CHINA'S REGULATORY CHANGE: THE EVOLUTION OF NATIONAL MEDICAL PRODUCTS ADMINISTRATION

ABSTRACT

The purpose of this paper is to provide an overview and review of the major regulatory changes that National Medical Products Administration has undergone in China since 2015 in order to accelerate new product production and registration in accordance with international standards, as well as to raise the profile of Chinese medical products on a global scale. China's regulatory structure has always been highly complex. China's health authority has been modifying the organisational structure in China in order to bring Chinese therapeutic products up to international standards in terms of suitability, safety, and dependability, as well as to more likely locate individuals' general prescription drug requirement and expand access to new drugs and treatments from around the world. By applying worldwide standards and technical criteria, enhancing review and approval transparency, and speeding up the examination and approval of new drugs, medical devices, and other items, all of the regulatory improvements are making it simpler to manufacture creative products. The Chinese Ministry of Health has also published instructions on medication development and technical evaluation, as well as the implementation of electronic common technical documentation and post-approval safety surveillance. Regulations for priority review and approval, a data protection system, imported medical product registration, and new product categorization have all been put in place to encourage the development of innovative goods. China's regulatory framework is in the process of being overhauled. In the near future, it is conceivable to accomplish simultaneous growth and approval on par with existing regulated markets.

Keywords: National Medical Products Administration, Regulatory, Reforms, Standards, innovative products, approval transparency

INTRODUCTION

China is considered to be an epitome where tradition meets technology. It is evident that cultural preservation and innovations towards an advanced future go hand in hand in this country. It can be said about the health care system in place. Even though majority of people still practice traditional medicine, the domestic demand for effective drugs, and novel medical devices have increased [1]. This can be due to the growing old-age population and the countries economical status on a global level. This has resulted in tremendous changes as the whole healthcare is evolving towards a new universal healthcare[2].

This also means that China is constantly changing and expanding with vast opportunities in terms of manufacturing, import and export of innovatory products, drugs, cosmetics, and medical devices. It is no secret that initially the walls around the Chinese market were looming high due to its language barrier and the regulations that were a bit difficult to comprehend and incorporate as it deviated so much from the harmonized approval process, it appears to be individual and tedious [3].

The product registration process varies from that of many other countries in that all imported drugs, whether sold internationally or not, must contain evidence from local clinical trials; in terms of quality, there are substantial differences between global standards and certain domestic products and suppliers; the period it takes to evaluate and approve new medicines is longer than in most other major countries[4].

Regional Chinese industries have historically been uninterested in the development of innovative new products due to strong competition in the generics market, and their current capacity for doing so is limited which can related to Indian market[5].

These companies have previously focused on bioequivalence (BE) trials for generic drug registration, but with due to the regulatory shift and the evolution of CFDA into National Medical Products Administration new standards, they will have to begin focusing on generic consistency and efficacy. As a result, any data that is deemed incorrect or incomplete will not be accepted, potentially causing current licenses to be revoked. This can also pave way for the industries to consider new innovative products in future [6].

Evolution of Regulatory Authorities in China

China’s drug regulatory system before the reform policy (1949~1977)

The role of China's competent departments for pharmaceutical industry China's competent Departments responsible for the domestic pharmaceutical industry were a series of regulatory bodies in the government. They took charge of planning and other important decision-making for state owned pharmaceutical enterprises. In 1956 there were about 500 privately-owned pharmaceutical factories, more than 300 privately owned factories of medical devices, more than 7000 privately-owned pharmacies, and more than 100,000 merchants of Chinese traditional herbal medicine.

