Review Article

Human vaccines industry in China, 2019: Part III

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Abstract

There are five multinational companies (MNCs), operating in China in the vaccine field. These companies have made a sizable investment in China on various counts, including the establishment of local offices, teaming up with certain Chinese companies, and some have also made a sizable investment in R&D for pursuing both basic types of research as well as application-oriented research and/or manufacturing or repacking facilities. The MNCs sell their proprietary vaccines either directly or have teamed up with Chinese companies for sale.

Keywords: Childbirth rate, Chinese vaccines manufacturers, expanded program on immunization

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INTRODUCTION

In the Part I of the paper, the numbers of human vaccines manufactured in China, the capacities created, the factors responsible for the generation of demand, and the seven government companies of the country manufacturing human vaccines were discussed. In Part II of the paper, the profiles of the Chinese companies have been brought out. In this concluding and Part III of the paper, some useful information about the multinational companies (MNCs), which are manufacturing or selling their human vaccines and are operating in China have been discussed. The MNCs are operating either singularly have teamed up with certain Chinese companies.

STUDY METHODOLOGY

The study on the Chinese human vaccines industry was carried out in the same manner as was done while writing the Part I and Part II; the data and information were collected from the Internet, certain Chinese government publications, industry publications on the websites, and scientific publications by the Chinese scholars, which are available on the web. The sources of information have been cited in the text.

Received: 25-05-2020
Accepted: 28-05-2020
Published: 18-08-2020

Access this article online	
Quick Response Code:	Website: www.mgmjms.com
	DOI: 10.4103/mgmj.mgmj_51_20

MULTINATIONAL VACCINE MANUFACTURING COMPANIES IN CHINA

Several MNCs produce and supply vaccines across the world. The major vaccine manufacturing companies of the world in 2019 were GlaxoSmithKline (GSK), United Kingdom; Novartis, Switzerland; Sanofi Pasteur, France; Merck, United States; Pfizer, United States; Emergent Bio Solutions, United States; CSL, Australia; Inovia Pharmaceuticals, United States; Bavarian Nardoc, Denmark; and Mitsubishi Tanabe, Japan. The total global sale of vaccines in 2019 was estimated at US$35.2 billion, and that over 80% of this sale was from these 10 MNCs.[1] Among these MNCs, the five companies, which have made

How to cite this article: Ghosh PK. Human vaccines industry in China, 2019: Part III. MGM J Med Sci 2020;7:148-54.

their profound presence in China are GSK, Novartis (sold out to GSK later), Sanofi Pasteur, Merck, and Pfizer.

Vaccine business hovers around the demand generated from the annual childbirth numbers, the size of the population in the country, the number of senior citizens, the health policy of the country, the average per capita income of the citizens, and also the disease pattern of any country besides other factors. The demand for vaccines from all these counts scores positively for manufacturing as well as trading in vaccines in China. MNCs that have high-tech proprietary medicines and vaccines against infectious microbes, including certain bacterial diseases, multiple dreaded ribonucleic acid (RNA) viral diseases, and certain fearful deoxyribonucleic acid (DNA) viral diseases, can provide effective solutions and therefore can do business in China. The science and technology of China in the whole area of drugs and pharmaceuticals is also quite high, thereby offering the availability of skilled manpower and technological infrastructure in the country. Several MNCs that have in possession proprietary vaccines and medicines to treat alarming bacterial as well as viral diseases have come forward to do business in China. There are currently five MNCs that have a significant presence in China as discussed below.

GlaxoSmithKline (GSK), Unites Kingdom

GSK is a global medical and healthcare company.[2,3] Approximately 25% of the global vaccine supply comes from GSK. The company claims to have delivered over two million vaccine doses per day to people living in over 160 countries. Their vaccine business generated sales of £7.2 billion (approximately US$9.2 billion) in 2019. GSK is a high science and technology–based company, and its R&D employs more than 15,000 scientists all over the world. Glaxo was in China from 1910, although their large-scale investment in China started in 1984. A joint-venture company by the name Sino-American Tianjin SmithKline and French Laboratories (TSKF), China, was established in 1987, which was a joint-venture consumer healthcare company created by Glaxo, Tianjin Zhong Xin Pharmaceutical, China and Tianjin Medicinal Corporation, China. This joint-venture company is not a manufacturer of vaccines. In December 2000, Glaxo Welcome and Smith Barney were merged to form GSK. GSK has invested more than US$500 million in China. GSK China has nearly 7000 employees, six major production bases, and five regional office centers spread across China. For conducting R&D in China, the efforts of GSK date back to 1990. Initially, as Glaxo and later as GSK, the company made its worthwhile presence in the medical and healthcare arena of China. The R&D center of GSK in China is the third-largest R&D center in the world. The R&D team is composed of more than 400 scientists and doctors. The focus areas of research include certain degenerative diseases such as Alzheimer's disease and Parkinson's disease. They are also involved in the field of hyperexcitable diseases, which include pain and epilepsy.

