



国家药品监督管理局

National Medical Products Administration

13th Global Summit on Regulatory Science (GSRS23)

# Scientific Process of Drug Regulation in China

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**国家药品监督管理局**

National Medical Products Administration

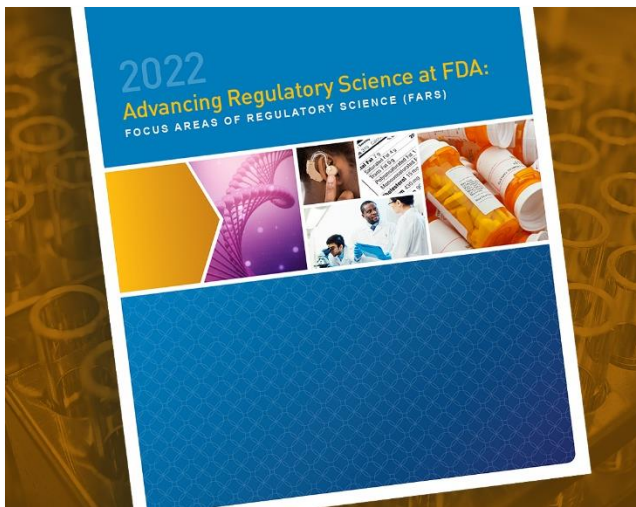
NMPA

## **Regulatory responsibilities of China National Medical Products Administration (NMPA)**

- One of the largest regulatory authorities in the world
- Responsibilities: build a “scientific, efficient and authoritative” drug regulation system; protect and promote public health
- Role: ensure the safety and effectiveness of innovative drug, vaccines for human use, medical devices, cosmetics and other medical products

# Development of drug regulatory science

- Based on the understanding and exploration of the law of regulation, drug regulatory science is aimed at formulating guidelines for evaluation and inspection as well as testing methods and standards to evaluate the safety, effectiveness and quality of medical products by studying new regulatory tools, new standards and new methods.



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## Development History of Drug Regulatory Science in China

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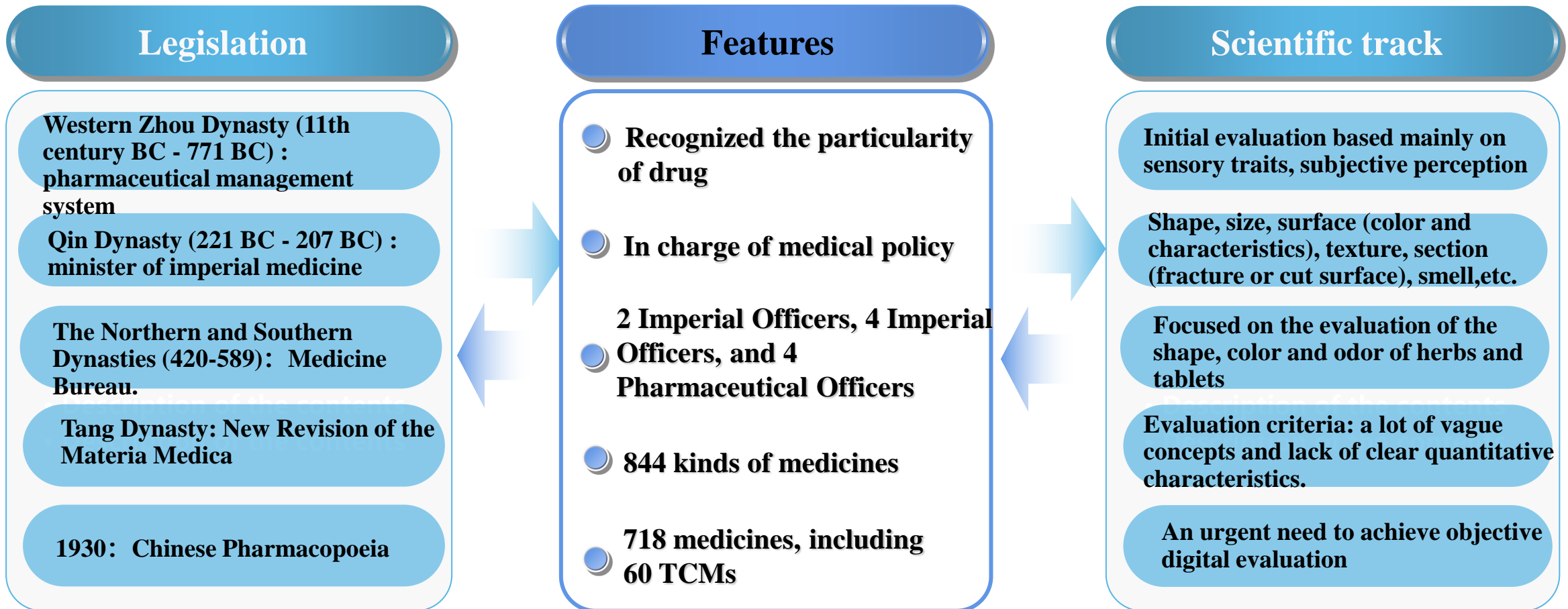
## Main Achievements of China's Action Plan on Drug Regulatory Science

