CCCMHPIE

ANNUAL HIGHLIGHTS OF CHINA'S HEALTHCARE INDUSTRY

2019

中国医药保健品进出口商会

CCCMHPIE

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PREFACE

Address by Mr. Zhou Hui, President of CCCMHPIE

Dear friends and partners:

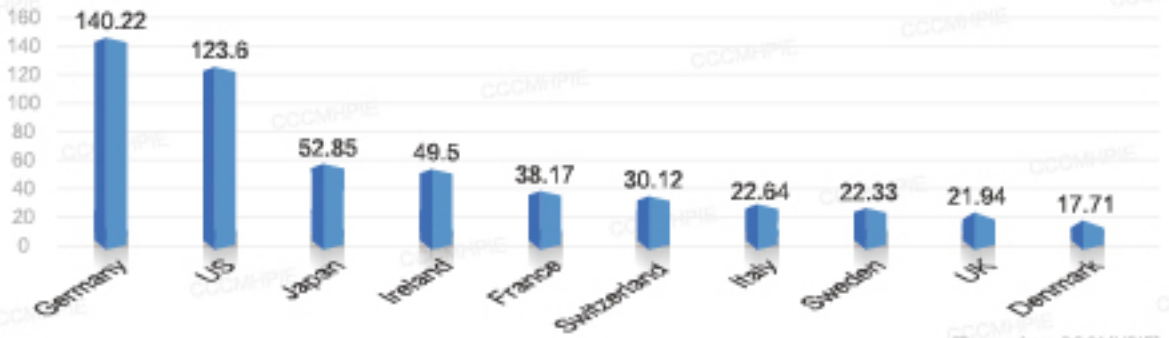
Against the backdrop of global economic slowdown, profound restructuring and uncertainties in 2019, the Chinese healthcare foreign trade witnessed strong growth. Statistics of China Customs revealed a total import and export trade volume of 145.691 billion USD, up by 26.85%, the highest since 2011. Europe, Asia and North America were China's top three trading partners in terms of healthcare foreign trade. US continued to be China's top 1 trading partner, followed by Germany, Japan, India and Ireland.

Since the beginning of 2020, an unexpected outbreak of Novel Coronavirus (COVID-19) quickly became a global pandemic that instantly connects the health of everyone together. We are facing a health threat unlike any other in our lifetimes. Meanwhile, the virus is spreading, the danger is growing, and we have no other options but to stand and act together and look after each other.

In the era of profound transformation, as a responsible national industry association, China Chamber of Commerce for Import & Export of Medicines and Health Products(CCCMHPIE), together with the Chinese healthcare industry, shall work closely with all partners and friends, to serve as the link between the government and the industry, domestic and overseas markets, and pave the way for smooth, successful and healthy business for the industry.

Zhou Hui
President
CCCMHPIE

Chart 2: China's top ten importing countries (Unit:100 million USD)



(Source from CCCMHPIE)

2. Registration and Certification at Stringent Regulatory Authorities

US market

NDA:

On November 15, 2019, BeiGene's self-developed BRUKINSA (zanubrutinib) received accelerated approval from FDA as a treatment for mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy.

ANDA:

In 2019, FDA granted 808 ANDAs and 149 tentative approvals, of which 92 ANDAs were given to Chinese drug companies, or 76 active substances from 28 manufacturers. Fosun Pharma(mainly its affiliating Gland and Yaopharma), gained the most number of ANDAs(16), followed by Novast(12). Fosun pharma, Novast, Hisun Pharma and Sungen Pharma had seen increases in the number of ANDAs compared with 2018.

FDA Site Inspection:

From January 1st to December 31st of 2019, 200 Chinese facilities were evaluated by FDA as in compliance with applicable laws and regulations (including 99 sites for drugs, 45 sites for medical devices and 56 sites for health and nutritional products).

(Data collected by CCCMHPIE from FDA website)

EU market

The number of CEPs acquired by Chinese companies totaled 247.

According to EudraGMP, So far the Chinese companies gained 453 EU GMP certificates, including 47 gained in by December 10, 2019.

(Data collected by CCCMHPIE from EDQM and EudraGMP website)

WHO PQ

Medicines: By Feb.5, 2020, there are 37 medicines passing WHO PQ.

Active ingredients: By December 19, 2019, there have been 56 APIs passing WHO PQ, including 24 APIs newly approved in 2019.

Vaccines: 6 products in total, including Japanese Encephalitis Vaccine (live, attenuated), Influenza Vaccine (Split virion, inactivated), Hepatitis A (Human Diploid Cell), Inactivated (Adult), Polio Vaccine – Oral (OPV) Bivalent Types 1 and 3, Hepatitis A (Human Diploid Cell), Inactivated (Paediatric).

IVD: By Dec.18, 2019, there have been 6 IVDs passing PQ, including (ONE STEP Anti -HIV (1&2) Test,Rapid Anti -HCV Test,One Step HIV1/2 Whole Blood/Serum/Plasma Test,Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2,Rapid Test for HIV)

Vector Control: 6 products passed PQ.

(Data collected by CCCMHPIE from WHO website)

PART ONE

Progress on The Internationalization of The Chinese Healthcare Industry

In 2019, China's healthcare import and export volume both saw an increase from the previous year, making a record high since 2011. Europe, Asia and North America were China's top three trading partners in terms of healthcare foreign trade. US continued to be China's top 1 trading partner, followed by Germany, Japan, India and Ireland. Under the Belt and Road Initiative, there have been quicker paces of overseas investment, M&A, license-in and license-out. The deepening of healthcare reform in China continued to unleash new market opportunities. The number of international registration and certification acquired by Chinese companies was also on the rise.