Although GSK vaccines were available in the Chinese market from imports, GSK teamed up with Zhejiang Tianyuan Bio-Pharmaceutical (ZHEJIANG TIANYUAN BIO), China in 2015, through a three-party deal involving GSK, Novartis, and ZHEJIANG TIANYUAN BIO. Earlier in 2009, GSK had announced that GSK and Shenzhen had entered into an alliance[4] to develop and manufacture influenza vaccines in China. The terms of the alliance were that GSK would take a 40% stake in the joint venture by contributing in cash and assets equivalent to £21 million. Shenzhen would have a 60% stake in cash and assets equivalent to £31 million. One condition of the alliance was that within the next 2 years, GSK might purchase additional shares and obtain a majority equity interest. In June 2011, GSK announced[5] that it had increased its equity share from 40% to 49% in August 2010, and that the remaining 51% of the equity share held by ZHEJIANG TIANYUAN BIO would be acquired by GSK for a total cash consideration of £24 million (US$39 million). GSK, China shall focus on the development and manufacture of influenza vaccines, both seasonal and pandemic, and that the finished vaccines shall be sold in China, Hong Kong, and Macau. In 2015, GSK acquired[6] global vaccines business (excluding influenza vaccines). Through this acquisition, ZHEJIANG TIANYUAN BIO became a part of GSK.

GSK[7] is one of the largest manufacturers of vaccines in the world. According to the company, in 2019, GSK sold 701 million doses of vaccines around the world; the company claims that around 40% of the world's children are immunized against at least one serious infectious disease with a GSK vaccine. The current estimate on the global sale of pharmaceutical substances sets nearly 8.5% from China, placing the country at the second-largest position among each individual country in the world. GSK was trying to get approval for the sale of their two key vaccines, namely Shingrix and Bexsero in China and the United States. Presently, China and United States happen to be the two largest market destinations of all vaccines. Shingrix is a combination vaccine to protect against shingles. Bexsero is a vaccine indicated to prevent disease caused by *Neisseria meningitidis* serogroup B.

Novartis, Switzerland

Novartis[8] was created in 1996. Novartis AG is a Swiss holding company, operating through Novartis Group.

Two Swiss companies, namely Ciba–Geigy and Sandoz Laboratories, merged in 1996 to form Novartis. Ciba–Geigy was formed in 1970 by the merger of J. R. Geigy (founded in 1758 in Basel) and CIBA (founded in Basel in 1859). Novartis is one of the largest global pharmaceutical companies that are manufacturing and marketing drugs and pharmaceuticals, including a wide range of active pharmaceutical ingredients, formulations, vaccines, diagnostics, and other products. Novartis has been acquiring vaccine manufacturing companies in developing countries during the past few decades.

Novartis had earlier planned[9-11] to explore new vaccine developments in addition to aspirations to become a vaccine industry leader in China. On March 22, 2011, Novartis acquired an 85% stake in Zhejiang Tianyuan Bio-Pharmaceutical (ZHEJIANG TIANYUAN-BIO) Zhejiang, China. ZHEJIANG TIANYUAN-BIO produced the first Chinese vaccine against hantaviruses, which causes hemorrhagic fever with renal syndrome (HFRS). The Vaccines and Diagnostics Division of Novartis was a large manufacturer of multiple numbers of vaccines and was a prominent supplier of flu vaccines in the United States. It was probably thought that the acquisition of ZHEJIANG TIANYUAN-BIO would provide Novartis with more strength of becoming a prominent supplier of vaccines in the Chinese vaccines market. Novartis and GSK entered into an agreement in May 2014, wherein it was agreed that while Novartis shall sell its vaccines business to GSK, the latter would sell the rights of its oncology portfolio including its related R&D activities in development, to Novartis. Later, when GSK acquired the vaccines business of Novartis in 2015, ZHEJIANG TIANYUAN BIO became a part of GSK.