The development of the Campaign of State-Private Joint Ownership eventually turned most privately-owned enterprisesin to state-owned enterprises. Similarly, most privately-owned hospitals and clinics were also transferred from private sector to direct government control. In order to operate all of its state-owned enterprises a series of competent departments were set up to manage the pharmaceutical industry. The new Pharmaceutical Company of China was assigned to take charge of the nation's wholesale trade of pharmaceuticals in 1950. The Agency of Pharmaceutical Industry was assigned to take charge of the manufacturing business of chemical medicine and medical devices in 1952. The Traditional Herbal Medicine Company of China was assigned to take charge of the wholesale trade of traditional herbal medicine in 1955. All of these competent departments were responsible for high-level management of the state-owned enterprises no matter what their names and no matter the ministries to which they were assigned. They took charge of business arrangements and administrative affairs as well as drug quality control

The main aim of the study is

- To provide a chronological review of guidelines and regulatory framework that led to the evolution of NMPA.
- To delve on the organization of NMPA, its function and navigation across its official websites.
- To review of new guidelines for Drugs, Medical devices, and cosmetics

Discussion

The aim of this shift is to encourage systemic change and improvise the pharmaceutical industry, bringing drugs, devices, and cosmetics which already on the market in China as

well those that need to be formulated up to international effectiveness, protection, and quality standards [10].

These reforms aimed to:

- Rectifying the current accumulation of registration applications.
- Create a global-development environment that promotes research and innovation of novel medications;
- Increase the transparency & consistency of the evaluation and approval process [11].

ADMINISTRATION IN CHINA

Pharmaceutical policy in China has historically been relatively disjointed and uncoordinated between provinces, autonomous regions and national levels. They have various levels of authority based on the hierarchy. National Medical Products Administration have published norms to dissolve and maintain a unified chain of command amongst the regions [7].
Below is a brief outline of the administration in China [8]:

Figure 1: Political Map of China

A three-level system division amongst the country currently exist namely provinces, counties, and townships. The country is divided into regions, independent nations, and municipalities, all of which report directly to the Central authorities. China is currently divided into 23 provinces, 5 autonomous regions, 4 municipalities directly subordinate to the Federal Government, and 2 special organizational entities.

Navigating legal documents can present to be a bit different since rule (guizhang) and regulations (xingzheng fagui) are published in forms of circulars, notice, decree and letters [9].

Organization structure of National Medical Products Administration

Department of Comprehensive Affairs, Planning, and Finance Affairs

• Division of General Affairs (Office of Public Complaints and Proposals)

• Division of Secretariat I

• Division of Secretariat II (Office of Emergency Management)

• Division of Documentation, Communication and Confidentiality

• Division of Superintendence

• Division of Media and Survey (Office of Media)

• Division of Planning

• Division of Budget and Audit

• Division of Finance

Department of Policies and Regulations

• Division of General Affairs

• Division of Policy Research

• Division of Regulations

• Division of Enforcement

Supervision Department of Drug Registration

• Division of General Affairs (Office of Drug Regulation Reform)

• Division of Drug Research

• Division of Traditional Chinese Medicines and Ethno-Medicines

• Division of Chemical Drugs

• Division of Biological Products

Department of Medical Device Registration

• Division of General Affairs

• Division of Registration I

• Division of Registration II

• Division of Registration

Research Department of Cosmetics Regulation

• Division of General Affairs

• Division of Supervision I

• Division of Supervision II

Department of Science, Technology and International Cooperation

• Division of General Affairs (Division of Hong Kong, Macao and Taiwan Affairs)

• Division of Science and Technology

• Division of International Organizations

• Division of Bilateral

Cooperation Department of Human Resources

• Division of General Affairs (Division of Training)

• Division of Personnel I

• Division of Personnel II (Division of Salary)

• Division of Personnel Supervision

Functions of National Medical Products Administration

• Responsible for the safety supervision and management of drugs (including Chinese medicine, ethnic medicine, the same below), medical equipment and cosmetics. Formulate supervision and management policy planning, organize drafting of draft laws and regulations, formulate departmental regulations, and supervise implementation. Study and develop management and service policies that encourage new technologies and products for pharmaceuticals, medical devices, and cosmetics.

