The Development Status and Future Trends of China's Vaccine Industry

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ABSTRACT
The outbreak of the COVID-19 has focused the attention of various countries on the vaccine industry. China's vaccine industry started late, has a small scale and has been presented less in international conference journals, but in the wake of this COVID-19, China has drawn significant attention to the vaccine industry to make a representative role. This research examines the history of China's vaccine industry, the sector's current state, how it compares to other countries, and the industry chain analysis. The vaccine sector in China is modest, but it is developing quickly and has many opportunities for improvement. Although there is still a significant gap with developed countries, the number of vaccine batches issued and the figures of domestic manufacturers are getting better every year. Many companies are actively involved in overseas clinical trials, and the internationalisation process is accelerating. The industrial chain of China's vaccine industry involves manufacturers, batch issuing units and distributors, and disease control and prevention centres. With many vaccines on the market, the demand for vaccine packaging materials will increase significantly; the number of vaccine-related enterprises registered is picking up, and the number of medical institutions is also growing. In addition to improving medical laws and regulations, China should also innovate technical routes to speed up vaccine development.

Keywords: *Vaccine industry, China, COVID-19.*

1. INTRODUCTION

Vaccines are a milestone in the history of human medical development and a primary measure for human beings to control infectious diseases. The vaccine industry is of great significance in improving the health of the whole population and enhancing citizens' sense of well-being, gain and satisfaction, and is one of the key strategic industries that China is currently vigorously developing. Since the outbreak of the COVID-19, Chinese residents have become much more aware of preventive health care due to its impact, which has also driven the vaccination rate. The R&D, clinical, and commercialisation experience accumulated by the COVID-19 vaccine would help a group of outstanding domestic Chinese vaccine companies to grow up rapidly. Against this backdrop, the Chinese vaccine industry is expected to usher in a golden period. The next ten years will be a decade for China's biopharmaceuticals to move from catching up to surpassing a 'golden decade' for the Chinese vaccine industry.

Xue and Ouellette emphasised that vaccines serve a critical role in improving global public health by preventing the spread of infectious illnesses and maybe eradicating them. The research summarised that vaccines have an anaemic development pipeline due to two fundamental factors. It showed how both characteristics make vaccinations less profitable than repeat-purchase therapies even with comparable IP protection. Xue and Ouellette argued that innovation policy should experiment with higher government-set incentives for vaccine manufacturing and usage[1].

Milstien and Kaddar studied the role of emerging manufacturers as participants in assuring worldwide access to new vaccines of public health value and updated the findings of the 2005 BCG study. The evolution and desirability of emerging markets were depicted in some charts and data. In addition, the current rising manufacturers' "focus" and "capabilities" were contrasted to the condition discovered in the 2005 study, and a case study and analysis of some of its primary advantages and disadvantages were utilised to reinforce the explanation. To ensure that this happens, Milstien

and Kaddar believed that new strategic thinking and activities, as well as increased international oversight, would be required[2]. Douglas and Samant first introduced the business and activities of the vaccine industry and pointed out that in 2018, most of the new vaccines approved globally in the past 20 years have been developed in the United States. In addition, the five stages of vaccine development were explained in detail. Then Douglas and Samant took India, China, and Brazil as examples and compared them to conclude that the Indian vaccine industry is the most advanced of these three developing countries, has provided a large part of the world's vaccine supply, and is developing new vaccines. China is on the verge of transforming from the only domestic supplier to a vaccine exporting country and has made solid progress in vaccine innovation. Brazil is approaching the tipping point of meeting its domestic demand, mainly by transferring technology from developed countries. They believed that these emerging companies from middle-income countries would collectively have an increasing impact on the global vaccine industry in the next few years[3]. Gupta et al. offered a critical examination of India's vaccine development and deployment achievements, possibilities, and problems during the last several decades in India. Furthermore, the research revealed the evolution of the Indian vaccine business, policy backing, and the current situation. It also emphasised the benefits and drawbacks of introducing new and underutilised immunisations at home. The National Regulatory Authority for reviewing new technology, according to Gupta et al., must be reinforced if the Indian manufacturers are to remain competitive in the global market and provide affordable and high-quality vaccines for domestic use[4].