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## New Goals and New Initiatives to Comprehensively Strengthen the Drug Regulatory Science System



# I. Development History of Drug Regulatory Science in China



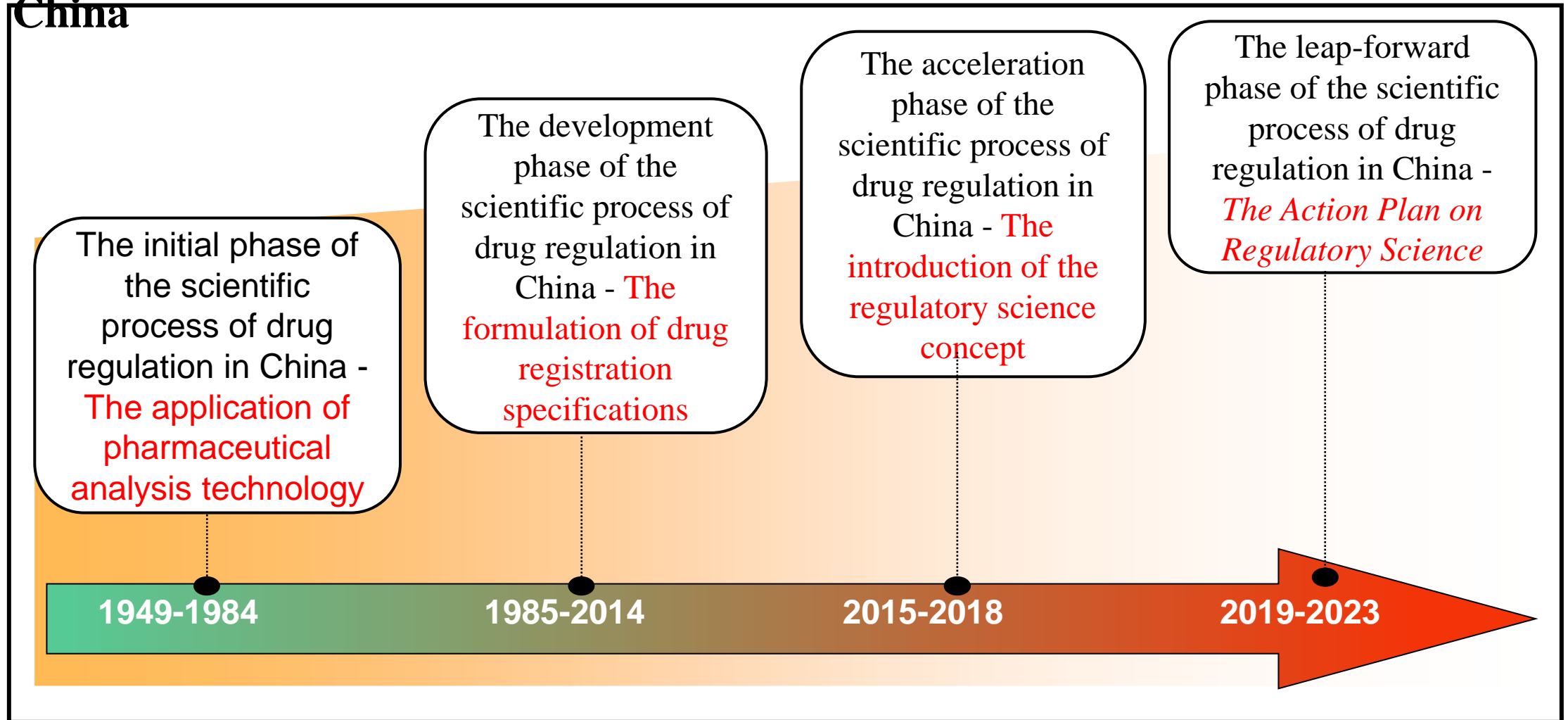


# Development of drug regulatory science

- The promulgation of the *Pharmacopoeia of the People's Republic of China* in 1953 marked the beginning of the scientific process of drug regulation in China
- On July 30, 1978, the State Council of China promulgated *the Regulations on Drug Administration*
- On September 20, 1984, the National People's Congress (NPC) Standing Committee of China passed the first edition of the *Drug Administration Law*, which marked the legalization of drug regulation
- On April 16, 1998, the State Drug Administration (SDA) of China was officially established to exercise unified law enforcement and supervision over drug and medical devices
- On February 28, 2001, the revised edition of the *Drug Administration Law*, for the first time, specified that SDA was in charge of drug regulation and related law enforcement



# The legislation and scientific process of contemporary drug regulation in China



## **Phase I: The initial phase of the scientific process of drug regulation in China**

### **The application of pharmaceutical analysis technology (1949 - 1984)**

- This phase is a period of rapid development of world pharmaceutical technology and drug regulation. During this period, the modern drug regulatory system in China just started, which mainly served the pharmaceutical industrial system with priority given to generic drugs.



## **Phase II: The development phase of the scientific process of drug regulation in China**

### **The formulation of drug registration specifications (1985 - 2014)**

- In this phase, China began to pay much attention to the relatively well-developed international drug regulatory system and new drug evaluation methods. The focus of the scientific process of drug regulation was to introduce three evaluation factors including modern drug quality, drug efficacy, and drug safety, encourage R&D of new drugs, and build a centralized, standardized, and professional drug review and approval system.

## **Phase III: The acceleration phase of the scientific process of drug regulation in China**

### **The introduction of the regulatory science concept (2015 - 2018)**

- In this phase, with the rapid development of the pharmaceutical industry in China, drug quality and standards were increasingly improved to better satisfy public demand. Although there was no definite idea of regulatory science in China at that time, the regulatory science concept and methods started to be introduced. At the same time, the internationally compatible new theories, new tools, new technologies, and new standards for review and approval were introduced and applied rapidly. On the whole, China's drug and medical devices review and approval system reform made some achievements by developing an integrated risk-benefit evaluation method, improving drug review and approval criteria, optimizing the review and approval system, and accelerating the marketing of innovative drugs.

# Phase IV: The leap-forward phase of the scientific process of drug regulation in China

## *The Action Plan on Regulatory Science (2019 - 2023)*

- China officially established the important status and role of drug regulatory science research at the national level
- In April 2019, NMPA officially initiated *China's Action Plan on Drug Regulatory Science*, so as to further enhance scientific, forward-looking, and adaptive regulation by innovating regulatory tools, standards, and methods. Moreover, the action plan can lead to more science-based, international and modern regulation under the rule of law to better satisfy the public's new