• Responsible for the registration management of pharmaceuticals, medical devices and cosmetics. Formulate a registration management system, strictly review and approve the listing review, improve the facilitation measures for review and approval, and organize implementation.

• Responsible for the quality management of pharmaceuticals, medical devices, and cosmetics. Develop quality management practices and supervise implementation. Formulate production quality management regulations and implement them according to their duties. Develop management, use quality management practices and guide implementation.

• Responsible for risk management of drugs, medical devices, and cosmetics after listing. Organize the monitoring, evaluation, and disposal of adverse drug reactions, medical device adverse events and cosmetic adverse reactions. To undertake the safety emergency management of drugs, medical devices, and cosmetics in accordance with the law.

• Responsible for the admission management of licensed pharmacists. Formulate a system for the qualification of licensed pharmacists and guide the supervision of the registration of licensed pharmacists.

• Responsible for organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics. Formulate an inspection system, investigate and deal with illegal acts in the registration of drugs, medical devices and cosmetics according to law.

Reforms	
2016	Self-inspection of clinical data
	Priority review
	Additional capacity at CDE
	Marketing Authorization Holder rationalization/new classification/definition of new drugs
	Generic drug quality and efficacy consistency Evaluation (GQCE)
2017	Opening up of first-in-human (FIH) Phase I trials to global development
	Simplified process for gaining a marketing approval
	Clinical trial management
	Acceleration of drug and medical device registration review process
	Drug and medical device life cycle management
	Protecting innovators' rights
2018	NHC Rare Disease list
	NMPA elected member of ICH Management Committee
	Technical Guideline for Acceptance of Overseas Drug Clinical Trial Data
	Adjusting the Approval Process for Drug Clinical Trial Evaluation (Circular 50)
	MAH pilot project extended one year
	Accelerated approval
	Independent Vaccine Administration Law
	CDE website
2019	Medical device site qualification notification
	MAH ADR direct reporting system online
	Oncology and rare disease drugs
	eCTD implementation progress and plan

Figure 2: List Of Major Reforms In NATIONAL MEDICAL PRODUCTS ADMINISTRATION During The 13th 5-Year Plan [12]

Table 1: Rules and Regulations published under National Medical Products Administration during the 13th 5-year plan for drugs [13]

Drugs				
FILE	**NAME**	**PHASE**	**IMPLEMENTED BY**	**ISSUE DATE**
General Decree				
Decree No. 28 of 2020	Approaches for Drug Manufacturing Control and Management	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	January 22, 2020

Decree No. 39 of 2017	Administrative Measures for Batch Issuance of Biological Products	Implemented	SFDA	December 29, 2017
	Approaches for Drug Manufacturing Control and Management	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	November 21, 2017
	Measures for the Administration of Internet Drug Information Services	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	November 21, 2017
	Measures for the Administration of Pharmaceutical Business Licenses	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	November 21, 2017
	Provisions for Administering the People's Republic of China's Drug Administration Law	Implemented	SFDA	February 6, 2016
Registration/Filling				
Notice No. 119 of 2020	Online application of drug registration	Implemented	Comprehensive Department of the State Drug Administration	
Notice No. 2 of 2020	The filing procedures and requirements of provincial-level Chinese herbal medicine preparation specifications	Implemented	NFDA	
Notice No. 193 Of 2015	The filling out relevant items in the Drug Production License	Implemented	SFDA	
GMS/QMS				

Notice No. 160 of 2016	Guiding Principles for On-site Inspection of Good Drug Management Practices	Implemented	SFDA	December 14, 2016
	Pharmaceutical business quality management practices	Implemented	SFDA	June 30, 2016
Clinical Evaluation				
Notice No. 108 of 2019	The Principles and Procedures of Drug Sampling and Other Documents	Implemented	Comprehensive Department of the State Drug Administration	December 26, 2019
Notice No. 34 of 2016	Clinical trial data verification work procedures	Implemented	SFDA	March 28, 2016
Post Market Surveillance				
Notice No. 78 of 2015	Guidelines for Reporting, Monitoring and Inspection of Adverse Drug Reactions	Implemented	SFDA	July 2, 2015