Sanofi Pasteur, France

Sanofi Pasteur[12] is a division of Sanofi that manufactures and sells vaccines. Sanofi is a multinational French company, headquartered in Paris. Sanofi's core global business units in Sanofi are specialty consumer health care, vaccines, and general medicine. It employs more than 100,000 people representing 142 nationalities and is present in 100 countries across the globe. It has 73 manufacturing sites in 32 countries. In 2019, the company attained sales of Euro 36.126 billion (US$40.2 billion). Sanofi focuses on all potential emerging markets, including China. Sanofi's endeavor is to market all its established specialty products, including products used to treat diabetes and cardiovascular diseases. Sanofi has established a firm based in China. Among its international presence across the globe, its presence in China happens to be the third largest after the United States.

Sanofi Pasteur manufactures and markets a large number of vaccines. These include[13,14] a whole range of conventionally inactivated vaccines such as those against diphtheria, tetanus, pertussis, and combinations thereof; they killed polio vaccines, and inactivated cholera vaccines. Among the live-attenuated vaccines, Sanofi Pasteur manufacturers live-attenuated measles, mumps, rubella, polio, and BCG vaccines. They also have modern inactivated *Haemophilus influenzae* type b vaccines, meningococcal vaccines, and typhoid vaccines. The recombinant hepatitis B vaccine is also being manufactured. Other vaccines include Japanese encephalitis virus vaccines, yellow fever vaccine, rabies vaccine, small pox vaccine, and influenza vaccine. A modern vaccine against dengue fever by the trade name Dengvaxia is also in its product range. The dengue vaccine used among the Philippine children has resulted in doubts about their safety.

Sanofi Pasteur currently offers[15] a broad range of vaccines to protect against 19 infectious diseases. The company produces more than 1 billion doses of vaccines each year, through which more than 500 million people across the globe are protected against infectious diseases. Their current manufacturing methods of vaccines include large-scale cell culture techniques; production of chosen viruses in large scale, separation, concentration, inactivation (where required) and formulation; manufacture of bacterial vaccines including multiplication, isolation, purification, deactivation, and formulation; and manufacture of conjugate vaccines where carbohydrate antigens are encountered. In addition to manufacturing and marketing the aforementioned vaccines, Sanofi Pasteur has research interest in multiple areas, which include discovery and identification of novel antigens; carrier proteins and novel conjugation technology; development of vaccines useful for delivery through oral or nasal routes; and newer and novel ways of administering vaccines.

Sanofi Pasteur has made its presence in China[16] since 1990s and has been supporting immunization and disease prevention through the initiation and launches of several crucial and life-saving vaccines. The company invested about US$94 million in 2017 to construct its dedicated influenza vaccine facility in Shenzhen. The company has made considerable efforts in China to assist the Chinese to expand the immunization programs of the country. As mentioned earlier, Sanofi created the company Shenzhen Sanofi Pasteur Biological Products in Shenzhen, to manufacture influenza vaccines.

Merck, United States

Merck is a global multinational healthcare company[17] from the United States. It manufactures and sells innovative

prescription medicines, vaccines, biologic therapies, and animal health products. The pharmaceutical segment of Merck includes pharmaceuticals and vaccine products for human health, which are generally sold by prescription, for the treatment of human disorders as well as protection against infectious diseases. During 2019, the total sales of pharmaceutical products were US$46.84 billion. The main vaccines contributing to the sale were recombinant human papillomavirus vaccines, namely Gardasil and Gardasil-9; attenuated measles, mumps, rubella, and varicella, namely Pro Quad; the measles, mumps, and rubella live vaccine prepared from a more attenuated line of measles virus and the other two attenuated viral lines and sold by the trade name M-M-R II; varicella vaccine to help prevent chickenpox, namely Varivax; and the vaccine against pneumococcal bacteria by the name Pneumovax-23.

Merck's business has grown rapidly in the past few years in China. Merck has been expanding its business in China in an environment of multiple innovative new policies introduced by the Chinese government to improve access to new inventions in vaccines.

In 1994, Merck teamed[18] up with Shenzhen Kangtai Biological Products (SHENZHEN KANGTAI BIO), China, to produce a recombinant DNA-based hepatitis B vaccine at a capacity of 20 million doses per annum. The Chinese government catalyzed the teaming up. SHENZHEN KANGTAI BIO was already producing human plasma–derived hepatitis B vaccine at that time. Earlier, Merck had signed an agreement with SHENZHEN KANGTAI BIO in 1989. Extending this agreement, Merck teamed up with SHENZHEN KANGTAI BIO in 1994 to provide the recombinant hepatitis B vaccine manufacturing technology. Details of the collaboration are not known. Merck agreed not to charge any royalty for the sale of the vaccine in China. The Chinese scientists and technologists of SHENZHEN KANGTAI BIO received hands-on training in the hepatitis B plant of Merck in the United States, and thereafter, the whole plant of Merck was dismantled and shipped to China and reassembled at SHENZHEN KANGTAI BIO. The technology transfer process is an unparalleled technology transfer effort, and the vaccine created a solution to almost eliminate the devastating hepatitis B infection from China.

