



**国家药品监督管理局**

# **Introduction to the Progress of Regulations on the Supervision and Administration of Medical Devices in China**

**ZHANG Hua**

**Department of Medical Device Registration**

**National Medical Products Administration**

**December 1, 2021**



## **A Keep the Bottom Line to Ensure Safety**

Ensure safe use of drugs and medical devices by the public and maintain public health.

## **B Pursue the High Standard to Promote Development**

Meet the public's needs for high-quality advanced medical device.



## Order of State Council of the People's Republic of China

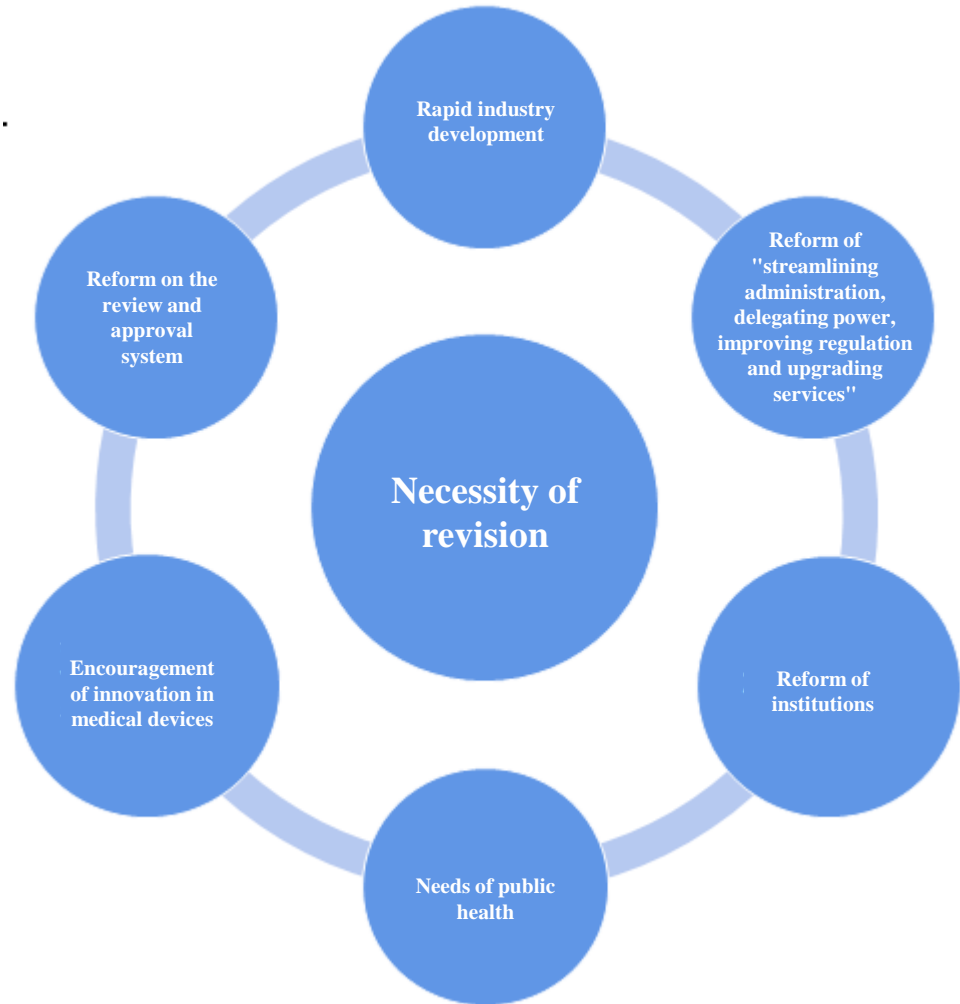
No.739

The *Regulations on the Supervision and Administration of Medical Devices* revised and passed at the 119<sup>th</sup> executive meeting of the State Council on December 21, 2020 has been issued and implemented as from June 1, 2021.