Pagliusi and Jarrett summarised the main points of the 21st Annual General Meeting of the Vaccine Manufacturers Network in Developing Countries in November 2020. Overall, Pagliusi and Jarrett agreed that developing-country vaccine producers play a crucial role in global vaccine research, development, and supply for a healthy future, with more collaboration and partnering between them becoming a growing strength[5]. To demonstrate the development of China's vaccine industry and immunisation program, Zheng et al. described the history, classification, supply, and prices of vaccines available and used in China compared to high- and middle-income countries. The research showed that although China is a well-regulated vaccine producer, some vaccines that are significant globally are not covered by China's EPI system. A sustained and coordinated effort will be required to elevate China's vaccine business and EPI into a global leadership position [6]. Xu et al. went over the history of Chinese vaccine development, the current state of the Chinese vaccine business, and its contribution to infectious disease prevention and control. It also discussed China's decades of national quality control and vaccine regulating experience. Moreover, the research relieved that China still has a long way to go before becoming a major global vaccine supplier. According to the study, China still has a long way to go before becoming a major global vaccine supplier[7].

Compared to other countries, China's vaccine industry started late and is lagging but full of potential in terms of the market landscape, technology and products. Analysis of the Chinese vaccine industry has also rarely appeared in the international literature to bring more international attention to the Chinese vaccine industry. This article provides an overview of the Chinese vaccine industry and trends.

2. HISTORY AND CLASSIFICATION OF THE VACCINE INDUSTRY IN CHINA

2.1. History of development

China's immunisation programme started late and has much space for improvement in the future. The history of China's immunisation programme can be divided into two stages: the first stage was before the founding of the People's Republic of China. China was the first country to use artificial immunisation methods to prevent infectious diseases, having invented the technique of growing pox to prevent smallpox as early as the 10th century AD. After founding the People's Republic of China, the second stage is divided into three main periods: the pre-planned immunisation period, the planned immunisation period, and the immunisation planning period.

The pre-planned immunisation period: in 1950, the State Council issued the Instruction on Launching the Autumn Pox Campaign, calling for free vaccination against cowpox throughout the country. In 1959, the Institute of Medical Biology of the Chinese Academy of Medical Sciences was established in Kunming, mainly for the research and production of polio vaccines. In 1961, smallpox was eradicated nationwide. In 1963, the Ministry of Health issued the Measures for the Implementation of Vaccination Work for the first time, and vaccination work was gradually put into a planned vaccination track in various places[8].

The planned immunisation period: in 1978, China participated in the Expanded Programme on Immunization(EPI) initiated by the World Health Organization(WHO) and strengthened its work on organisational development, cold-chain construction, target management and planning implementation. Four vaccines and six diseases were first introduced into China's immunisation programme (BCG, polio vaccine, measles vaccine and diphtheria mixture for children within one year of age, and their counterparts against tuberculosis, polio, measles, diphtheria, pertussis and

tetanus). In 1988, 1990 and 1995, the goal of universal childhood immunisation was achieved at the provincial, county and township levels, respectively, i.e. an immunisation rate of 85% for BCG, polio, measles and diphtheria vaccines for children within one year of age.

The immunisation planning period refers to the implementation of the Expanded Program on Immunization(EPI) in China: in 2002, hepatitis B vaccine for newborns was included in the national immunisation plan; in April 2008, hepatitis A, influenza, encephalitis B and measles&mumps&rubella vaccine (MMR) were included in the national immunisation plan for routine vaccination of school-age children. In 2016, inactivated polio vaccine was included in the national immunisation plan, and there are currently 14 federal immunisation plan vaccines to prevent 15 diseases. In 2017, the first National Immunization Programme Expert Advisory Committee was officially established, which would gradually improve the dynamic adjustment mechanism for the types of vaccines in the National Immunization Programme, incorporated more non-immunisation vaccines into the National Immunization Programme, optimised existing immunisation strategies and promoted the application of new combination vaccines.