Merck is a multinational American company, which is known as MSD outside of the United States and Canada. The company announced[19] in 2013 that it had created another new manufacturing establishment for the packaging of Merck medicines to be made available to China and the Asia Pacific region. The new facility was created by spending US$120 million and was built to comply with current Good Manufacturing Practices (cGMP). The location of the facility was in the Hangzhou Economic and Technology Area, China. Merck has already constructed its R&D center in Beijing and three other manufacturing facilities throughout the country. The marketing and sales organization was in Shanghai. The sales revenue of Merck in China exceeded US$1.0 billion in 2012. Merck, China, had established its Asia R&D headquarters in Beijing in 2011 and had invested more than US$1.5 billion.

In 2012, Chongqing Zhifei Biological Products (CHONGQING ZHIFEI BIO) entered into an agreement[20] by signing a memorandum of understanding (MOU) between CHONGQING ZHIFEI BIO and Merck for marketing the oral pentavalent live rotavirus vaccine in China. The trade name of the product is Rota Tag. Through the MOU, most of Merck's vaccines were sold in China by CHONGQING ZHIFEI BIO. Gradually, more of the Merck's products were sold by CHONGQING ZHIFEI BIO in China. The MOU lasted for 6 years and expired in 2018. The current status of the MOU is not known.

Pfizer, United States

In 1849, Pfizer was founded[21] in New York City by German–American Charles Pfizer and his cousin Charles F. Erhart from Ludwigsburg, Germany. By 1906, sales reached a total of US$3.4 million. Since then, Pfizer has come a long way. Pfizer is presently one of the largest pharmaceutical companies in the world. Their product range includes pharmaceutical products in areas such as immunology, including vaccines, oncology, cardiology, endocrinology, and neurology. Its products are Lipitor (atorvastatin) used to lower low-density lipoprotein (LDL) blood cholesterol; Lyrica (pregabalin) for controlling neuropathic pain and fibromyalgia; Diflucan (fluconazole), which is an oral antifungal drug; Zithromax (azithromycin), which is a wide-spectrum antibiotic; Viagra (sildenafil) for treating erectile dysfunction; and Celebrex, which is an anti-inflammatory drug.

Pfizer's biopharmaceutical business[22] includes oncology, inflammation and immunology, rare diseases, hospital unit, vaccines, and internal medicine. Each business unit is committed to delivering medicines to take care of the specific needs of the patients. Among the vaccines, the top-selling brand is the Prevnar-13 vaccine, also spelled as Prevenar-13. The biopharmaceutical business generated revenues of US$39.419 billion in 2019, up from the 2018 sales of US$37.558 billion. The total revenue generated by Pfizer during 2019 was US$51.750 billion. In the preceding year, in 2018, sales revenue was US$53.647 billion. The total

sale of all vaccines manufactured by Pfizer during 2019 was US$6.504 billion, of which the sale of Prevenar-13 alone was US$5.847 billion.

Pfizer has a rich and long history in vaccine research.[23] Pfizer's research is concentrated on infectious diseases, especially the diseases caused by *Streptococcus pneumoniae* and *N. meningitidis*. These bacteria can cause illness of multiple types, including pneumonia and meningitis, affecting the lungs, the covering around the brain, and the spinal cord, and ear and sinus infections. *N. meningitidis* can cause inflammation of the membranes around the brain or spinal cord. The symptoms can be sudden but can develop gradually also. General symptoms include headache, fever, or stiffness of neck with aching muscles. Skin rashes are also observed. It is a life-threatening disease. Pfizer has developed vaccines against these diseases. Pfizer has also designed a novel vaccine delivery system. The company is engaged in R&D for the development of other invasive and noninvasive pneumococcal infections caused by *Clostridium difficile* infection. *C. difficile* is a gram-positive, anaerobic, and a spore-forming rod or spindle-shaped bacteria present in the human intestine. A small percentage of *C. difficile* infections can cause serious gastrointestinal infections when individuals have been exposed to antibiotic therapy, for example in hospital settings. The risks from such infections can be life-threatening, especially for immunosuppressant patients and elderly individuals.