1. International Trade Performance

Overall trade performance

Table 1: China's healthcare trade performance in 2019(Unit:100 million USD)

Commodity	Export	YoY%	Import	YoY%	Import & Export	YoY%
Total	738.3	14.6	718.61	42.5	1456.91	26.85
TCM	40.19	2.82	21.55	15.93	61.75	7.05
Herbal extracts	23.72	0.19	8.49	16.85	32.21	4.1
TCM finished products	2.63	-0.45	3.93	-2.51	6.55	-1.69
TCM prepared slices	11.37	10.32	3.58	25.82	14.96	13.68
Health products	2.47	0.21	5.56	24.77	8.03	16.02
Pharmaceuticals	411.09	11.46	429.2	62.55	840.29	32.77
APIs	336.83	12.1	107.5	24.7	444.34	14.91
FDF	41.09	0.23	199.1	52.79	240.19	40.22
Biochemicals	33.16	21.25	122.6	157.96	155.76	108.02
Medical devices	287.02	21.46	267.85	20.84	554.87	21.16
Medical consumables	27.16	4.16	5.44	25.13	32.61	7.15
Medical disposables	54.88	39.39	41.91	18.55	96.8	29.53
Hospital diagnostics and treatment	124.56	23.61	186.65	23.39	311.21	23.48
Rehabilitation products	67.11	11.5	23.53	8.68	90.64	10.75
Dental devices and materials	13.3	34.55	10.31	14.15	23.61	24.81

(Source from CCCMHPIE)

China's total healthcare trade volume: 145.691 billion USD, 26.85% ↗
- Export volume: 73.83 billion USD, 14.6% ↗
- Import volume: 71.86 billion USD, 42.5% ↗
- Trade surplus: 1.97 billion USD, 85.92% ↘

3. Mergers &Acquisitions

Overseas M&A cases covered diversified fields in 2019, involving cases in blood products, generic drugs, medical devices, CDMO, CRO, biopharma, health and nutrition,etc. While M&A has become an important step to break into the international market as it helps to expand overseas distribution channel, extend product line, conduct overseas clinical trials and increase market share. In terms of the target markets, the US is undoubtedly the most eye-catching market, while some European companies seem to have bigger competitive edges in specific niche markets. The medical service market of Southeast Asia and nutraceutical market of Australia are equally attractive in the eyes of Chinese companies. The below table presents an overview of major overseas M&A cases in this sector in 2019:

Table 3: M&A cases in the Chinese healthcare sector in 2019 (Equity participation included)

Acquirer	Target	Transaction model	Transaction volume	Areas	Country of origin of target company	Status
Shanghai RAAS	Grifols Diagnostic Solutions Inc.	45% stake	RMB 13.246 billion	Blood testing and reagents	Spain	Active
Baring Private Equity Asia	Lumenis	Full (100%)	USD 1 billion	Medical devices: surgical, eye and beauty care	U.S.	Active
Bluesail	New Valve Technology AG	Full (100%)	RMB 1.39 billion	Medical devices: Cardiovascular medical products	Switzerland	Active
Yifan	Bioton S.A.	31.65% stake	RMB 716 million	Biotech-Insulin products manufacturing	Poland	Completed
Kingfriend	Meitheal Pharmaceuticals	83.33% stake	USD 95million	Generic drugs	U.S.	Completed
AIER Eye	ISEC Healthcare Ltd	ISEC 58.53%	RMB 340 million	Ophthalmic medical services	Singapore	Completed
JOINN Laboratories	Biomere	Full (100%)	USD 27.28 million	CRO business and vaccine R&D capability	U.S.	Completed
Wuxi Apptec	Pharmapace	Full (100%)	RMB 182 million	CRO	U.S.	Completed
By-Health	Pentavite Pty Ltd	Full (100%)	USD 14.96 million	Health & nutrition-Children's health supplements	Australia	Completed
Essex Bio-Investment	Antikor Biopharma Ltd	Equity/Equity Option (<50% Stake) - Standalone)	USD 3.1 million	Biotechoncology	U.K.	Active
Raybow Pharmaceutical	PharmAgra Labs In	Full (100%)	Unknown	CRO,CDMO	U.S.	Active
Stedical Scientific	PermeaDerm	Full (100%)	Unknown	Medical devices -Skin wound care	U.S.	Completed

(Source from Cortellis Deals Intelligence)

Licence-in & Licence-out

Licence in & out has become a new pathway to enrich the pipeline of innovative biopharma players and launch in-depth cooperation with their overseas partners in R&D, manufacturing and commercialization. In 2019, **the number of Licence-in transactions totaled 80,** with a special focus on oncology, AI technology-based drug development, ophthalmology and cell therapy are also hot on the list. Such partners are very much concentrated in the U.S, Europe, Japan and South Korea. **In terms of license-out,** there were 13 transactions, involving development of anti-cancer drugs, nervous system drugs, immunotherapy and blood-lipid lowering drugs. The below two tables present an overview of license-in and license-out cases with transaction volume above 100 million USD:

Table 4 : License-in cases worth over 100 million USD

Time	Principle Company from China	Partner Company	Contents of the Trade	Therapy Area
November	Sincere. Pharmaceutical Co Ltd	GI Innovation, Korea	Development and commercialization of GI Innovation's novel product GI-101 in China	Anti-cancer; Multivalent monoclonal antibody (Primary); Biological therapeutic; Immuno-oncology; Protein fusion
November	Shanghai Fosun Pharmaceutical Industrial Dev Co Ltd	MimiVax, America	SurVaxM Development and commercialization of MimiVax's SurVaxM for cancer immunological therapeutic in China	Anti-cancer; immunological therapeutic
November	Jiangsu Hengrui Medicine Co Ltd	Novaliq, German	Development, manufacture and commercialization of Novaliq's CyclAsol and Nov-03 for dry eye disease in China	Ophthalmology
November	BeiGene Co Ltd	Seattle Genetics, America	Exclusive license to develop and commercialize Seattle Genetics' preclinical candidate drug for treating cancer in Asia (except for Japan) and in other countries worldwide	Anti-cancer: antibody
October	BeiGene Co Ltd	Amgen, America	Commercialization license of Amgen's XGEVA, KYPROLIS and BLINCYTO in the mainland of China, and collaboration with the development of Amgen's 20 anti-cancer drugs worldwide	Anti-cancer; Small molecule therapeutic; Antibody; Biological therapeutic, etc.
October	Jiangsu Zhengda Fengrui Pharmaceutical Co Ltd	Insilico Medicine, America	Discovery and development of two AI drug discovery programs for the treatment of triple-negative breast cancer	AI drug discovery
September	Jiangsu Hansoh Pharmaceutical Group Co Ltd	Atomwise, America	Collaboration in design and discovery of drug candidates for up to 11 undisclosed target proteins in multiple therapeutic areas	AI drug discovery
August	Biotheus Inc	Alligator Bioscience, Sweden	Rights to develop up to 3 bispecific molecules with ALLIGATOR-GOLD antibody in Greater China (including the Mainland of China, Hong Kong, Taiwan and Macau)	Anti-cancer: antibody
July	I-Mab Biopharma	MacroGenics, America	Exclusive license to develop and commercialize B7-H3 antibody enoblituzumab in the Mainland of China, Hong Kong, Macau and Taiwan	Anti-cancer: antibody
July	Asieris Pharmaceuticals Co Ltd	Photocure, Norway	Development and commercialization of the product Cevira(R) for HPV induced cervical precancerous lesions worldwide	Anti-cancer: HPV
June	Zai Lab Limited	Deciphera, America	Development and commercialization of Deciphera's ripretinib against GIST and other solid tumors driven by KIT or PDGFR-α in Greater China	Anti-cancer
May	Jiangsu Hansoh Pharmaceutical Group Co Ltd	Viela Bio, America	Development and commercialization of antibody inebilizumab for autoimmune disorder and hematologic malignancy indications in the market of China	Anti-cancer: antibody
April	Shanghai Fosun Pharmaceutical Industrial Dev Co Ltd	ReNeuron, British	Exclusive license for the development, manufacture and commercialization of ReNeuron's neural stem cell line product CTX and human retina progenitor cell line product hRPC in the People's Republic of China	Cell therapeutic
April	BeiGene Co Ltd	BioAtla, America	Development, manufacture and commercialization of BioAtla's on-going CAB CTLA-4 antibody BA3071 worldwide	Anti-cancer: antibody
March	BeiGene Co Ltd	Ambrx, America	Discovery and development for biologic drug candidates using Expanded Genetic Code platforms worldwide	Drug discovery technology

(Source from Cortellis Deals Intelligence)

Product-specific figures:

TCM: Total trade volume 6175 mil USD. (export 4019 mil, import 2155 mil)
Pharmaceuticals: Total trade volume 84.03 bn USD. (export 41.1 bn, import 42.9 bn)
Medical devices: Total trade volume 55.49 bn USD. (export 28.7 bn USD, import 26.79 bn USD)
Nutraceuticals: Total trade volume 803 mil USD. (export 247 mil USD, import 556 mil USD)

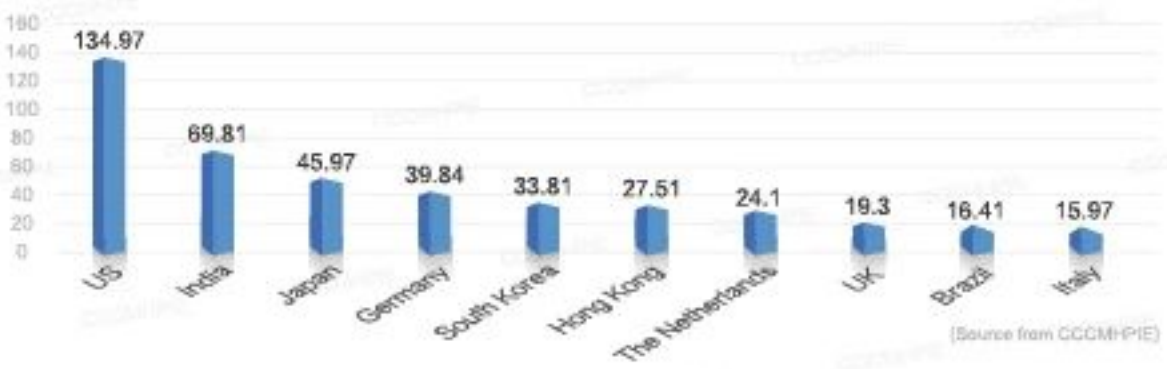
Table 2: List of CCCMHPIE member companies supplying to international organizations