2.2. Immunisation programme

In terms of whether they are included in the national immunisation plan(Table 1), there are national immunisation plan vaccines (A-class vaccines) and non-immunisation plan vaccines (B-class vaccines). National immunisation plan vaccines are vaccines provided free of charge by the government to citizens, including those developed by the national immunisation plan, those added by provincial governments in implementing the national immunisation plan, and those used in vaccination outbreaks or mass vaccinations organised by the government agencies. Non-immunisation plan vaccines are other vaccines that citizens voluntarily pay for themselves[9]. In addition, the profit margin of A-class vaccines is narrow, and the pattern is stable, dominated by the seven state-owned enterprises (73%), while the profit margin of B-class vaccines is more extensive and the competition is fierce, dominated by several private enterprises (66%).

Table 1. Specific names of vaccines included in A-class and B-class vaccines respectively

Immunization program vaccines (A-class)	Non-immunization program vaccines (B-class)
Bacillus Calmette Guerin vaccine (BCG)	Influenza vaccine
Hepatitis B vaccine	Chickenpox vaccine,
Poliovirus vaccines	Rotavirus vaccine,
Diphtheria& Pertussis& Tetanus vaccine (DPT)	Pneumonia conjugate vaccine
Japanese Encephalitis vaccine (JE-i)	Haemophilus influenza type B(Hib) vaccine
Measles&Mumps&Rubella vaccine (MMR)	Human Papillomavirus vaccine (HPV)
Group A Meningococcal Polysaccharide vaccine (MenA)	Enterovirus type 71 vaccine(EV71)
Group A and Group C Meningococcal Polysaccharide vaccine (MenA+C)	Rabies vaccine

3. CURRENT STATE OF DEVELOPMENT

3.1. Vaccine splitting

Looking at the split between A-class vaccines and B-class vaccines, the batch issue of A-class vaccines reached 348 million pieces in 2020, an increase of 0.62% per year, while the batch issue of B-class vaccines went 303 million pieces, 35.76% up year-on-year, which was the highest growth rate of B-class vaccines since 12 years(Figure 1). Domestic vaccines have swept away the gloom of two vaccine incidents in the same year, with the number of domestic vaccine batches issued up to 609 million pieces, an increase of 15.52% year-on-year. The number of imported vaccines batch-issued was 0.42 billion pieces, up 21.51% year-on-year. The vaccine industry under the influence of the COVID-19, the Center for Disease Control(CDC) further promoted terminal vaccine propaganda and vaccination, which in turn increased the penetration rate of vaccines, the batch issuance volume growth rate is significant, and the vaccine industry ushered in new opportunities (Figure 2).

As can be seen from Figure 1: the market share of A-class vaccines gradually decreases from 79.85% in 2016 to 53.45% in 2020. Considering that the current vaccination rate of A-class vaccines in China is generally over 90% if the number of newborns in China remains stable in the future, and assuming that the variety of A-class vaccines is not expanding, the size of the A-class vaccine market in China is expected to remain stable in the future. The size of the B-class

vaccine market is expanding rapidly, rising from 20.14% in 2016 to 46.54% in 2020. With more new and multiple polyvalent vaccines coming to market as B-class vaccine varieties and further releasing current cervical cancer, pneumonia, and influenza, the future B-class vaccine market will still maintain rapid growth.

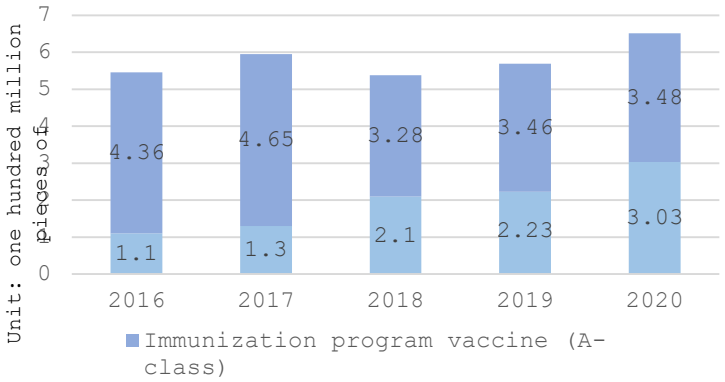

Figure 1 Statistics of the total batch issuance of the A-class vaccine and the B-class vaccine, respectively, from 2016 to 2020.