Premier

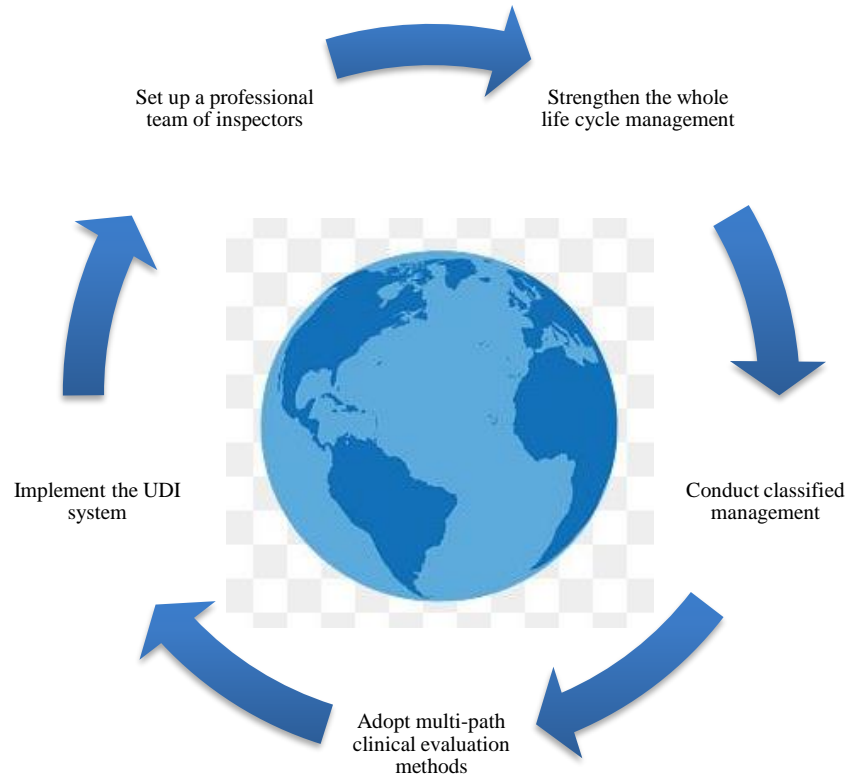
李强

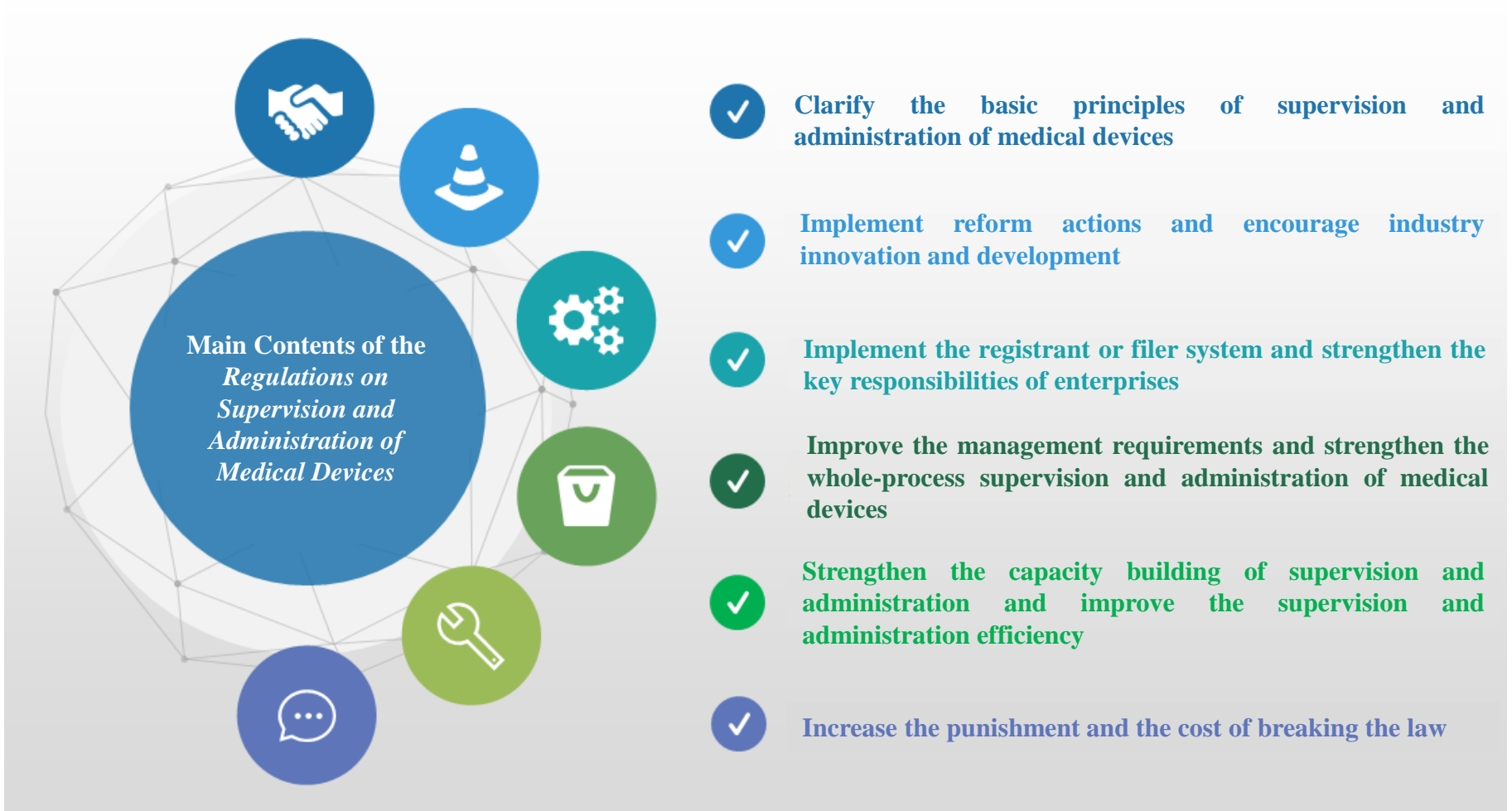
February 9, 2021