2017 — demand for drug safety — 2019 — 2020 — 2021 — 2021 — 2023 — 2023



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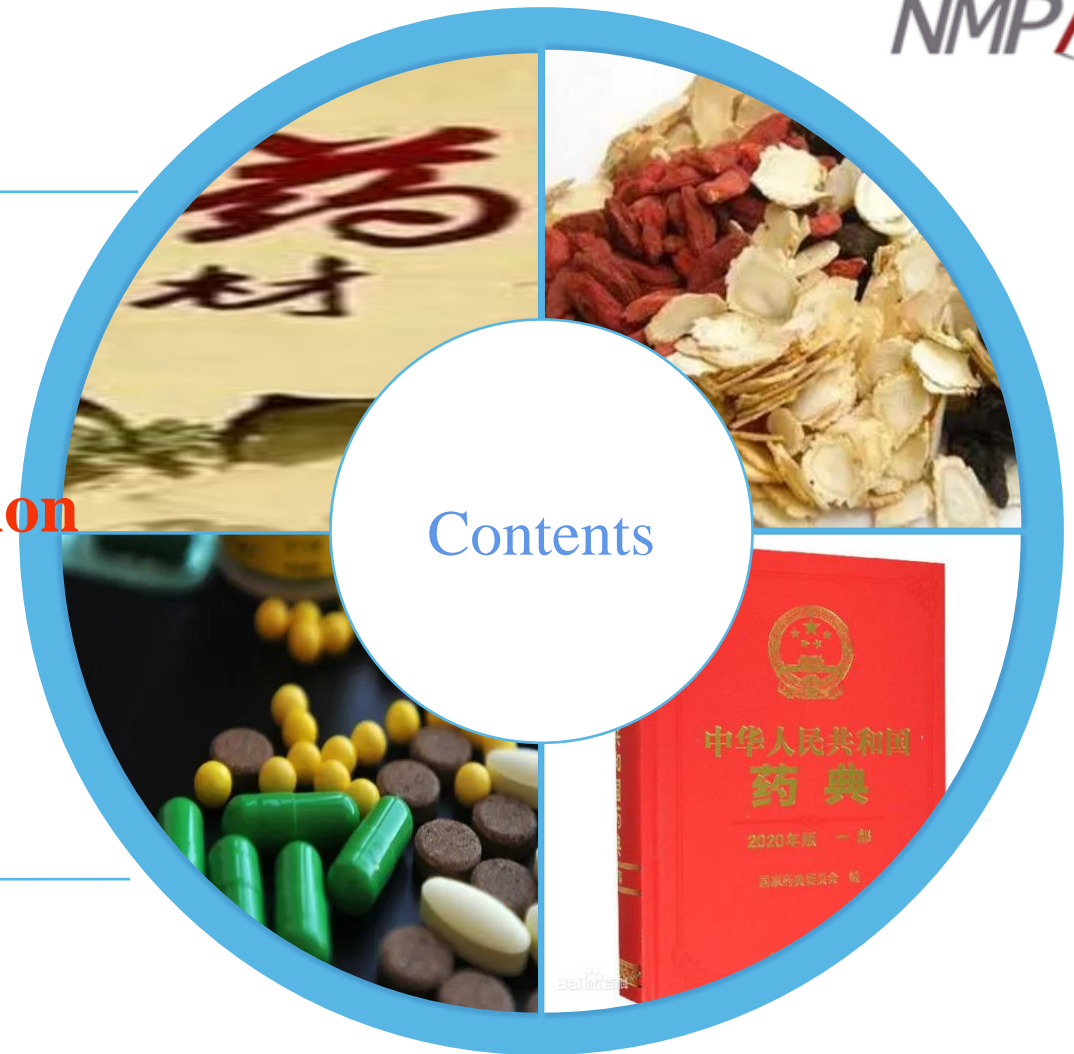
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**Main Achievements of China's Action  