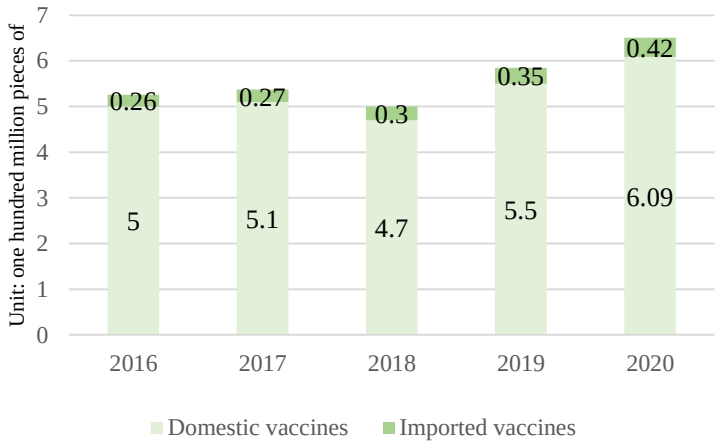

Figure 2 Statistics on the issuance of domestic and imported seedling batches from 2016 to 2020.

3.2. Comparison with foreign countries

3.2.1. China's vaccine market is small but growing fast

Major regional markets can segment the global vaccines market into six major markets: the US, Europe, China, Southeast Asia, Africa, and the rest of the world. In 2020, the US vaccine market accounted for the largest share of about 34%, followed by Europe and China with 29% and 16%, respectively. Southeast Asia, Africa, and Other regions accounted for a smaller share of about 6%, 5%, and 10%, and the comparison showed that the Chinese vaccine market was a relatively small share of the global vaccine market(Figure 3).

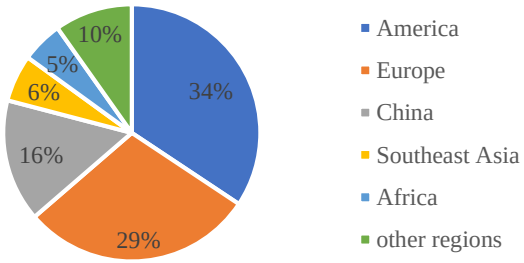

Figure 3 Global vaccine regional market share in 2020 (including America, Europe, China, Southeast Asia, Africa and other regions).

As seen in Figure 4, the US has been leading the world in vaccine market size, reaching 14.9 billion US dollars in 2016 and increasing to 20.3 billion US dollars in 2020, growing at a compound annual growth rate(CAGR) of 8.8% over five years. This is followed by the size of the European vaccine market, which grew to 17.3 billion US dollars by 2020, with a CAGR of 8.6% from 2016 to 2020. The vaccine market size in China has grown at a faster rate in recent years, with its market size increasing from 3.4 billion US dollars in 2016 to 9.1 billion US dollars in 2020, growing at a CAGR of 27.9% from 2016-2020, and accounting for approximately one-sixth of the global vaccine market size.

