A Brief Introduction to the Regulatory Environment of Medical Device Supervision

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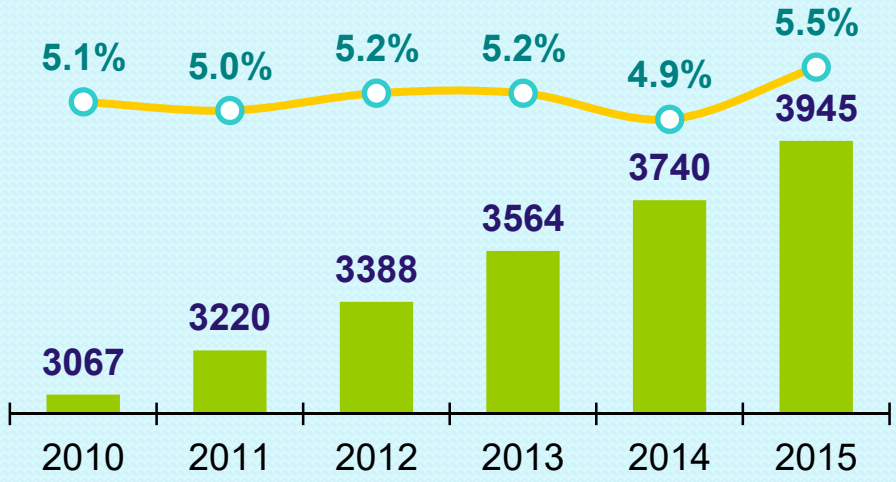
Development Trend of Medical Device Industry

Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

The impact of regulations and policies on encouraging innovation and industrial development

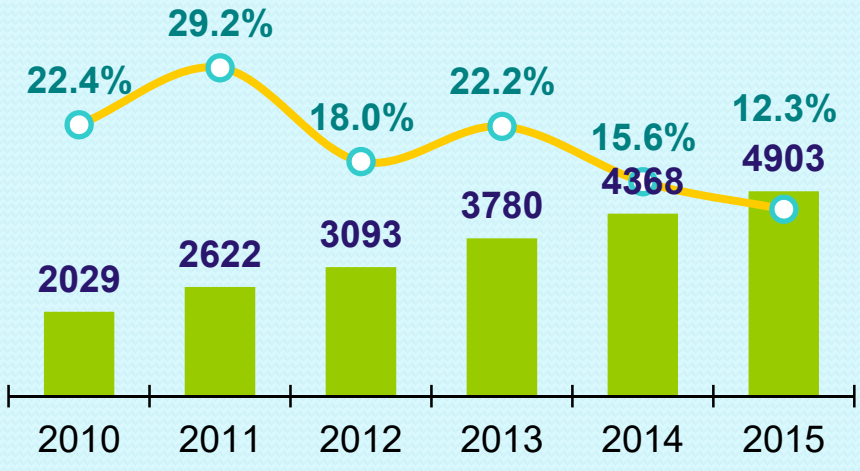
I. Development Trend of Medical Device Industry

- **2010-2015 Market Scale of Global Medical Device Industry**



(Unit: 100 million US dollars)

- **2010-2015 Market Scale of China's Medical Device Industry**



(Unit: 100 million Yuan)

- **Over the past five years, the world's medical device market has experienced an average growth of 5.2%, while China's medical device market has showed a rapid growth, with an average annual growth rate of 19%, and reaching 490.3 billion Yuan in 2015.**