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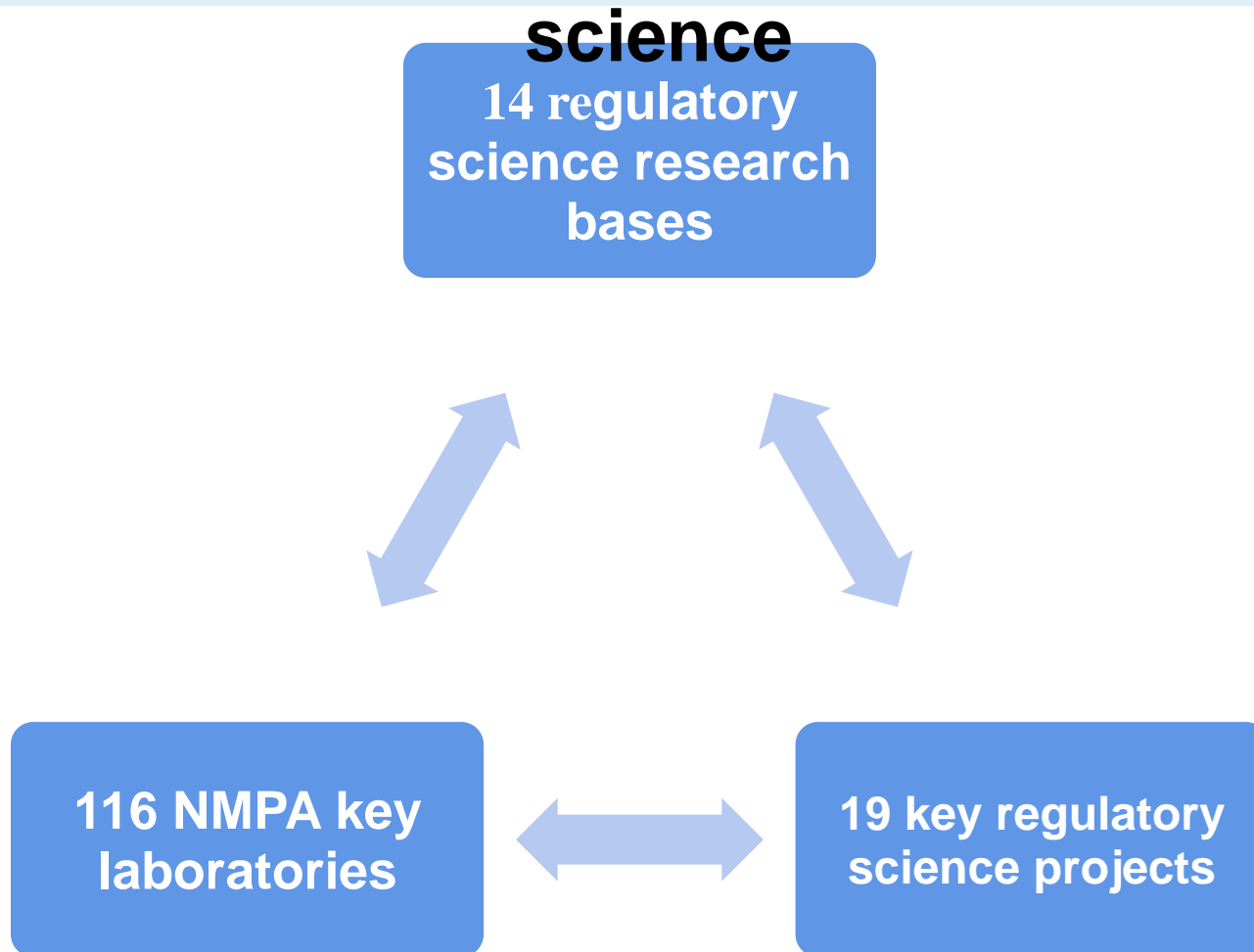
New Goals and New Initiatives to  
Comprehensively Strengthen the Drug Regulatory  
Science System