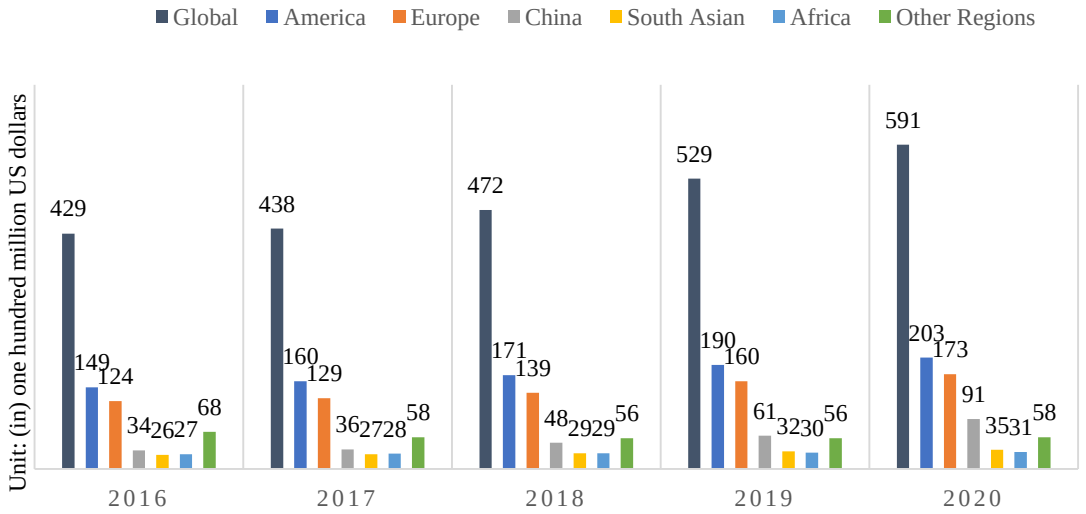

Figure 4 From 2016 to 2020, the vaccine market size in six regions.

3.2.2. China is dominated by old varieties and enterprises produce a single variety

As seen in Table 2, there are 12 mandatory vaccinations for infants in the United States and only 9 in China. Comparing the vaccination spectrum in China and the United States, it can find that there is a large gap between domestic and foreign vaccines[10]. For example, MenA or MenA+C is used in China for meningitis, while it has been replaced mainly by MCV4 abroad. For polio, the inactivated poliovirus vaccine(IPV) is an injectable vaccine in the US, while in China, most of the vaccines are oral vaccine pills(OPV). In addition to fewer innovative vaccines, more than half of domestic enterprises can only produce one vaccine product. As of 2019, there are still 18 companies that can only have one vaccine, while only three companies can produce more than five vaccines, making them small and homogeneous (Figure 5).

Table 2. Comparison of vaccines that infants in China and the United States must vaccinate

Name of vaccines	China	America
Hepatitis B vaccine (HepB)	√	√
Measles&Mumps&Rubella vaccine (MMR)	√	√
Hepatitis A vaccine(HepA)	√	√
Inactivated Polio vaccine(IPV)	√	√
Pepcid DTap	√	√
Rotavirus vaccine		√
Influenza vaccine		√
ACWY group influenza vaccine (MenACWY)		√
Haemophilus influenza(type B Hib)		√
13-valent Pneumococcal Conjugate Vaccine (PCV)		√
Varicella vaccine		√
Human Papilloma Virus (HPV) vaccine		√
Bacillus Calmette Guerin Vaccine (BCG)	√	
Group A Meningococcal Polysaccharide Vaccine (MenA)	√	
Group A and Group C Meningococcal Polysaccharide Vaccine (MenAC), Hepatitis A Vaccine.	√	
Japanese Encephalitis Vaccine (JE-i)	√	

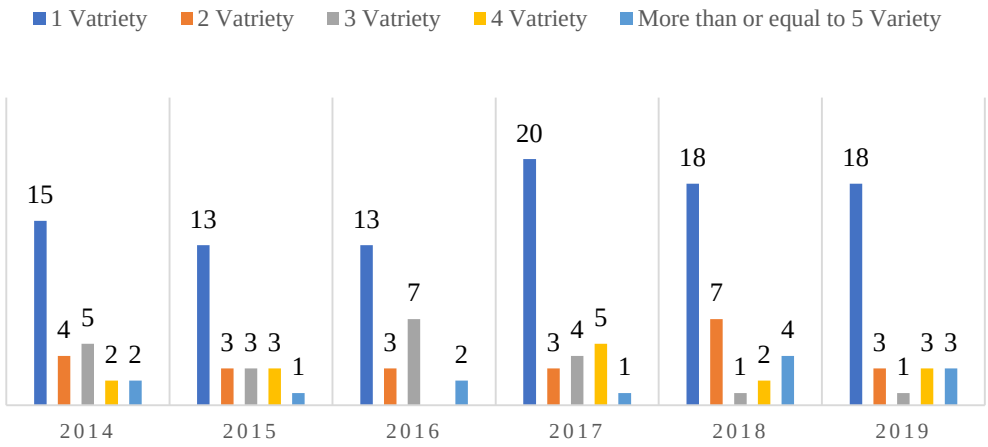

Figure 5 Number of vaccine varieties produced by China's local vaccine companies from 2014 to 2019.