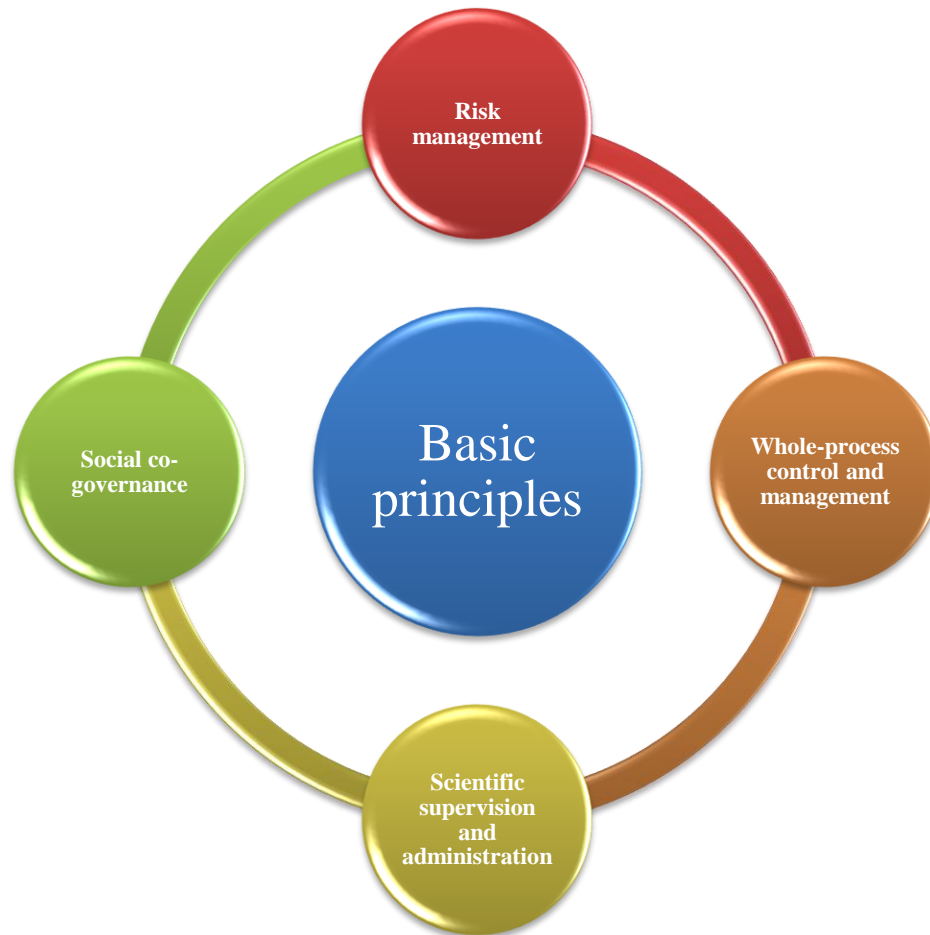
## Learn From the Useful Experience of the International Community