## II. Main Achievements of China's Action Plan on Drug Regulatory Science



### 1. Build a “three-in-one” support system for regulatory science



## II. Main Achievements of China's Action Plan on Drug Regulatory Science

### 2. Accelerate the transformation of new pharmaceutical technologies and products

- 187 new guidelines, standards and methods
- In 2022, 1,279 drug were approved for marketing in China, including 18 innovative drug
- 2,500 medical devices were approved for initial registration, including 55 innovative medical devices
- Over the past five years, a total of 106 innovative drug and 192 innovative medical devices have been marketed
- Historical progress has been made in the quality and efficacy consistency evaluation of generic drug



## II. Main Achievements of China's Action Plan on Drug Regulatory Science

### 3. Facilitate the modernization of drug regulatory capacity

- In line with the requirements of common international rules, the whole Chinese drug regulatory system has continuously strengthened regulatory capacity building and the construction of professional and specialized inspector team.
- China has also conducted research closely associated with regulatory modernization, such as regulatory policies for the high-quality development of traditional Chinese medicine decoction pieces, the evaluation of the safety, effectiveness, and quality control of nano-medical devices and the standard system for the safety and efficacy of cosmetics.

## II. Main Achievements of China's Action Plan on Drug Regulatory Science

### 4. Vigorously promote international drug regulatory harmonization

- China has always been continuously strengthening exchanges and cooperation with the World Health Organization (WHO), the International Coalition of medicines Regulatory Authorities (ICMRA), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF), the Global Harmonization Working Party (GHWP), and the International