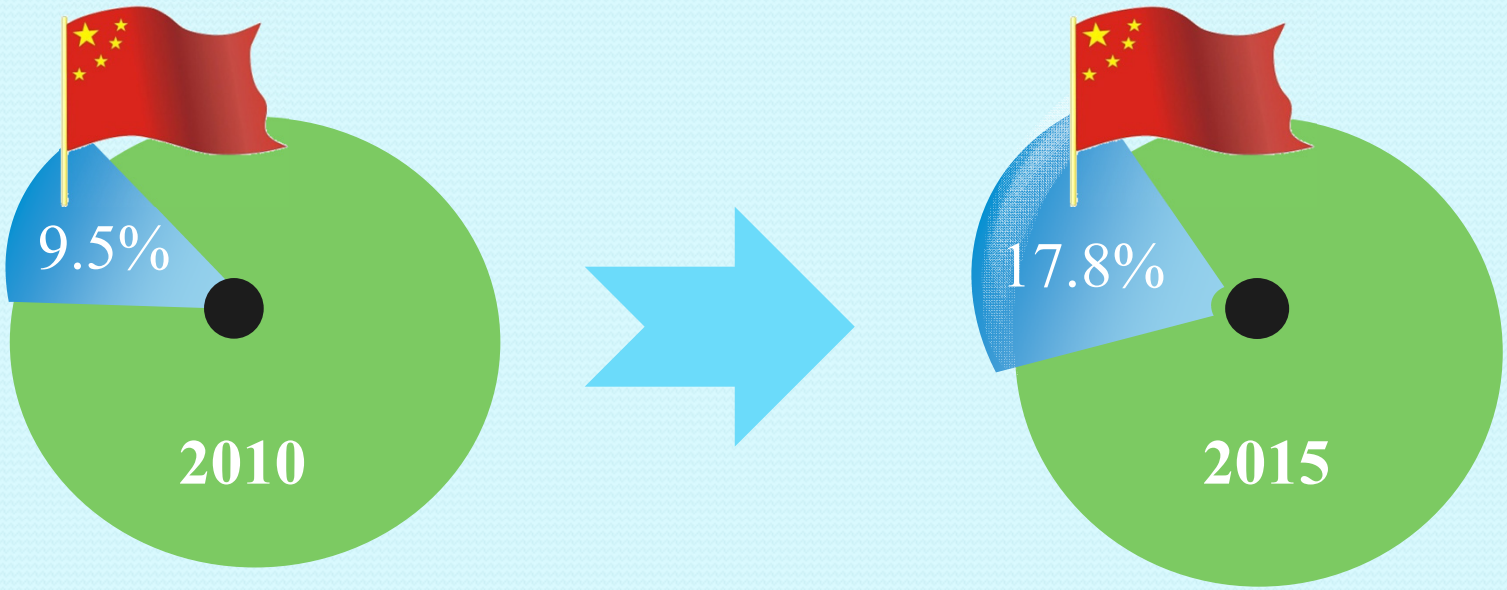
I. Development Trend of Medical Device Industry

- **With the rapid economic development and the rising elderly population in China, the market demand for medical devices continues to increase**
  - **2015 Medical Device Market Growth Rate of Some Countries and Regions**

Country or Region	Medical Device	Country or Region	Medical Device
North America	**4.3%**	Latin America	**-18.8%**
Asia-Pacific	**-12.9%**	Central and Eastern Europe	**-14.4%**
Including: China	**12.3%**	Middle East and North Africa	**1.8%**
Western Europe	**-3.0%**	Sub-Saharan African	**3.8%**

I. Development Trend of Medical Device Industry

- The proportion of China's medical device market to the world has increased from 9.5 % in 2010 to **17.8%** in 2015



Globe: 306.7 billion US dollars

China: 202.9 billion Yuan

Globe: 394.5 billion US dollars

China: 490.3 billion Yuan

II. Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

Market demand, technological innovation, global integration

- Provide new driving force for industrial development

Outline of "Healthy China 2030" Plan
Deepen the reform of medical and health system

- Put forward new requirements for the industrial development

Linkage amongst medical care, medical insurance and medicine

- Provide new path for industrial development

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II. Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

New driving force

Market demand
- Continuous and stable economic growth and rising living standards
- Improvement of medical insurance system
- Reform in medical service system and aging population

Technological innovation
- R & D strength, transformation of scientific achievements
- Scientific and technological input, technological progress

Global integration
- Technological exchanges, merger and reorganization
- International market, policy reference

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II. Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

New requirements

On May 8, 2015, the State Council issued the Made in China 2025 Plan

On Nov. 29, 2016, the State Council issued the "13th Five-Year Plan" for the Development of the National Strategic Emerging Industry

On Feb. 14, 2017, the State Council issued the "13th Five-Year Plan" for National Drug Safety

On Oct. 25, 2016, the State Council of the CPC Central Committee issued the *Outline of* "Healthy China 2030" Plan