Company names	Category
FUJIAN YAMEI INDUSTRY & TRADE CO., LTD.	Laboratory and Testing Equipment
ANHUI TIANKANG MEDICAL PRODUCTS CO	Medical Equipment
BEIJING BIO INSTITUTE BIOLOGICAL PRODUCT	Pharmaceuticals, Contraceptives, Vaccines
CHENGDU INSTITUTE OF BIOLOGICAL PRODUCTS	Pharmaceuticals, Contraceptives, Vaccines
CHINA RESOURCES ZIZHU PHARMACEUTICAL CO	Pharmaceuticals, Contraceptives, Vaccines
FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO LTD	Pharmaceuticals, Contraceptives, Vaccines
GUANGZHOU DOUBLE ONE LATEX PRODUCTS	Pharmaceuticals, Contraceptives, Vaccines
GUILIN PHARMACEUTICAL CO LTD	Pharmaceuticals, Contraceptives, Vaccines
GUILIN ZIZHU LATEX CO LTD	Pharmaceuticals, Contraceptives, Vaccines
NORTH CHINA PHARMACEUTICAL CO	Pharmaceuticals, Contraceptives, Vaccines
QINGDAO HAIER BIOMEDICAL CO LTD	Material Handling Machinery
REYOUNG PHARMACEUTICAL CO LTD	Pharmaceuticals, Contraceptives, Vaccines
SHANGHAI DAHUA PHARMACEUTICAL CO LTD	Pharmaceuticals, Contraceptives, Vaccines
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS	Laboratory and Testing Equipment
SHENZHEN ZHIJUN MEDICAL AND PHARMACEUTICAL TRADING CO LTD	Pharmaceuticals, Contraceptives, Vaccines
SOUTHWEST INTERNATIONAL MEDICAL EQUIPMENT MALL CO LTD	Medical Equipment
TIANJIN YORKOOL INTERNATIONAL	Medical Equipment
WUYI ANBO MEDICAL EQUIPMENT MANUFACTURING CO LTD	Medical Equipment
XIAN SIWAY SCIENTIFIC INSTRUMENT CO.LTD	Laboratory and Testing Equipment
ZHEJIANG DAJI MEDICAL INSTRUMENTS CO LTD	Medical Equipment
ZHEJIANG MEDICINES & HEALTH	Medical Equipment

(Data collected by CCCMHPIE from United Nations Global Marketplace)

Figures by major markets:

Chart 1: China's top ten exporting markets (Unit: 100 million USD)



(Source from CCCMHPIE)

Table 5: License-out cases worth over 100 million USD

December / 3D Medicines / TRACON, America

An exclusive and non-transferrable license to Tracon on KN-035 (a PD-L1 monoclonal antibody) for treatment of human Soft Tissue Sarcoma in America, Canada and Mexico.

Anti-cancer: antibody

December / Shanghai Henlius Biotech Co Ltd / Farma de Colombia, Columbia

Farma de Colombia entered into an exclusive license agreement to commercialize HLX-01 (Rituximab Injection) in Colombia, Peru, Ecuador and Venezuela.

Anti-cancer: antibody

November / Pharmaron Beijing Co Ltd / Bayer Animal Health GmBH, German

Collaboration agreement for developing molecular medicines for veterinary purposes. Bayer entered into an agreement with Pharmaron to develop small molecules using Chemistry, Manufacturing and Controls (CMC) service platform for veterinary medicines, including active pharmaceutical ingredients, finished medicine products, to meet the requirements of Bayer in drug discovery and commercialization.

CDMO

November / Hefei Cosource Pharmaceuticals Inc / Fruithy Medica, Australia

Agreement to investigate Hefei Cosource Pharmaceuticals ' HYR-PB21 in a phase I study for acute postoperative pain.

Nervous system

November / Wuhan University / Populas Biopharmaceutical, Hong Kong

Collaborate to develop anti-Nav1.9 antibody for the treatment of pain.

Nervous system

October / Jiangsu Quanxin Biopharmaceutical Co Ltd / Seneca Biopharma, America

Seneca Biopharma obtained the license to develop and commercialize partial QYuns's novel drug programs worldwide, including QX005N for asthma and atopic dermatitis, QX004N for ankylosing spondylitis and so on.

Immune system

September / Beijing Health Guard Biotechnology Co Ltd / R-Pharm, Russia

Collaboration in developing and commercializing nonavalent HPV vaccine in Russia by importing Beijing Health Guard Biotechnology's technology in manufacturing nonavalent HPV vaccine.

HPV vaccine

September / Shanghai Henlius Biotech Co Ltd / PT Kalbe Genexine Biologics, Indonesia

An exclusive license of commercialization (including and not limited to export, import, promotion, storage, offered sale sale and so on) and commercialization-related intellectural property of the on-going product HLX-10 (recombinant human PD-1 monoclonal antibody injection) for the primary indication, two combination therapies and two other indications selected by KalbeGenexine under the agreement in in Asia Pacific territory (10 countries in total, including Philippines, Indonesia, Malaysia, Singapore and so on).

Anti-cancer: antibody

May / Sumitomo Pharmaceutical (Suzhou) Co. Ltd / Mochida Pharmaceutical Co Ltd, Japan

Collaboration for the development of icosapent ethyl for Hypertriglyceridemia in China

Cardiovascular system

May / Nanjing Leads Biolabs Co Ltd / Pneuma Respiratory, America

Pneuma obtained an exclusive license on Leads Biolabs' technology of pulmanray delivery of antibodies and molecular drugs, allowing Pneuma to develop a battery of Leads Biolabs' immuno-oncology monoclonal antibodies and fusion protein molecules. Both parties would explore the potential of pulmonary delivery using Pneuma's digital inhaler platform against oncologic or immune-mediated lung diseases.

Anti-cancer: antibody

May / HitGen Pharmaceuticals Ltd / Kaken Pharmaceutical, Japan

HitGen transferred its core technology platform of DNA-encoded library design, synthesis and screening, which covered over 400 billion drug-like small molecular compounds based on diversified skeletal structures. The transfer included several lead compounds with noval structures, whose detailed targets were not revealed.

Small molecule compounds

April / Adagene Inc / ADC Therapeutics, Switzerland

ADC Therapeutics and Adagene entered into a discovery collaboration and license agreement to develop safe antibody drug conjugate candidates using Adagene's SAFEbody™ technology against a solid tumor target.

Anti-cancer: antibody

March / Suzhou Sinovent Pharma Co Ltd / SinoMab Bioscience Ltd, Hong Kong

Related technology and application of BTK tyrosine kinase inhibitor (SN-1011) for autoimmune diseases.