3.3. COVID-19 promotes comprehensive upgrade of China's vaccine industry

3.3.1. Sales of COVID-19 vaccines have led to a significant increase in the financial strength of the overall vaccine market

The sales of the COVID-19 vaccine generated enormous profits for domestic and foreign associated production companies, making the global vaccine market size surge. Pfizer Inc. worked with BioNTech, and it realised 11.3 billion US dollars in revenue from COVID-19 mRNA vaccine in H1 2021, while BioNTech's COVID-19 vaccine sales were 8.44 billion US dollars[11]. Moderna, AstraZeneca, Johnson & Johnson sales were 5.93 billion US dollars, 1.17 billion US dollars, and 260 million US dollars. Large foreign companies with combined sales of 27.1 billion US dollars of COVID-19 vaccine in the H1 2021, compared to a global vaccine production value of 34.2 billion US dollars in 2020. Domestically, in the first half of 2021, China National Pharmaceutical Group Corporation was expected to earn more than 8.3 billion US dollars in profits from the sale of the COVID-19 vaccine, while Anhui Zhifei Longcom Biopharmaceutical Co., CanSino Biologics Inc. and Shanghai Fosun Pharmaceutical (Group) Co., Ltd would achieve sales of 886 million US dollars, 343 million US dollars and more than 83 million US dollars respectively(Table 3).

Table 3. Major vaccine manufacturers in Europe, America and China COVID-19 vaccine sales in the first half of 2021

Foreign company	Sales (billion)	Domestic company	Sales (billion)
Pfizer Inc.	11.3	China National Pharmaceutical Group Corporation	Over 8.33
BioNTech	8.44	Anhui Zhifei Longcom Biopharmaceutical Co.	0.89
Moderna Inc.	5.93	CanSino Biologics Inc.	0.34
AstraZeneca	1.17	Shanghai Fosun Pharmaceutical (Group) Co., Ltd.	Over 0.08
Johnson & Johnson	0.26	-	-
Total	27.1	Total	Over 9.63

3.3.2. Chinese vaccine companies are accelerating their internationalisation process

More Chinese vaccine companies with overseas clinical and registration experience. Overseas clinical, registration, sales are highly experience-dependent and often costly due to the cumbersome processes involved, such as language/regulations/differences in application documents. Before the outbreak of the COVID-19, the only COVID-19 vaccine manufacturer to have accumulated overseas clinical trials in the early stages of Ebola research and development was CanSino Biologics Inc. However, from 2020 onwards, several domestic COVID-19 vaccine manufacturers have conducted clinical trials overseas, generating close communication and cooperation and experience sharing with foreign countries(Table 4).

Table 4. Domestic vaccines in overseas clinical trials

Vaccine	Time	Company	Test country
Recombinant COVID-19 Vaccine	2020.03	CanSino Biologics Inc.	Russia/Pakistan etc.
Inactivated COVID-19 Vaccine	2020.07	China National Pharmaceutical Group Corporation	United Arab Emirates etc.
COVID-19 Vaccine (CHO cell)	2020.12	Anhui Zhifei Longcom Biopharmaceutical Co.	Uzbekistan/Indonesia etc.
mRNA Vaccine	2021.09	Stemirna Therapeutics	Laos etc.
mRNA Vaccine	2021.09	Abogen/ Walvax Biotechnology Co., Ltd.	Mexico/Indonesia etc.

4. INDUSTRIAL CHAIN

The vaccine industry chain involves many fields and is characterised by comprehensive coverage, many processes and large operations. China's vaccine industry chain involves manufacturers, batch issuing units and distributors, disease control and prevention centres, etc. The upstream of the vaccine industry is mainly the culture media, chemical reagents and pharmaceutical packaging industry; the midstream includes R&D and production and issuance and distribution; the downstream application areas are the healthcare industry and individual consumers.