Table 2: Rules and Regulations published under National Medical Products Administration during the 13th 5-year plan for medical devices [14], [15][16][17]

Medical Device				
FILE	**NAME**	**PHASE**	**IMPLEMENTED BY**	**ISSUE DATE**
General Degree				
MJPRC-20180825-1	Amended Regulation on Supervision and Management of Medical Devices of Medical Devices (Draft)	Draft	Ministry of Justice	June 25, 2018
Decree No.7 CFDA, 2017	Measures for Supervision and Administration of	Implemented	CFDA	November 21, 2017

	Medical Device Production			
Decree 4 CFDA, 2014	Provisions for Medical Device Registration	Implemented	CFDA	July 30, 2014
<u>Registration/Filling</u>				
Notice, CMDE-20190103	Operation Specification for Record Filing of Medical Device Master Files	Draft	CMDE	January 3, 2019
Notice, CMDE-20190103	Record Filing Requirement of Medical Device Master Files	Draft	CMDE	January 3, 2019
Notice, CMDE-20190103	Guideline for Record Filing of Medical Device Master Files	Draft	CMDE	January 3, 2019
Notice, CMDE-20190103	Announcement on Record Filling of Medical Device Master Files	Draft	CMDE	January 3, 2019
Notice, No. 83, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Innovation Device Approval Procedure	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	November 5, 2018
Notice, NATIONAL MEDICAL PRODUCTS ADMINISTRATION-20180822	Unique Device Identification (UDI) Implementation Plan	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	August 22, 2018
Notice, No.131, CFDA, 2017	Using Chinese Name for Registrant or File Submitter of Imported Medical Devices	Implemented	CFDA	November 2, 2017
Decree 6, CFDA, 2014	Regulation on Instructions for Use and Labels of Medical Devices	Implemented	CFDA	July 30, 2014
<u>GMP/QMS</u>				
Notice No.101 NATIONAL MEDICAL	Regulations for the Administration of Overseas Inspection of Pharmaceutical	Implemented	NATIONAL MEDICAL PRODUCTS	December 26, 2018

PRODUCTS ADMINISTRATION, 2018	& Medical Devices		ADMINISTRATION	
Notice No.19 CFDA, 2016	Good Manufacturing Practice in Class III Medical Device Manufacturers	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	February 5, 2016
Notice No.218 Annex 3, CFDA	Good Manufacturing Practice Guidelines for Onsite Inspection of Implantable Medical Devices	Implemented	CFDA	September 25, 2015
Notice No. 218 Annex 2, CFDA	Good Manufacturing Practice Guidelines for Onsite Inspection of Sterile Medical Devices	Implemented	CFDA	September 25, 2015
Notice No.218 Annex 1, CFDA	Good Manufacturing Practice Guidelines for Onsite Inspection	Implemented	CFDA	September 25, 2015
Notice, No.103, CFDA, 2015	Good Manufacturing Practices on In Vitro Diagnostic Reagents	Implemented	CFDA	July 10, 2015
Notice, No.102, CFDA, 2015	Good Manufacturing Practice for Implantable Medical Devices	Implemented	CFDA	July 10, 2015
Notice, No.64, CFDA, 2014	Good Manufacturing Practice for Medical Devices	Implemented	CFDA	December 29, 2014
<u>Clinical Evaluation</u>				
Notice CMDE-20181122-2	Technical Guideline for Comparing the Same Variety of In-vitro Diagnostic Reagents Exempted from Clinical Trials (Draft)	Draft	CMDE	November 22, 2018
Notice CMDE-20181122-1	Guidelines for Clinical Trials of In Vitro Diagnostic Reagents (Draft)	Draft	CMDE	November 22, 2018
Notice No.6, CFDA, 2018	Medical Device Clinical Trial Design Guideline	Implemented	CFDA	January 8, 2018