Anti-cancer: antibody

(Source from Cortellis Deals Intelligence)

In a nutshell, there are several features in M&A cases in 2019:

Multinationals are focusing more on innovative drugs, particularly propelled by centralized procurement strategy, which will leave little leeway for companies with only common products.

CRO business in China is getting more internationalized than ever, as many more Chinese CRO companies are making their presence overseas.

Medical device companies will quicken paces of mergers and acquisitions to expand their scale and increase market penetration.

For companies in this sector, the only way out seems to be an expanded pipeline and more proactive approach in the international market. A company's continued growth relies heavily on innovative products being brought into the market, during which mergers and acquisitions will not only be a pathway to quickly expand their business in the global markets, but will be undeniably crucial for increasing market scale in the home market.

PART TWO

Health Sector and Industry Policies of 2019

1. Health Sector and Changing Policy Landscape

China celebrated the 70th anniversary of its founding in 2019, a year which also marked the first 10-year anniversary of the new medical reform. During the past one decade, China stepped into a new era in the progress of its health sector, featured by a restructured government framework, an array of policies, and tangible outcomes of medical reform ranging from public hospital reform, universal health coverage, medical insurance payment to drug supply system.

According to the National Bureau of Statistics, by the end of October 2019, **the number of health and medical institutions in China reached 1.01 million**, an increase of 10,738 from the previous year. There were around 34,000 hospitals in total, including 12,000 public hospitals and 22,000 private hospitals. Compared with the corresponding period last year, the number of public hospitals dropped by 169, whereas the number of private hospitals rose by 1720.

There were 956,000 primary-level health and medical institutions in China, including 35,999 community health centers, 36,000 township hospitals, 621,000 village health centers and 240,000 clinics. There were also 18,000 professional public health institutions, including 3,445 disease prevention and control centers and 3,113 health supervision centers.

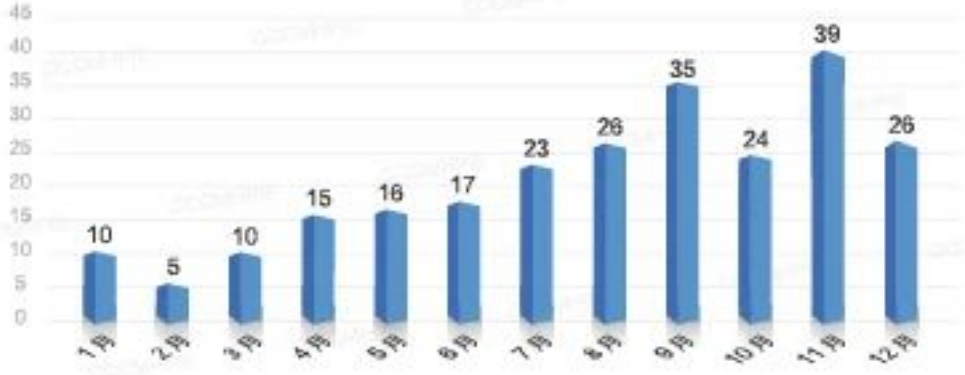
The number of medical services offered are also on the rise, which could be seen from the below chart:

Chart 3: The quantity of medical services in China surges.
The number of inpatients (Unit: 100 million persons times)

(Source from NHC)

Against such a backdrop, a number of policies have been introduced to boost the development of all segments. By the end of 2019, there were 246 policies relating to medical reform (including that of medical insurance, medicines and medical services), of which policies relating to medicines and medical devices accounted for 47% of the total, representing nearly half of all medical reform documents.

Chart 4: Number of health policies issued in 2019



(Source from NMPA, NHC, NHSA)

2. Major Industry Policies of 2019

Among all the policy documents relating to pharmaceuticals and medical devices, those concerning drugs accounted for 73%, while those concerning medical devices accounted for only 13%. The year 2019 was also a historical year for vaccines, as the first comprehensive vaccine management law was promulgated. It is expected that in 2020, there will still be promising progress in the following areas, just to name a few:

- The generic drug equivalency assessment and medical reimbursement reform will provide more opportunities for innovative products;
- Companies might consider innovation as their main strategy to win out in the next round of competition, while the value heavily relies on price negotiation with the medical securities authority;
- China will gradually become a strategic hub for pharma companies;
- Bio-pharma companies will embrace unprecedented opportunities;
- China's medical care services will continue to be shaped by digital communication model.

A Glance Over the Highlights of Major Policies:

A Science-based Legal Framework

- The *Vaccine Management Law* was passed on June 29th, 2019, making it the first comprehensive vaccine management law in the world, and was put into official implementation since December 1st, 2019.
- The *Drug Administration Law*, considered to be the strictest drug administration law ever in the history of drug regulation in China, was put into official implementation since December 1st, 2019.
- *Regulation on the Implementation for the Food Safety Law of the People's Republic of China* (draft) was passed on March 26, 2019.

Clinical Trials

Improve the management of drug clinical trials

Rules On Drug Clinical Trials Organizations was formulated by NMPA and NHC, and was put into official implementation since December 1, 2019. According to the new rule, organizations conducting drug clinical trials are asked to be filed, instead of certified to carry out clinical trials (the drug default CTA system was passed in 2018, according to *Notice on Adjusting Drug Clinical Trial Review and Approval Procedures of NMPA*, No.50, released on July 27, 2018).