On Dec. 27, 2016, the State Council issued the "13th Five-Year Plan" for Healthcare

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II. Development Opportunities for Medical Device Industry during the "13th Five -Year Plan" Period

New requirements

Outline of "Healthy China 2030" Plan

- Accelerate the transformation and upgrading of the medical device industry
- Improve the quality standard system and the quality control technology. Implement green and intelligent transformation and upgrading, and keep the quality standard of drug and medical devices in full line with the international standard of excellence in 2030
- Realize medium-to-high speed development for the pharmaceutical industry, and set the mid-to-high end as the target

"13th Five -Year Plan" for Healthcare

- Vigorously develop intelligent medical equipment
- Improve the industrialization and quality of medical equipment
- Develop wearable physical activity monitoring equipment, portable diagnostic equipment and other portable medical products, as well as telemedicine systems for monitoring, diagnosis and treatment guidance

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II. Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

Enjoy the priority in review and approval

New requirements

On Feb. 14, 2017, the State Council issued the "13th Five-Year Plan" for National Drug Safety

- Encourage clinical institutions and doctors to participate in the R& D of innovative drugs and medical devices
- Clinical urgently needed medicines and medical devices included in the national key R&D plans and major special scientific and technological projects
- Innovative medical devices with invention patent of core product technology and significant clinical value

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II. Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

Accelerate development in biomedical engineering

New requirements

On Dec. 20, 2016, the National Development and Reform Commission issued the "13th Five-Year Plan" for Biological Industrial Development

- Build intelligent diagnostic and therapeutic ecosystems
- Increase the market share of high-quality equipment
- Promote the innovation of implantable (interventional) products
- Provide fast, accurate, and easy detection methods

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II. Development Opportunities of Medical Device Industry during the "13th Five -Year Plan" Period

On May 26, 2017, the Ministry of Science and Technology issued the "13th Five -Year Plan" for the Science and Technology Innovation Special Projects in Health Industry

New require ments

- **Core** — **Assure the health needs of the entire population in the full life cycle**
- **Focus** — **: develop three categories of products i.e. innovative drugs, medical devices and health products**
- **Direction** — **Develop precise, digital, intelligent and integrated new healthcare methods**
- **Plan** — **Health service model issued the "13th Five -Year Plan" for the Science and Technology Innovation Special Projects in Medical Devices**

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III. The impact of regulations and policies on encouraging innovation and industrial development

Regulatory and supervisory framework of medical devices

Highlights in the revised Regulations for the Supervision and Administration of Medical Devices