Notice No. 179, CFDA, 2017	Basic Requirements for Clinical Evaluation Materials of IVD Exempted from Clinical Trial (Draft)	Implemented	CFDA	November 8, 2017
Decree 25, CFDA, 2016	Good Clinical Practice for Medical Device	Implemented	CFDA/National Health Commission	March 23, 2016
Guideline & Standard				
	Current China NATIONAL MEDICAL PRODUCTS ADMINISTRATION Clinical Pathways for Medical Device Registration (Draft)			November 18, 2020
	Drug-Medical Device Combination Products in China (Draft)			September 21, 2020
Notice No.7, CMDE, 2019	Guideline on AI-Aided Software	Implemented	CMDE	July 3, 2019
Notice No.50, CFDA, 2015	Guideline for Technical Review of Medical Device Software Registration	Implemented	CFDA	August 18, 2015
Post Market Surveillance				
Decree 1 Annex 9, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Guidance on Inspecting Medical Device Adverse Event Monitoring Activity	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	September 20, 2018
Decree 1 Annex 7, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Guidance on Focus Points when Monitoring Medical Device Adverse Events	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	September 20, 2018
Decree 1 Annex 5, NATIONAL MEDICAL	Guidance for License Holder on Collecting and Reporting Individual Cases of Medical	Draft	NATIONAL MEDICAL PRODUCTS	September 20, 2018

PRODUCTS ADMINISTRATION, 2018	Device Adverse Event		ADMINISTRATION	
Decree 1 Annex 3, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Guidance on Medical Device Adverse Event Monitoring Scope	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	September 20, 2018
Decree 1 Annex 1, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Guidance on Medical Device Adverse Event Monitoring	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	September 20, 2018
Decree 1, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Measures for the Administration of Medical Device Adverse Event Monitoring and Re-evaluation	Implemented	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	August 31, 2018
Decree 29, NATIONAL MEDICAL PRODUCTS ADMINISTRATION, 2018	Measures for the Administration of Medical Device Recall	Implemented	CFDA	January 25, 2017

Table 3: Rules and Regulations published under National Medical Products Administration during the 13th 5-year plan for Cosmetics [18][19][20]

Cosmetics				
FILE	**NAME**	**PHASE**	**IMPLEMENTED BY**	**ISSUE DATE**
General Decree				
Announcement No. 265 of 2015	Cosmetics Production licensing	Implemented	SFDA	December 15, 2015
	Cosmetics Supervision and Administration Regulations	Draft	CSAR	June 30, 2020
Registration/Filling				
Drug Administration Letter (2020) No. 105	Administrative Measures for Cosmetics Labeling	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	September 21, 2020
	Administrative Measures for Cosmetic Supplementary Inspection Methods	Draft	CSAR	November 12, 2020
	Cosmetic Sampling Inspection Management Regulations	Draft	CSAR	September 27, 2020
Announcement No. 195 of 2017	General Administration on Regulating the Registration and Filing of Cosmetics Related Matters	Implemented	SFDA	November 30, 2017
Announcement No. 31	Pilot Implementation of the Filing Management	Implemented	SFDA	March 8, 2018

of 2018	of Imported Non-Special Purpose Cosmetics			
Drug Administration Letter (2020) No. 105	Administrative Measures for Cosmetics Labeling	Draft	NATIONAL MEDICAL PRODUCTS ADMINISTRATION	2020-09-21
GMS/QMS				
	Cosmetic Production Quality Management Standards	Draft		September 27, 2020
Notice No. 4 (2018)	Regulating the Risk Monitoring of Cosmetics	Implemented	SFDA	January 5, 2018
Guidelines and Standards				
Drug Administration Letter〔2020〕82	Technical Guidelines for Safety Assessment of Cosmetics	Draft	Department of Cosmetics Supervision, National Food and Drug Administration	July 29, 2020
Drug Administration Letter (2020) 82	Rules for Classification of Cosmetics and Classification Catalogue	Draft	Department of Cosmetics Supervision, National Food and Drug Administration	July 29, 2020
Post Market Surveillance				
Notice No. 94 (2020)	Cosmetics Adverse Reaction Monitoring Management Measures	Draft	SFDA	September 27, 2020