Improve the supervision and management of medical device clinical trials

- Issued the *Guidelines for Medical Device Clinical Trial Design* and Technical *Guidelines for Acceptance of Overseas Medical Devices Clinical Trial Data*

  Issued the *Notice on the Issues Pertaining to the Communication of Clinical Trials* of *the Medical Devices that Require Approval,* and the *Announcement on Adjusting* the *Approval Procedure of Medical Devices Clinical Trials*. According to the documents, applicants are allowed to communicate with CMDE (Center for Medical Device Evaluation) of NMPA about submission issues beforehand. Within 60 days after the submission of the medical device clinical trial application, if the applicant does not receive any notification of negation (including request for expert consultation meeting or supplementary documents), then it is deemed as consent for the clinical trial (or the medical device default CTA system). The approval result will be released on the CMDE website and inform the applicant, instead of via the form of an approval letter. Researches have been conducted to use real-world data to assess the clinical risks and benefits of products.
- Issued the *Basic Requirements on Clinical Evaluation Document of Clinical Trial-Exempted in Vitro Diagnostics* (Trial implementation); drafted the *Regulation on the Expanded Clinical Trials of Medical Devices.*
- Issued the *Key Inspection Points and Principles of Decision in Clinical Trials of Medical Devices.*

Regulation of the People's Republic of China on the Administration of Human Genetic Resources

The document was put into official implementation since July 1st, 2019, stipulates specific requirements on using, storing, collecting and sharing human genetic resources in clinical trials in China conducted by foreign organizations or entities set up by foreign organizations or individuals.

Clinical trials in hotspot areas(anti-cancer drugs):

In 2019, a total of 474 anti-cancer drug clinical trials were approved to be conducted in China, accounting for 21.8% of all clinical trials approved. From 2016 to 2019, there were **452** registered clinical trials initiated in the Clinical Trials Center, of which **138** were initiated in 2019, an increase of **31.4%** over the previous year. Of the **127** IND trials, **38(29.9%)** were in Phase I. There were **129** multicenter trials. Lung cancer and breast cancer were the most common, with **40** and **13** trials respectively. Trials on biological antibody agent and small molecule targeted agent accounted for the largest proportion (Data source from *Clinical Trials Center 2019 Annual Report of the Cancer Hospital Chinese Academy of Medical Sciences).*

Review and Approval

Drugs

- Accelerate review and approval process for drug marketing
- Promote drug innovation and generic drug development
  - -The development of *Catalog of All Drugs Listed on the China Market*
  - -Push forward the classification and registration of chemical drugs, changing the definition of new drugs from "New in China" to "New in the world".
  - -Release the expiration information of drug patent rights and the list of over-duplicated drugs
  - -Accelerate the consistency evaluation of the quality and efficacy of generic drugs
- Implement the legal liability of the marketing authorization holder
  - -Orderly promote the pilot of Drug Marketing Authorization Holder (MAH) System
  - -Clarify the responsibilities of MAH in the entire product life cycle
  - -Establish the adverse reactions direct reporting system by MA holder, and strictly investigate and punish those who fail to report directly.
- Improve technical capacity
  - -Improve technical evaluation system
  - -Improve review and inspection ability
  - -Establish a team of professional inspectors
  - -Join ICH and enhance international cooperation

Medical devices

Since the implementation of *Special Examination and Approval Procedures for Innovative Medical Devices in 2014*, the number of products that entered into the special approval procedures and got approved kept increasing. The innovative development of the industry is well guided and supported. Up until July, 2019, 68 innovative medical devices have been approved to the market.

Registration of imported medical devices

- Apply the consistent procedures and standards on domestic and imported devices.
- Consider the characteristics of imported devices and domestic devices.
- Possible points to consider in the next step:
  - The registration application of innovative medical devices can be exempted from providing the overseas marketing approval files;
  - The applicant is allowed to submit self-testing report for registration;
  - Improve the management of domestic agents of imported devices and the inspection on overseas quality management system.

Pilot of MAH system

- Since 2017, the NMPA has approved Shanghai, Guangdong and Tianjin to start the MAH pilot program.
- Up until August 31st, 2019, Shanghai has approved 10 products from 7 companies to register according to the piloting plan. 16 products from 8 companies entered the prioritized registration and testing procedure, and 334 products from 109 companies have the intention to join in the pilot.
- *Notice on Expanding the Medical Device Registrant System.* No. 33 Notice of NMPA, August 1st, 2019.

Outcomes (As of November 2019):

Approval timeline for drugs was shortened to 12 months on an average level;
Approval timeline for innovative medical devices and priority review were shortened by 83 days;
16 national-level new drugs were approved;
62 overseas imported new drugs were approved;
The first domestic HPV vaccine was approved;
The first domestic biosimilar rituximab was approved.

Table 6: List of China-made new drugs field at NMPA in 2019

Chemical names	Manufacturers	Indications
Polyethylene Glycol Loxenatide Injection	Hansoh	Type II diabetes
Flumatinib Mesylate Tablets	Hansoh	Chronic myelogenous leukemia
Camrelizumab for Injection	Hengrui Pharma	Hodgkin's lymphoma
Remimazolam Tosilate	Hengrui Pharma	Intravenous anesthesia
NiraparibTosylate Monohydrate	Zai Lab	Recurrent epithelial ovarian cancer, carcinoma of fallopian tube
Tirelizumab	BeiGene	Hodgkin's lymphoma
Clomithromycin	Tonglian Group	Upper respiratory tract inflection
Influenza Vaccine (Split Virion), Inactivated, Quadrivalent	GDK	Influenza
Paeonia Granule for treating convulsion	Tasly	Tourette
Sodium Oligomannate Capsules(GV-971)	GreenValley	Alzheimer's disease
Benvitimod Cream	Tiaji pharma	Psoriasis

(Source from NMPA)

China's regulatory international cooperation

Established bilateral cooperation mechanisms with 66 regulatory agencies, including effective cooperative mechanisms with stringent regulatory authorities in the US, EU and Japan.

Actively participated in ICMRA, ICH and PIC/S activities, and conducted regulatory coordination and cooperation under multilateral cooperative mechanism including ECBS, IMDRF, etc.