Reform of the review and approval system for medical devices

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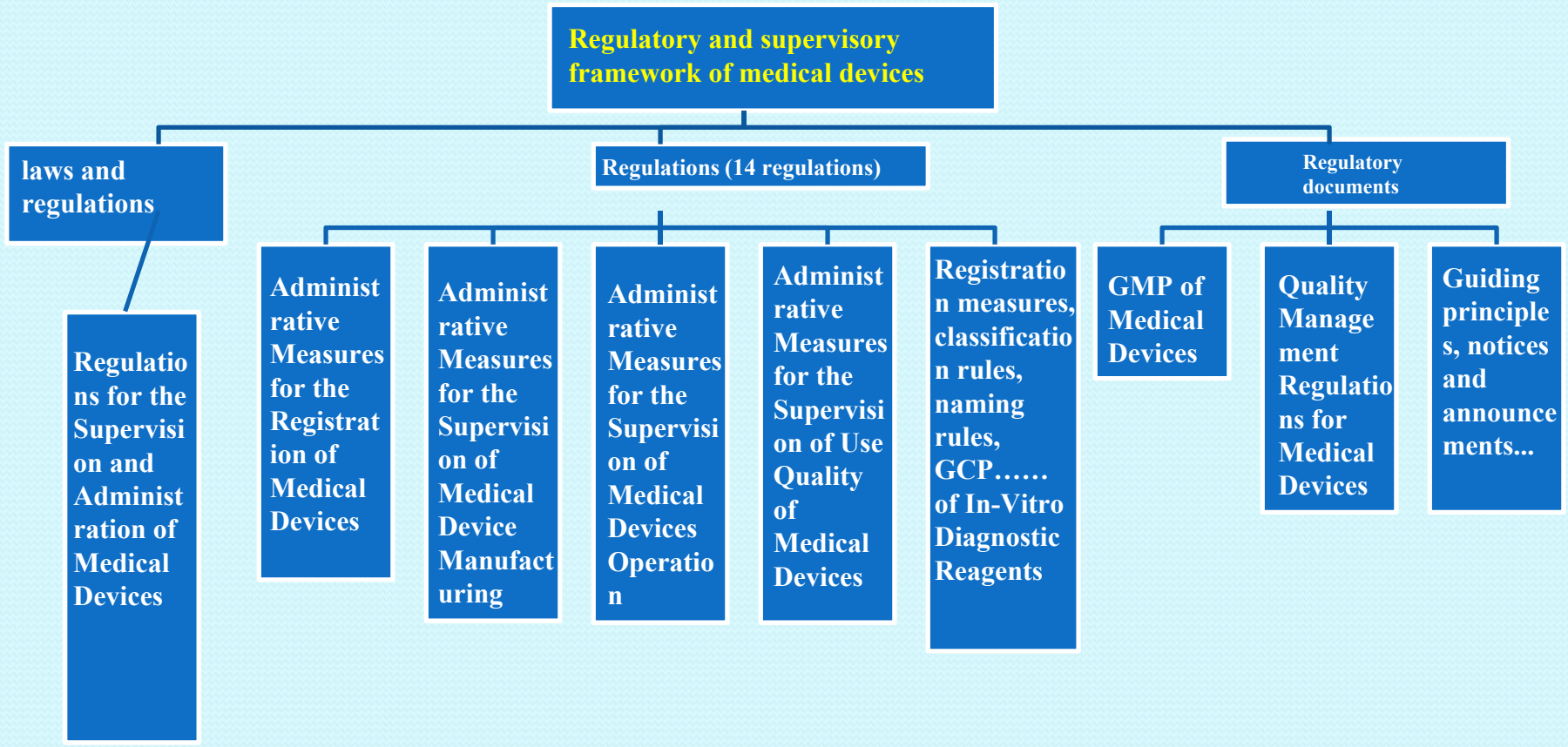
III. The impact of regulations and policies on encouragement of innovation and industrial development



III. The impact of regulations and policies on encouraging innovation and industrial development

- **Regulations for the Supervision and Administration of Medical Devices**
- **Jan. 4, 2000, Decree of the State Council No.276 Effective Apr. 1, 2000**
- **China's first standard administrative regulations on the research, manufacturing, operation and use of medical devices**

Conduct classified management on medical devices

Establish product registration system, mandatory certification system, re-evaluation and elimination system for medical devices

Implement admission management of production and operation

Develop basic specifications for the R&D, production, operation and use of medical devices

Develop a quality accident reporting system and announcement system

Specify the responsibilities of regulatory departments

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III. The impact of regulations and policies on encouraging innovation and industrial development

Major problems of previous regulations

Classified management not complete enough	**Corporate responsibility not clear enough**	**Legal liability not specific enough**	**Regulatory input not reasonable enough**

III. The impact of regulations and policies on encouraging innovation and industrial development

On Feb. 12, 2014, the State Council revised the Regulations for the Supervision and Administration of Medical Devices, which was put into force on Jun. 1, 2014.

Focus on scientific management based on classified management

Focus on the safety of device use safety as per risks

Reflect the rules of markets by combining loose and tight management

Improve regulatory effectiveness by decreasing advance examination and approval steps

III. The impact of regulations and policies on encouraging innovation and industrial development

Improve classified management
- Specify classification principles
- Emphasize dynamic adjustment
- Focus on the supervision and administration of high-risk products

Strengthen corporate responsibility
- Increase the responsibility of quality control
- Carry out incoming inspection and keep sales records
- Obligations of device use entities

Reduce administrative approval items
- 16 administrative licenses reduced by 7 items

Strengthen daily supervision and administration
- Improve management system
- Diversify regulatory means
- Strengthen regulatory duties
- Standardize regulatory behaviors

Perfect the legal responsibility
- Increase punishment: category, scale and measures

III. The impact of regulations and policies on encouraging innovation and industrial development

New regulations

- **Reform the product management system**
- **Adjust the clinical trial management system**
- **Perfect the registration management system**

III. The impact of regulations and policies on encouraging innovation and industrial development

- **Major reforms in product management system: the establishment of a manufacturing enterprise is no longer the pre-requisite of product registration**
- **Encourage innovation, avoid the downtime of production facilities, and make full use of resources**
- **More detailed division of labor, and complementary advantages**

Previous regulation
Article 21 Medical device manufacturers shall not start manufacturing products before obtaining the manufacturing enterprise license.