Cooperation on Cosmetic Regulation (ICCR). At present, China has initiated the procedure for joining the Pharmaceutical Inspection Cooperation Scheme (PIC/S). In August 2022, under the circumstance that the criteria of the WHO vaccine NRA assessment system had been greatly improved, China successfully passed the vaccine NRA assessment, laying a solid foundation for China's vaccines to be included in the International Organization Sourcing List.

## II. Main Achievements of China's Action Plan on Drug Regulatory Science

### 5. Accelerate and drive the industry development of drug, medical devices, and cosmetics

In 2022, the operating income of the pharmaceutical manufacturing industry reached RMB 4.2 trillion, including RMB 2.9 trillion for drug and RMB 1.3 trillion for medical devices. China's drug market accounted for 20.3% of the global drug market, and China's medical device market accounted for 27.5% of the global medical device market.

A total of 4975 enterprises, 174 toothpaste manufacturers, 80,234 registered special cosmetic products, including 16,091 domestic ones and 64,143 imported ones

cosmetics

117,198 domestic Class I medical devices, 8522 imported Class I medical devices, 28,682 medical device manufacturers, and 227,280 enterprises engaged in in vitro diagnostic reagents (IVD) business.

medical devices

117,198 domestic Class I medical devices, 8522 imported Class I medical devices, 28,682 medical device manufacturers, and 227,280 enterprises engaged in in vitro diagnostic reagents (IVD) business. 151,021 drug license numbers, 6,272 drug standards in the Pharmacopoeia and 16,258 published by the drug regulatory authority, and 609,681 drug distributors

drug

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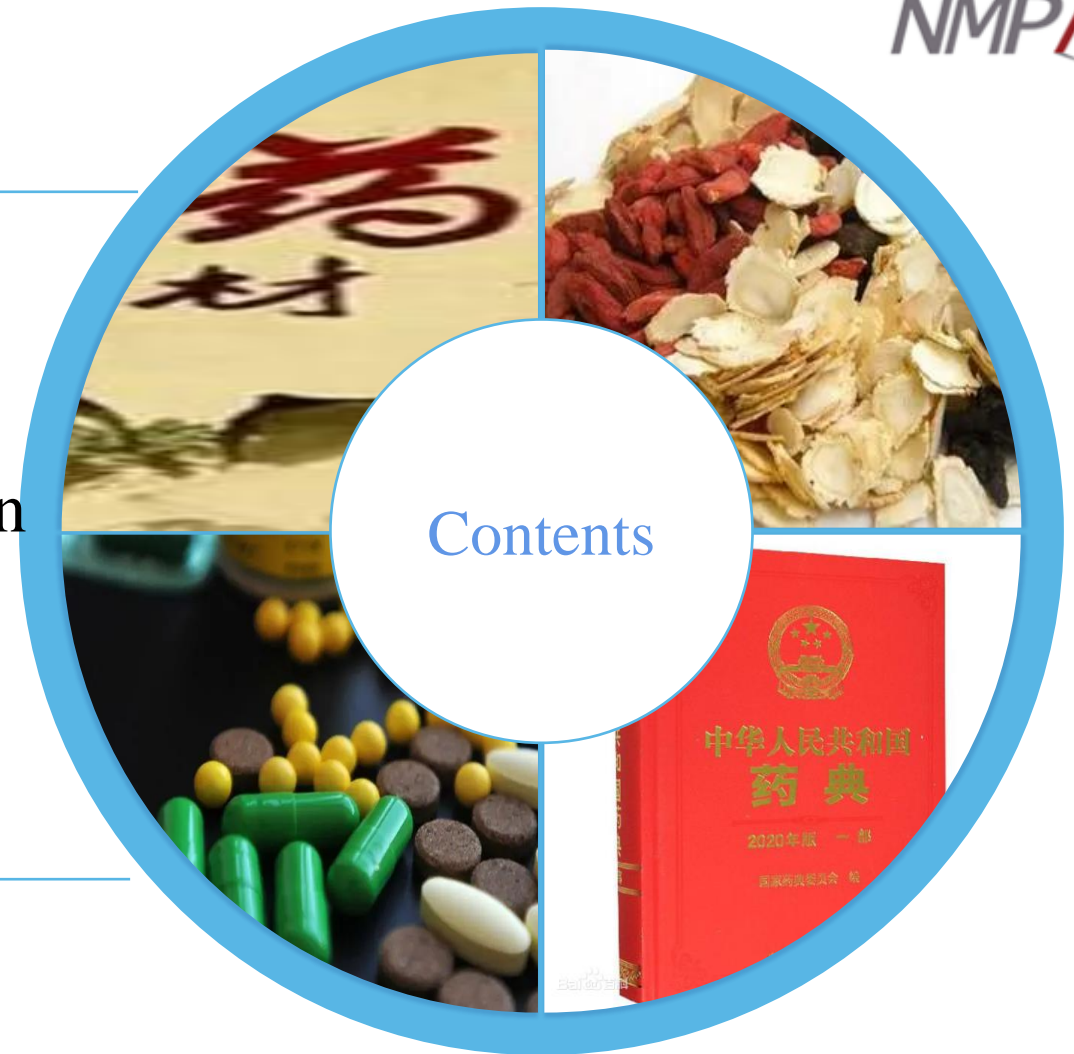
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**New Goals and New Initiatives to  
Comprehensively Strengthen the Drug  
Regulatory Science System**