The NMPA assumed presidency in IMDRF in 2018, to actively join in and promote international standards development of medical devices.

The NMPA became ICH member in 2017 and ICH management committee member in 2018, and so far has comprehensively participated in ICH standards building, harmonization and translation work in China.

The NMPA has signed a comprehensive cooperation document with WHO in October 2019, launched comprehensive evaluation on NRA in vaccine management, and enhanced communication related to WHO PQ program.

Procurement and Distribution

Centralized procurement

Policies and Measures to Deepen the Medical Reform by Leveraging Drug Centralized Procurement and Utilization, No. 3 of 2019 released by the State Council Medical Reform Steering Group, is often considered as a pathway to achieve Joint Reform of Medical Insurance, Medicines and Medical Services.

Trend of centralized procurement in the future

- Value-based purchasing: featured by group purchasing and medical combos.
- One-invoice system: to be paid by healthcare security authorities directly.
- A nation-wide unified public procurement marketplace: an open platform with unified code, standards and functions, supported by provincial drug procurement platforms, shall be set up to share resources and pricing information.

(According to *Notice on the Second Batch of Drug Centralized Procurement*, No.2, 2020, National Healthcare Security Administration, *Opinions on Expanded Pilot Areas of Drug Centralized Procurement and Utilization* released jointly by nine departments, different provinces are allowed to form purchasing alliance to include all public health institutions and army medical institutions on a compulsory basis and private medical institutions and retail drug stores on a voluntary basis. The joint purchasing office will carry out centralized procurement based on 50-80% of forecasted purchasing demand reported by participating medical institutions/drug stores).

Traceability system:whole life-cycle management

On April 28, NMPA issued the *Guideline on Developing Drug Information System and Requirements on Drug Traceability Code*. The two documents set rules on system building and coding requirements on drug information system. On December 12, NMPA and the NHC jointly issued the *Notice on Building Vaccine Traceability System*, and will initiate the pilot in 7 places, Beijing, Tianjin, Inner Mogolia, Shanghai, Jiangsu, Hainan and Chongqing. On August 27, the NMPA issued the *Rules on UDI System of Medical Devices*, and put into action since October 1st, 2019.

The above documents are considered to be real actions to ensure quality at the distribution level.

Payment Side

Medical Insurance Expense Reimbursement Catalogue

The updated medical insurance expense reimbursement catalogue was finalized in late November 2019. The new catalogue included 2709 drugs, of which 97 drugs succeeded in ending price negotiations with the authority (see table 7).

Table 7: Medical Insurance Expense Reimbursement Catalogue 2017 VS 2019 version

	2017	2019	Notes
Pharmaceutical Formulations	1297	1279	The updated version adds 148 product types (47 Pharmaceutical Formulations and 101 TCMs)
TCM	1238 (including ethnic drugs)	1316 (including 93 ethnic drugs)	
Negotiated drugs	–	97	

Features of the new adjustment:

1. **Widened coverage of drug types:** extending to national essential medicines, and drugs against cancer, rare diseases, chronic disease and pediatrics drugs

2. **More attention given to innovative drugs:** attention given to relatively high-priced patented drug, upon expert review and vote.

3. **Payment standards:** targeted policy measures on diabetes and high blood pressure, the two diseases with over 300 million patients in China.

DRG Reform

On October 23, the *Notice on the Technical Standards and Grouping Plan for National Pilot DRG Payment*, as well as two other documents– Technical Guideline for National DRG and Payment, and DRG (China Healthcare Security Diagnosis Related Groups-DRG) Grouping Plan were released officially.

Pharmaceutical companies should consider:

- Shift their focus from single product only to a package of products, targeting at the treatment of a disease.
- Give more attention to the ability of treatment solutions on cost control.

PART THREE

Trends and Outlook in 2020

1. Trends

Updates on the Chinese Pharmacopeia 2020

The Chinese Pharmacopoeia 2020 edition will be put into implementation on December 1, 2020. It will include 5,911 monographs, including 319 monographs newly added and 3,177 monographs revised.10 monographs will be removed, and another 6 will be reduced after product consolidation.

The main features of ChP 2020 includes:

- Steadily increase the number of monograph included
- Improve the national drug standards system
- Adopt more mature analytical techniques
- Improve requirements on drug safety and efficacy
- Raise standards on excipients
- Strengthen harmonization with international standards
- Strengthen the guiding role of the ChP
- Improve the working mechanism of the ChP

Based on scientific, advanced, practicality and standardized principle, the ChP 2020 edition aims to enhance the core status of ChP in national drug standards in China. The standards system and development processes are further improved, the standards contents more rigorous and are further aligned with international standards, thus increasing the overall level of drug standards system. The ChP 2020 edition gives a comprehensive overview of the current status of China's drug industry development and application of testing technologies. It will play an important role in improving drug quality, ensuring drug safety for the public, promoting healthy development of the industry, and enhancing the international influence of the ChP.

Improving healthcare security system

On March 5, 2020, the Central Committee of the Communist Party of China and the State Council released the document "Opinions on deepening the reform of medical security system."

Next step: Improvement of China's health care in the future would rely heavily on the reform and efficiency of the health care system, instead of just increasing medical expenditure.

Overarching objective: By 2030, a multilevel medical security system shall be established with basic medical insurance as the mainstay, medical relief as the baseline, supported by joint development of supplementary medical insurance, commercial medical insurance, charity donation and mutual medical assistance.

Industry supervision

- Introduce the third-party supervision
- Establish and optimize the credit management system
- Implement the big data dynamic and intelligent supervision

Procurement

- Further implement drug and medical consumables centralized procurement, establish provincial bidding platform for procurement, construct cross-regional purchase alliances, and promote direct payment between medical insurance funds and manufacturers.
- Improve the medical services pricing mechanism, and enhance the accessibility of health care services.

