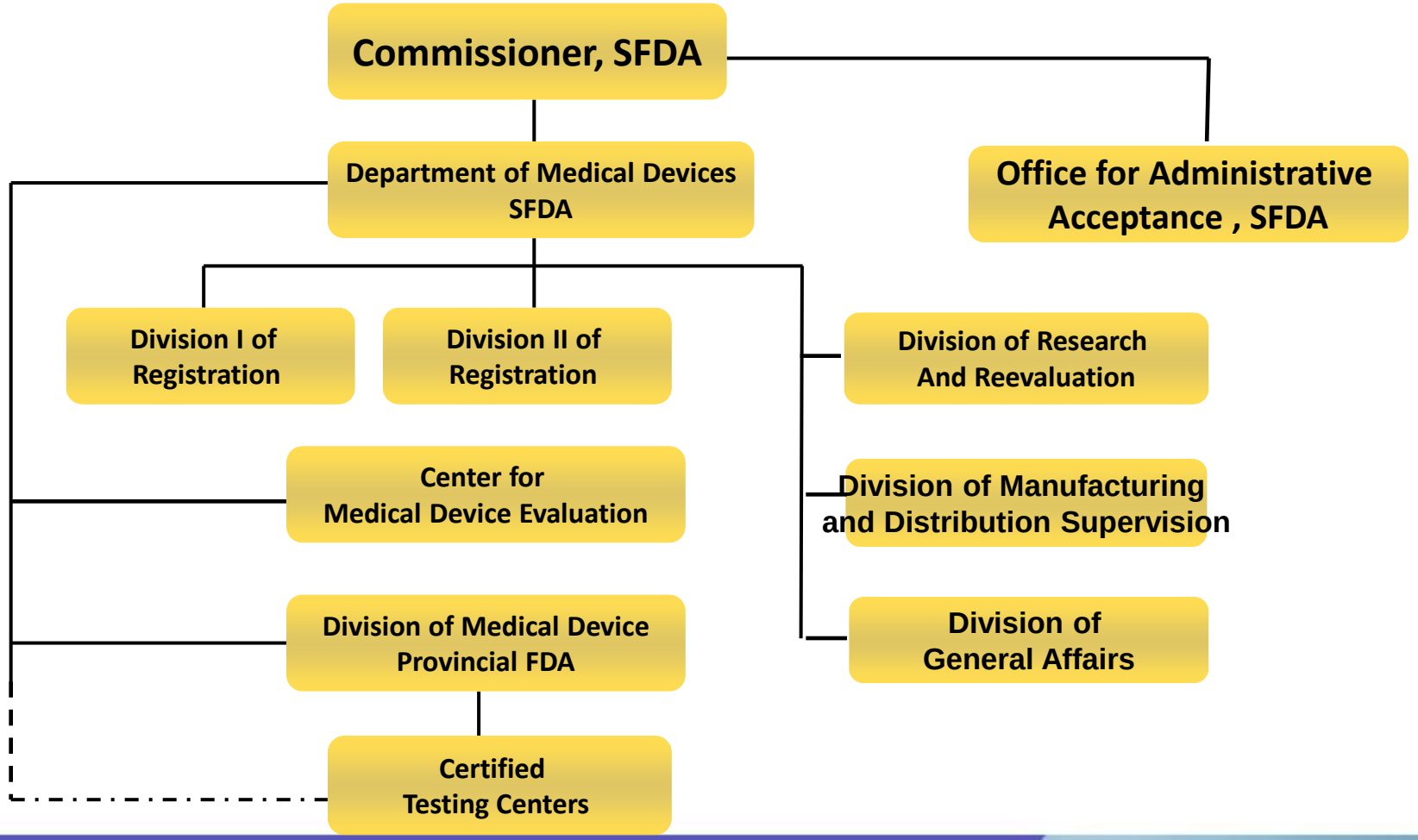
- Risked based classification
  - Class I, II and III
- Manufacturing and distribution permission
- Product market permission

As of June 2012, 15,000 manufacturing company, 80,000 product license

Administrative Framework

- SFDA – Supervision and management of medical devices nationwide.
- Province, City and County - Supervision and management of medical devices within their respective administrative areas.
- Technical support system has been established, including the technical review, quality system inspection, adverse event monitoring, testing and standard management.

SFDA Structure



Administrative Framework

- 26 technical review institutions, including SFDA CMDE and 25 provincial technical evaluation centers.
- Total of 53 testing institutions nationwide, 10 of them are certified national centers.
- SFDA's Medical Device Standards Management Center was established in 2001, to supervise 22 Standardization Technical Committees of Medical Device
- SFDA and each province have established adverse events monitoring institutions.

Current Regulations

Regulations for the Supervision and Administration of Medical Devices ***(Decree 276, Effective Date: April 1, 2000)***

More than 200 regulation from 2000 to 2012, key regulations

- Provisions for the Administration of Medical Device Registration
- Provisions for the Administration of Instruction, Labeling and Package Mark of Medical Device
- Provision on Clinical Trial of Medical Devices
- Provision on Medical Device Recall

Revision of the Regulations

- Regulation for the Supervision and Administration of Medical Devices
  - ***Final draft is collecting comments from public, to be announced in next year***
- A series of policies and measure will be revised according to the new device regulation, to reinforce the supervision for Registration, Clinical trial, Post market surveillance, Reevaluation, Recall etc.

To better serve and protect the Chinese public health by effective administrative system for medical device.

Thanks for your attention.