# III. New Goals and New Initiatives to Comprehensively Strengthen the Drug Regulatory Science System



## 国家药品监督管理局文件

国药监科外〔2023〕27号

### 国家药监局关于印发全面强化药品监管科学体系建设实施方案的通知

局机关各司局、各直属单位：

《国家药品监督管理局全面强化药品监管科学体系建设实施方案》已经局长办公会通过，现印发你们，请结合实际认真贯彻落实。



（公开属性：依申请公开）

— 1 —

**Strengthen and improve the conditions for regulatory science and the level of platform construction**

**Improve the service guarantee system for regulatory science**

**Focus on key issues in major fields**

# III. New Goals and New Initiatives to Comprehensively Strengthen the Drug Regulatory Science System



## 1. Strengthen and improve the conditions for regulatory science and the level of platform construction

- Cultivate scientific and technological strength in the field of drug regulation, organize and undertake key projects in the field of drug regulatory science, study and formulate a series of internationally compatible new technologies, new methods and new tools for drug evaluation
- Improve the management system for regulatory science research bases and NMPA key laboratories
- Further strengthen the construction of the drug testing system, enhance the technical support role of testing institutions in regulation



# III. New Goals and New Initiatives to Comprehensively Strengthen the Drug Regulatory Science System



## 2. Improve the service guarantee system for regulatory science

- Accelerate the construction of the service guarantee system for the regulatory science and technology innovation system, achievement transformation system, regulatory science discipline system, and international harmonization system.
- Provide vigorous support for the development of drug regulatory science to not only accelerate the output, transformation, and application of regulatory science achievements but also continuously improve the scientific and international level of drug regulation.

# III. New Goals and New Initiatives to Comprehensively Strengthen the Drug Regulatory Science System



## 3. Focus on key issues in major fields

- Conduct studies in such major fields as chemical drugs, biological products, traditional Chinese medicines, and medical devices of wide concern to the international community
  - · Conduct methodological studies on the clinical evaluation of innovative drug
  - · Improve the scientific and standardized system of standards for the technical evaluation of vaccines
  - · Construct a methodological framework for the clinical evaluation of medical devices based on real-world data (RWD)

# Summary

- Regulatory science will surely arouse more attention from all countries with the rapid development of modern biotechnology, the constant discovery of new targets and new mechanisms, and the emergence of new technologies and new methods such as gene therapy and cell therapy.
- This Global Summit on Regulatory Science will build a rare communication platform for us and provide an opportunity for regulatory authorities and industry representatives from various countries to gather together and discuss current hot issues.
- NMPA attaches great importance to international harmonization and is willing to strengthen dialogue and communication with all of you through the GCRSR and summit, striving to jointly cope with emerging new problems and new challenges, protect public health, and build a community of common health for mankind.



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**THANK YOU!**