Payment

- Focus on clinical needs, reasonable diagnosis and treatments, and appropriate technologies.
- Ensure the dynamic adjustment of the medical insurance expense reimbursement catalogue.
- Accept "Internet Plus medical care" into the coverage of medical insurance, and implement diversified payment modes special DRG-based payment as the core.

2. Annual Events and Industry Reports of CCCMHPIE

CHEXPO ASEAN

Organized by Ministry of Commerce of China, and co-organized by CCCMHPIE, the expo has been held successfully for two sessions. Over 200 enterprises exhibit and more than 3,000 professional visitors from over 20 countries and regions attend the event each year. The expo focuses on traditional products, medical consumables, medical devices, rehabilitation, medical services, etc. A series of visits, professional forums and b2b match-making meetings will be held, which provide enterprises with a platform to develop and facilitate their access to the international markets.

CPhI & P-MEC China

Each year, the show is held in June in Shanghai. Each year, the show attracts over 3,400 exhibitors from China and overseas and 70,000+ professionals from more than 140 countries and regions. The expo has set up 14 exhibition areas for different themes including pharmaceutical excipients, pharmaceutical preparation, bio-pharmaceutical, pharmaceutical machinery and equipment, package, laboratory, as well as environmental protection and clean technology, etc., becoming a large comprehensive service platform to link the whole industry chain of the pharmaceutical sector.

HNC

The Healthplex Expo, Natural & Nutraceutical Products China (HNC), organized by CCCMHPIE and Sinoexpo Informa Markets, takes place each year at the National Exhibition and Convention Center (NECC, Shanghai). As a flagship exhibition in big health sector, the expo gathers the world's leading health and nutrition brands and quality products, shares the latest science and technology and updates in big health sector, and attracts quality buyers from across the globe, making it an efficient and high quality one-stop trade and exchange platform for Chinese health brands and international buyers. Moreover, the exhibition is an ideal channel for international brands to enter Chinese markets.

HEP

Health Equipment & Products Shanghai (HEP), organized by CCCMHPIE and Sinoexpo Informa Markets, takes place each year at the National Exhibition and Convention Center (NECC, Shanghai). The exhibition aims to build an one-stop platform for health machinery and products procurement, including healthcare massage products, sports protective equipment, home care products, and pan-medical products, etc.

China International Import Expo

China International Import Expo (CIIE) takes place each year in November in Shanghai. CCCMHPIE helps organize the exhibition zone for medical equipment and medicines and health products. This year, the exhibition zone will add a special zone for global public health and epidemic prevention management, which aims to jointly fight against the global epidemic. CCCMHPIE will hold concurrent events such as Global Public Health Security Governance Conference and China Medicines and Medical Equipment Regulation Summit.

Research Reports

- *Annual Highlights of China's Healthcare Industry*
- *Competitiveness Report of Companies*
- *China Nutraceutical Industry Report*
- *Healthcare Market Report of 17 CEE Countries*
- *Blue Paper on the Internationalization of China's Healthcare Industry*
- *China–Africa Healthcare Cooperation Report*
- *Healthcare Report on 21 African Countries*

3. Services Offered by CCCMHPIE

International cooperation network

Lead/participant organization of bilateral dialogues of health collaboration

- China–UK JETC Healthcare WG (since 2007)
- China–Denmark Healthcare WG (since 2012 during the then President Hu Jintao's visit to Denmark)
- China–Italy Healthcare WG under the China–Italy Business Council (established in March 2015)
- 30+ MoUs with overseas partners

Lead/participant organization in extensive multilateral cooperation

Cooperation with international organizations:

- Partners: WHO, UNAIDS, UNFPA, UNIDO, UNICEF, UNOPS, BMGF, The Global Fund, MSF, etc.
- China Suppliers Survey/Conferences: in collaboration with UNICEF, The Global Fund, UNFPA, UNOPS, etc.

Flagship cooperative programs:

- The first China Healthcare Products EXPO(**CHEXPO ASEAN**) supported by MOFCOM
- Project of health cooperation with Africa: **HealthCAC** platform, Ethiopia industry park project supported by the Gates Foundation, **Roundtable on China–Africa Health Collaboration.**
- China–CEEC healthcare industry cooperation program: health ministers' meetings, high-level trainings, b2b sessions, etc.
- Regulatory Trainings: **International Regulatory Agencies Update & QA Session** in collaboration with FDA, EDQM, MHRA, PMDA, NMPA, WHO, USP, BP, ChP, etc.

Services for the government

Extensive cooperative with relevant Chinese governments, including Ministry of Commerce, National Health Commission, National Medical Products Administration, China International Development Cooperation Agency.

Projects entrusted by the government

- National projects concerning internationalization of the industry development, including Analysis of Distribution of TCM materials, Registration of THMP in the EU, WHO PQ Status Quo and Analysis, etc.
- Feasibility studies of Chinese Trade, Investment and Medical Assistance Projects to foreign countries, including compiling Catalogue of Medicines and Medical Devices of Chinese Aids to Foreign Countries
- EUCTP project to support China–EU sustainable development on economy and trade
- Assessment Report on CFDA's Entry into PIC/S, ICH
- Major international trade and investment platforms: CIIE, Canton Fair, etc.

Consultation services for the industry/companies

- Seeking the most appropriate trade and investment partners in traditional medicines, pharmaceuticals, medical devices, health and nutraceutical products, R&D and clinical services through the Chamber's strong connections and platform in China and overseas countries.
- Staying connected to the most up-to-date drug, medical device and health policies in China and major markets.
- Seeking market and specific product analysis in order to make more informed decisions for your business strategies in China.
- Getting involved in major bilateral and multilateral healthcare cooperation programs to participate in policy advocacy and changes.