New regulations
Article 22 An applicant engaged in production of Class II and Class III medical devices shall apply to the Food and Drug Administration Department of the people's government of the province, autonomous region and municipality directly under the central government where it is located for a production permit and submit the certification documents meeting the requirements given in Article 20 of these Regulations.

III. The impact of regulations and policies on encouraging innovation and industrial development

Adjustment of clinical trial management system:

- **Specify the conditions for clinical trial exemption, conduct record filing for most clinical trials, and narrow the scope of approval**
- A clinical trial is required for filing Class I products.
- A clinical trial should be conducted when a Class II or Class III product is submitted for registration application.
- The clinical trial can be exempted:

The specific list shall be formulated, adjusted and announced by the food and drug regulatory department under the State Council.

III. The impact of regulations and policies on encouraging innovation and industrial development

- **Better management of extension of registration**

- **Re-registration is replaced by extended registration**

- **No answer is considered a yes: Any failure in approving or disapproving such application within the specified period of time should be deemed as having been approved for extending registration**

- **It is strictly stipulated that the registration is not allowed for extension in the cases below:**

  (1) The applicant fails to submit the application for extending registration within the prescribed time limit;

  (2) The compulsory medical device standard has been revised, but the medical device submitted for registration extension application does not meet the new requirements;

  (3) Any medical device to be used to cure unusual diseases or respond to emergent public health event fails in meeting the requirements specified in the registration certificate within the specified period of time.

III. The impact of regulations and policies on encouraging innovation and industrial development

Special approval procedure for innovative medical devices

- Set the approval channel for innovative medical devices to improve the efficiency of review
- As of the end of 2016, a total of 488 applications for special approval of innovative medical devices had been received, 461 of which had been reviewed, and 89 products had entered into the special approval channel for innovative medical devices

Priority approval procedure

- **The first category is medical devices used for diagnosis or treatment of unusual diseases, malignant tumors, diseases unique or more prevalent to the elderly, specially used for children, or those urgently needed for clinical use, etc.**
- **The second category is medical devices included in the national major science and technology projects or national key research and development plans**

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III. The impact of regulations and policies on encouraging innovation and industrial development

- Improve the quality of review and approval: improve the transparency of review and approval, perfect the systems of processing, communication and exchange, secondary review of the committee of experts, and project managers , etc., and create a more scientific and efficient drug and medical device review and approval system so as to make the approved drugs and medical devices reach or get close to international advanced level in terms of effectiveness, safety and quality control

- Strengthen the whole-process of supervision of clinical trials to ensure the accuracy and reliability of clinical trial data

- In a timely manner revise the standards of medical devices, adjust the classification catalog of medical devices, and enhance the quality of domestic medical devices

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III. The impact of regulations and policies on encouraging innovation and industrial development

- Capacity construction: drive the construction of professional reviewers and inspection teams, enhance the support capacity of technical institutions

- Match international standards: actively participate in the activities of ICMRA (International Coalition of Medicines Regulatory Authorities) and IMDRF (International Medical Device Regulators Forum), conduct international inspections, strengthen forward-looking policy research, and improve international discourse

- Strengthen law enforcement: carry out unannounced inspections, strengthen spot checks, investigate major cases, and publicize information

- Diversified governance: strengthen the construction of a credit system by taking advantage of the power of government, enterprises, and social forces.

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III. The impact of regulations and policies on encouraging innovation and industrial development

On May 4, 2017, the State Council promulgated the Decision on Revising the Regulations for the Supervision and Administration of Medical Devices (Decree of the State Council No. 680)

- **Replace the accreditation of clinical trial organizations with record filing so as to encourage innovation in medical devices**
- **Add relevant provisions on allocation of large medical equipment in medical device use entities**

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THANK YOU