4.1. Upstream analysis

4.1.1. Culture media and chemical reagents

As the primary raw materials for vaccine production, culture media and chemical reagents account for about 10% of the total cost of vaccine production. The culture media and chemical reagents industry is fully competitive, has a strong supply capacity, and the products are not highly technical.

4.1.2. Medical packaging materials

Glass bottles for vaccines are not ordinary glass bottles, and they are made of a different material than regular glass. The higher the water resistance, the better the safety and stability of stored pharmaceuticals in terms of glass. Moreover, the cost of drug packaging accounts for a high proportion of the cost of vaccine production, accounting for about 35%. Affected by the COVID-19 in 2020, many vaccines would be listed, and the demand for vaccine packaging materials would increase significantly, with the market size reaching 126.47 billion yuan(Figure 6).

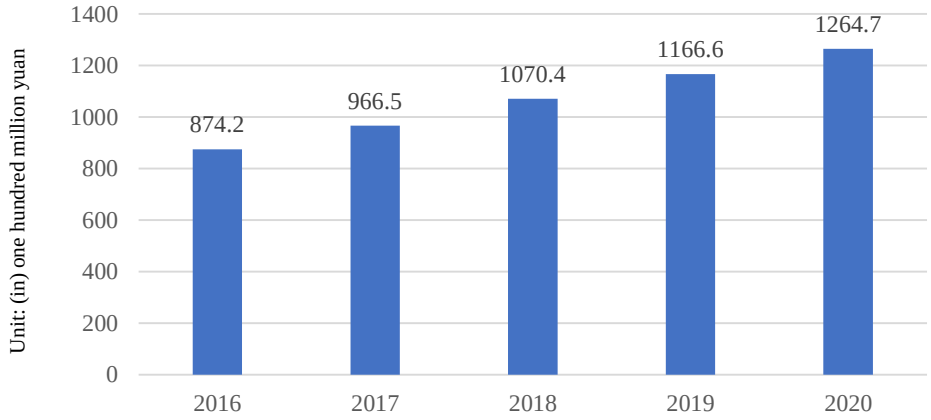

Figure 6 China medical packaging materials market size statistics from 2016 to 2020.

4.2. Midstream analysis

4.2.1. Number of enterprises

The vaccine industry has a large market capacity, and capitalists have been bullish on the vaccine industry and accelerated the layout of the vaccine industry. The R&D and production of the vaccine industry include living attenuated vaccines, inactivated vaccines, antitoxins, subunit vaccines (including peptide vaccines), carrier vaccines, nucleic acid vaccines, etc. In recent years, the registration of epidemic-related enterprises in China has continued to increase, and the registration of vaccine-related enterprises slowed down

in 2018 due to the impact of the vaccine incident. The number of vaccine-related enterprises registered in 2020 due to the COVID-19, with 1,585 vaccine-related companies registered in China[12]. Chinese vaccine R&D and production enterprises include seven significant institutes such as Beijing Institute, Shanghai Institute, Lanzhou Institute, Changchun Institute, Chengdu Institute, Wuhan Institute and Kunming Institute, as well as private enterprises such as Anhui Zhifei Longcom Biopharmaceutical Co., CanSino Biologics Inc. and Walvax Biotechnology Co., Ltd.(Figure 7).

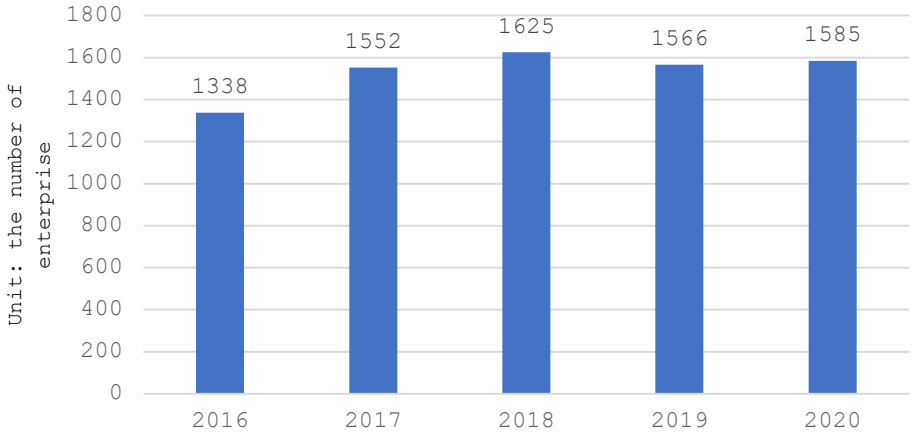

Figure 7 Between 2016 and 2020, the number of vaccine-related companies registered in China is shown.