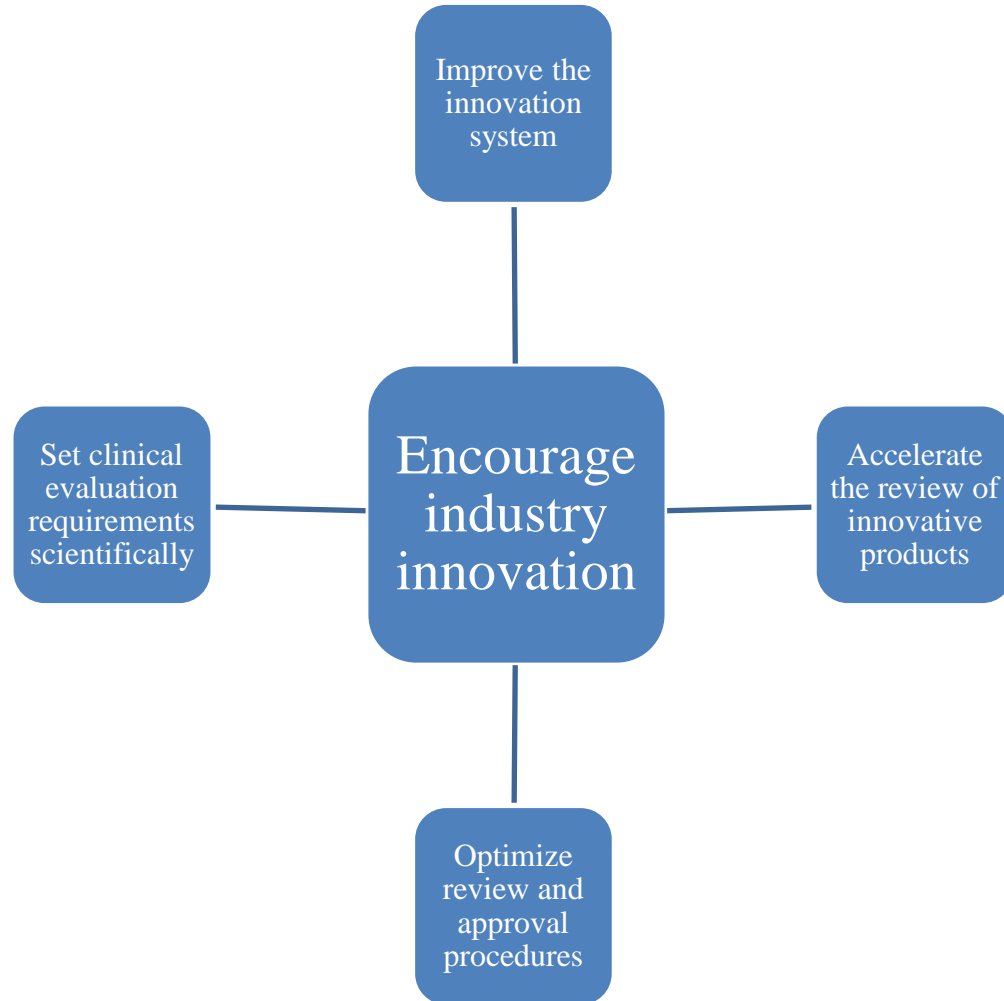


## (I) Clarify the Basic Principles of Supervision and Administration of Medical Devices



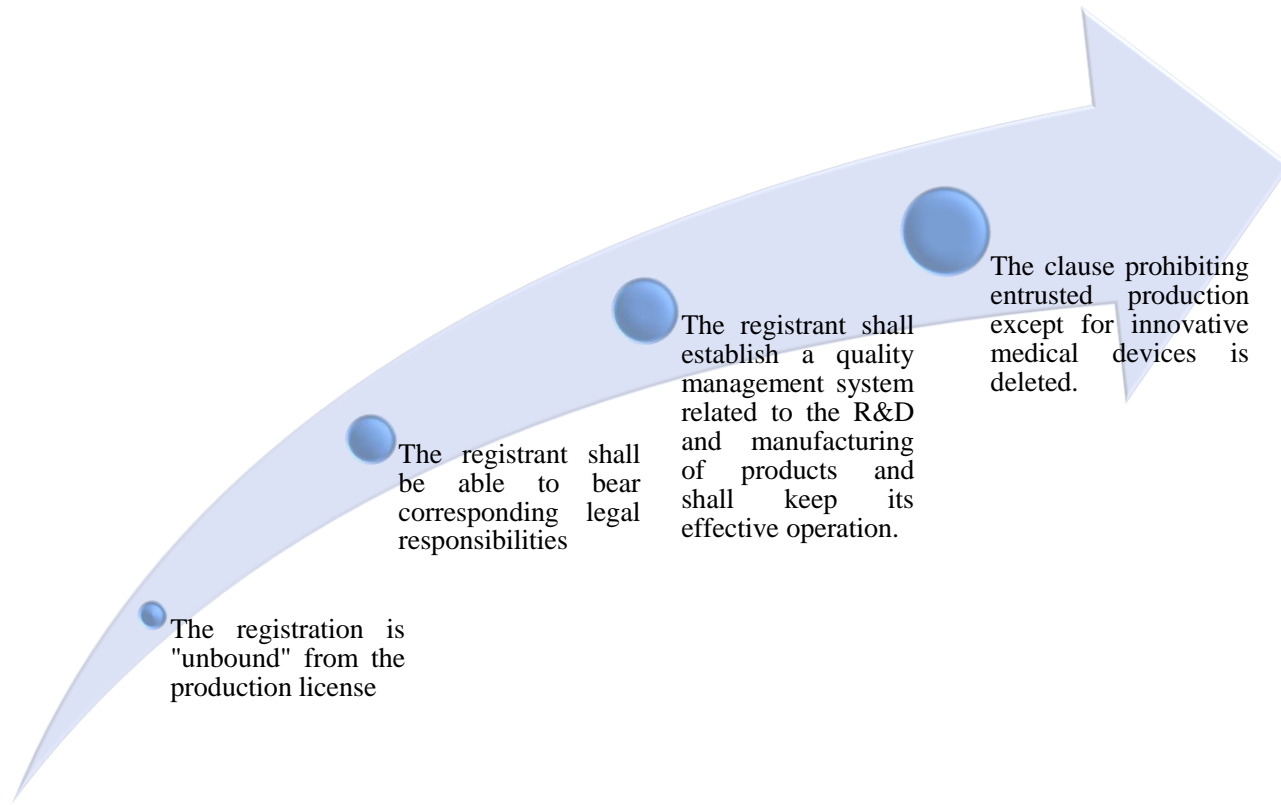