NATIONAL MEDICAL PRODUCTS ADMINISTRATION REFORMS

Prior to reform, China's regulatory system was extremely difficult and inconsistent

With international standards. The “Opinions on Reforming the Evaluation and Approval System for Drugs and Medical Devices” were approved by the China State Council and formally announced to the public on August 9, 2015. It contributes to the reform of the Drug Administration Law and the Drug Registration Regulation.

Figure 3: Reforms by National Medical Products Administration

Encourage Innovation	Promote Drug Quality	Enhance Supervision	Streamline Review & Approval	Transparency
New Chemical Drug Registration Classification	Generic Consistency Evaluation	Clinical Study on-site Inspection	Filing for BE studies	Communication mechanism for CTA & NDA
Priority review	Chinese Pharmacopeia	GMP Inspection (Domestic & Oversea)	Filing for BE studies	Disclose drug evaluation information
Registration technical requirement		Distribution administration	CDE communication meetings	Re-evaluation procedure in CDE new guidance & guidelines
MAH Pilot			Measures on Advisory Committee	

- 2017.06 CFDA Joining ICH
- 2017.10 Deeping Regulatory Reform Doc No 42-2017
- 2017.10 Adjustment of Imported Drug Registration (Order No.35)
- 2017.10 CFDA issued Chinese Orange Book

- 2017.10 Guideline for Conditional Approvals for urgently needed drugs (draft).
- 2018.10 Appling M4, E2A, E2D, M1, E2B Notice No.10
- 2018.07 Guideline for Acceptance of Oversea Clinical Data
- 2018.11 Independent Vaccine Administration Law

Few changes over the course of these 5 years speaks for itself taking into consideration in China, the number of clinical trial centres and institutions has increased. With the introduction of the record-filing system for clinical trial institution registration and management in China in November 2019, which will enable China to resolve the rising number of clinical trials currently underway in the country as well as promote the production of new drugs.

The National Medical Products Administration (NATIONAL MEDICAL PRODUCTS ADMINISTRATION) of China joined ICH in 2017, demonstrating the country's regulatory system's alignment with international standards. China, as the world's second-largest economy, is a strong supporter and defender of globalisation Clinical trial data from China and the rest of the world must be mutually recognised if Chinese pharmaceutical research is to go global. There was a five- to seven-year period between new drug approvals in the US and China prior to 2015. Due to the aforementioned changes, this time lag has been reduced to one or two years, and in some cases, just a few months.

As part of this internationalisation trend, China's domestic innovation capabilities and achievements are becoming more visible. China, along with Europe and Japan's innovative markets, was named to McKinsey's list of second-tier innovator countries in 2018, demonstrating China's impressive performance in pharmaceutical innovation.

CONCLUSION

China has seen an increase in the number of clinical research centres and clinical organisations. In April 2016, China only had 478 clinical trial institutions. In 2019, there will be 886 authorized clinical study organizations, an 185 percent rise over the past year. By introducing in November2019 the record-setting system for registering and administering clinical trials institutions, more and more healthcare facilities will be qualified for clinical trials. Chinese pharmaceutical innovation can only be

globalised by mutual recognition of clinical trials data from China and the world. Between new medicine licences in the United States and China there existed a delay between five to seven years before 2015. As part of this internationalisation process, Chinese domestic innovation capacities and achievements are rising rapidly. China was appointed in 2018 to McKinsey's second-level innovator list, alongside Europe and Japan's creative markets, representing China's remarkable success in pharmaceutical innovation. Previous limits on drug and medical-device innovation have been lifted as the breadth of these reforms spread across multiple stages of the products life cycle.

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