Pfizer manufactures and markets a couple of vaccines, among which the major ones are the pneumococcal vaccine Prevenar-13; vaccine against meningococcal disease caused by four types of *N. meningitidis* bacteria (types A, C, W, and Y), sold by the name Nimenrix; tick-borne encephalitis virus vaccine by the name TicoVac; and a vaccine to prevent infection from meningococcal serogroup B bacteria, by the name Trumenba; and certain other vaccines.

Pfizer, China, has invested[24] over US$1.5 billion in China creating a business infrastructure for the sale of a wide range of pharmaceutical products, which include prescription drugs and consumer health products. The prescription drugs include cardiovascular, anti-infection, arthritis, oncology, central nervous system (CNS), urology, vitamins and mineral supplements, calcium supplements, vaccines, and others. They have introduced more than 50 innovative drugs into China. Leading products include blood fat-lowering medicine Lipitor; antihypertensive drug Norvasc; anti-infective drugs such as Diflucan, Sulperazon, Zithromax, and Tygaci; antidepressants such as Zoloft and Efexor XR; and others. Pfizer, China, has also established an R&D center also. In China, Pfizer has over 11,000 employees.

A sizable portion of sales turnover in China was contributed to Pfizer through the sale of its blockbuster product, the Prevenar-13 vaccine, which was approved[25] for marketing in China in 2016. Prevenar-13 vaccine is one of Pfizer's top-selling products around the world. Earlier, Pfizer was marketing an earlier version of Prevenar in China, which was not as broad on the spectrum as it is on Prevenar-13.

In December 2019, the Chinese regulators approved[26] the marketing of 13-valent pneumococcal conjugate vaccine developed by the Chinese company Walvax Biotechnology (WALVAX-BIO). This product is similar to Pfizer's Prevenar-13. Pfizer's future sales are anticipated to be affected in China because of the emergence of a new competitor. Creating a competitive environment is beneficial to consumers.

Pfizer invested[27] in China's Zhejiang HISUN Pharmaceuticals (HISUN) and came up with a joint-venture company by the name Hisun Pfizer Pharmaceuticals, in 2012. The two companies made an aggregate investment of US$295 million and a registered capital of US$250 million in the new company and further agreed that HISUN would hold 51% of the equity share and Pfizer would hold 49%. The joint venture agreed to develop and manufacture off-patent pharmaceutical products and sell them in China and in global markets. HISUN does not manufacture vaccines.

DISCUSSION AND CONCLUSIONS

Human vaccines are manufactured, distributed, and sold by three main segments of the vaccine industry of China, namely by the state-owned companies (Part I of the paper), the Chinese private companies (Part-II of the paper), and the MNCs. In this paper, brief profiles of five MNCs operating in China, which are selling human vaccines in the country, have been provided along with a brief description of these companies. It has been observed that the MNCs have invested in China not only to create their own establishments but also have invested in certain Chinese private companies, both for manufacture and for research.

The Chinese government has classified its human vaccines into Category I and Category II. The Category I vaccines are procured by the government and used in the Chinese Expanded Program of Immunization (EPI) and certain other government programs; the vaccines are supplied by the government, free of cost to the eligible recipients. The profit margins in the Category I vaccines are low, and the major portions of supply come from government-owned companies. The Category II vaccines are sold on the open market; eligible recipients of such vaccines have to purchase

these from the market. Most Chinese private companies as well as the MNCs operate in the Category II area.

Several of the vaccines deployed as Category II vaccines are high-tech proprietary vaccines from the MNCs. Many such vaccines are not manufactured in China by the local companies probably because of intellectual property rights (IPR) restrictions, lack of technology in hand, and inadequate demand volume to achieve economy of scale, because of which such vaccines available from a single MNC source are expensive(Part II of the author's paper).

The total turnover of the Chinese vaccines industry in 2019 was estimated at between US$3.50 and US$3.95 billion (Part II of the author's paper). The unit prices of Category I vaccines had been hovering between US$0.10 and US$5.70 per dose[28] in China. The total number of doses estimated to have been procured was about 600 million (including process and operational losses) in the Chinese EPI in 2019. Therefore, the total cost of Category I vaccines may have been about US$1.45–US$1.80 billion, which is about 38%–44% (on the basis of a rough estimate) of the total turnover of human vaccines in China in 2019. The balance 56%–62% of the market share in value terms in 2019 appears to be the Chinese Category II vaccines market.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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