## (II) Implement Reform Actions and Encourage Industry Innovation and Development





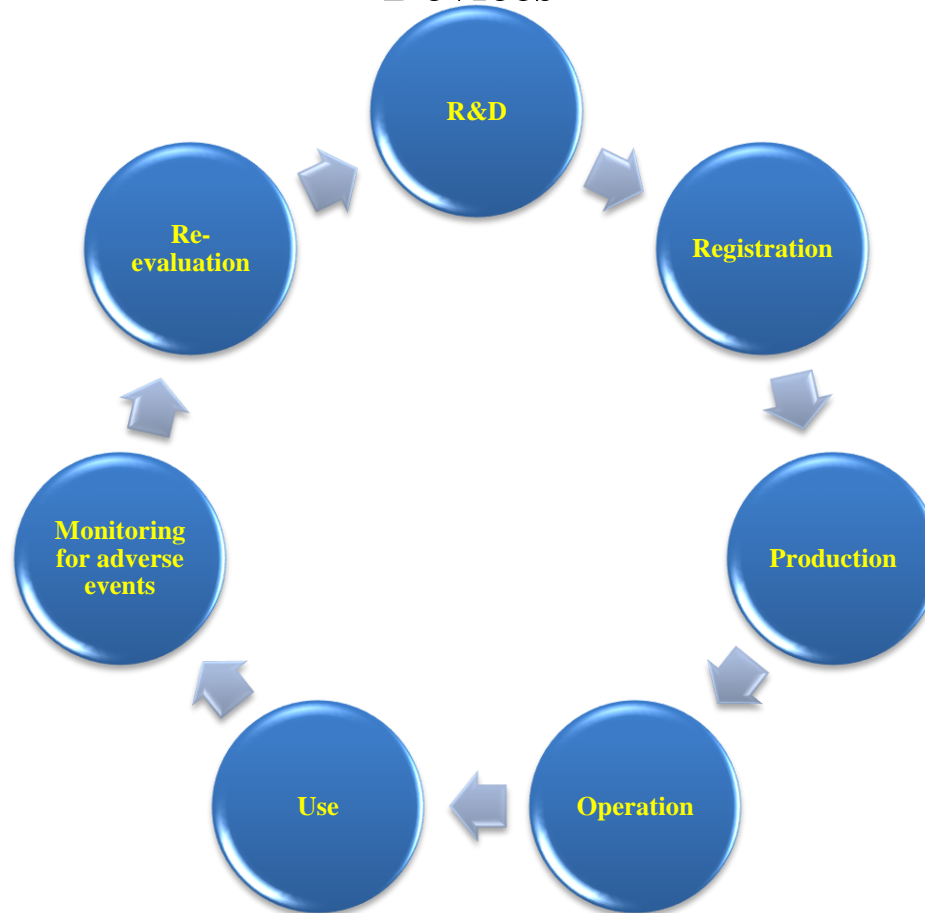
## (III) Fully Implement the Registrant System and the Key Responsibilities of Enterprises