4.2.2. Vaccine batch issuance and circulation

In recent years, the demand for vaccination has continued to increase as people's ability to pay, and their awareness of disease prevention has increased. The flow of vaccine issuance in China is dominated by the National Institutes for Food and Drug Control, Jilin Institute of Pharmaceutical Inspection and Shanghai Institute of Pharmaceutical Inspection, supplemented by provincial platforms for bidding and purchasing. As shown in Figure 8, the vaccine batch issuance data fluctuated over the past five years, showing an upward trend followed by a downward and upward trend. After a slight decline to 530 million pieces in 2018, the combined vaccine batch issuance in 2020 rose directly to 650 million pieces, increasing 14% year on year, and the overall industry trend grew well.

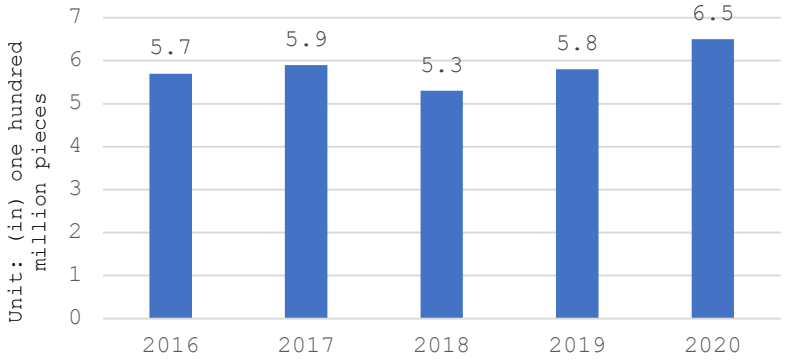

Figure 8 Statistics on the overall batch issuance of the vaccine industry between 2016 to 2020.

4.3. Downstream analysis

The downstream application area of the vaccine industry is the medical and health care industry, mainly including various hospitals and community medical centres. By the end of 2020, there were 1.023 million medical and health institutions, 971,000 primary medical and health institutions and 14,000 professional public health institutions, including 3,384 disease prevention and control centres and 2,736 health supervision offices (centres)(Table 5).

Table 5. Number of medical and health institutions in China in the year 2020

Name	Number (ten thousand pieces)
Total number of medical and health institutions	102.3
I. Hospital	3.5
Public hospital	1.2
Private hospital	2.4
II. Primary medical and health institutions	97.1
Community health centre	3.5
Outpatient department	29.0
Township health centre	3.6
Village clinic	61.0
iii. Professional public health agency	1.4
Centres for disease control and prevention	3384pcs
Sanitary supervision office (Center)	2736pcs
Family planning technical service agency	3884pcs

5. CONCLUSION

The outbreak of the COVID-19 has focused everyone's attention on the vaccine industry. This study has presented China's vaccine industry's development history and current state, compares it with other foreign countries, and analyses the industry chain. It is found that the Chinese vaccine industry started late compared to other developed countries, is small in scale but growing fast, and has excellent potential for development. The Chinese government has continued to improve A-class and B-class vaccines. After the outbreak of the COVID-19, China attached particular importance to the vaccine industry and invested a lot of workforces, material resources and financial capital, and achieved remarkable results. Many domestic companies have overseas clinical experience and are actively participating in the global market competition, which has hastened the internationalization of the Chinese vaccine industry. Viruses coexist with humans worldwide, and with the widespread outbreaks that have made people more conscious of health issues and raised awareness of vaccination, China should innovate technical routes to speed up vaccine development.

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