## (IV) Improve the Management Requirements and Strengthen the Whole-process Supervision and Administration of Medical Devices





## (V) Strengthen the Capacity Building of Supervision and Administration and Improve the Supervision and Administration

Team building of inspectors

Information-based supervision and administration

Unique device identification (UDI) system

Enrich the supervision and administration means

Strengthen the inspection on function and power

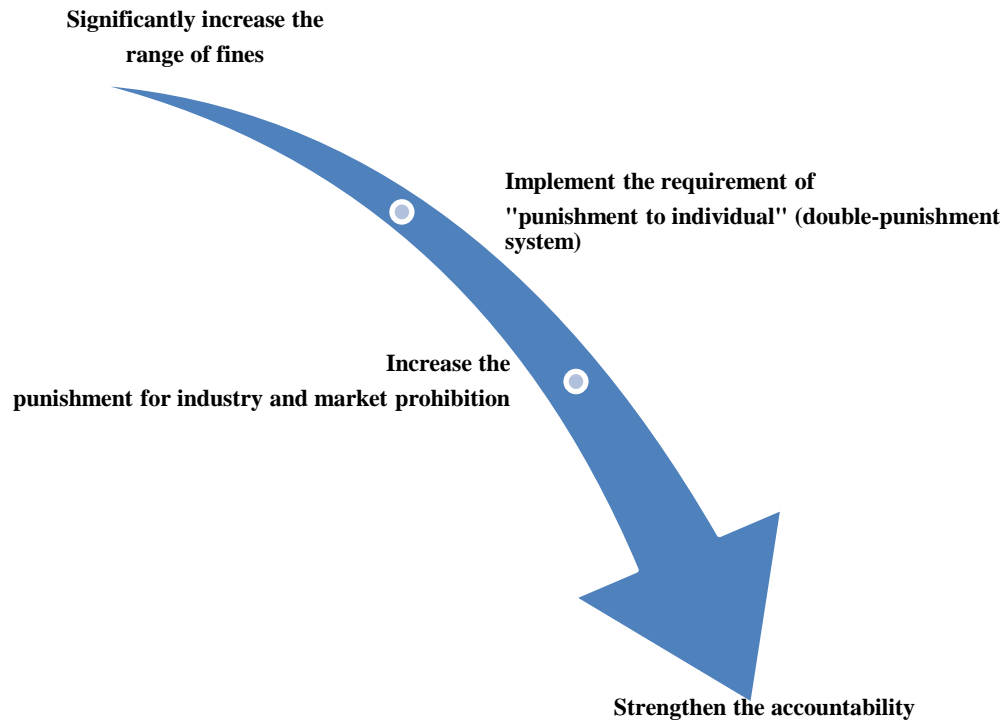
Strengthen the supervision and guidance of Provincial Medical Products Administrations in registration review

Further clarify the division of functions





## **(VI) Increase the Punishment and the Cost of Breaking the Law**





国家药品监督管理局

National Medical Products Administration

Thank You !

