

## Review Article

# Human vaccines industry in China, 2019: Part II

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### Abstract

There are a large number of private manufacturers of vaccines in China. Most of the Chinese private companies manufacturing vaccines were established in the decade of 1990 and thereafter. Local investors came forward to set up manufacturing facilities in an environment of China's growing demand for human vaccines and for exports. There are at present about 34 companies operating in the private sector, including MNCs. In this review, profiles of 25 private Chinese companies have been brought out. The turnover of vaccines manufactured in China is estimated at between US\$3.50 and US\$3.95 billion in 2019. Although the turnover of the vaccine industry was about 2.7%–3.1%, when compared to its pharmaceutical industry in value terms, it is a very important segment of healthcare infrastructure of the country.

**Keywords:** Human vaccines, Category 1 and 2 Chinese vaccines

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### INTRODUCTION

In Part I of the paper, the number of human vaccines manufactured in China, the capacities created, the factors responsible for the generation of demand, and the seven major government companies of the country manufacturing human vaccines were discussed. There are several other companies in the private sector in China also engaged in the manufacture of human vaccines. A brief description of the important ones among these is provided in this paper.

### STUDY METHODOLOGY

The study on the Chinese vaccine industry was carried out in the same manner as was done while writing Part I; the data and

information were collected from the Internet, certain Chinese government publications, industry publications on the web sites, and scientific publications by the Chinese scholars, which are available on the web. The sources of information have been cited in the text.

### Major Chinese companies other than major government companies producing human vaccines

There are a large number of human vaccine manufacturing companies in China other than the seven major government-owned companies. In Part I, the details of production in the government-owned companies have been described. According to one report,<sup>[1]</sup> the companies manufacturing vaccines in China are 34 in numbers, of which seven are state-run ventures (included in Part I), five are multinational companies (MNCs), and the rest are in the private sector. This paper (Part II) consists of a brief write-up of 25 major private vaccine manufacturing companies in China, described in alphabetical order.

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## Private Chinese companies

1. Aimei Kang Huai Biopharmaceuticals (Jiangsu) (AMY KANG JIANGSU BIO),<sup>[2]</sup> China Medical City, Taizhou City, Jiangsu Province, China, was established in 2011 with a registered capital of 250 million yuan. AMY KANG JIANGSU BIO is a subsidiary of Amy Bio-vaccine Technology Group, China. AMY KANG JIANGSU BIO is an innovation-focused enterprise engaged in research and development (R&D), manufacture, and sales of hepatitis A vaccine. They also have an interest in genetically engineered drugs, *in vitro* diagnostic reagents, and other modern biological products. The company obtained the hepatitis A vaccine production technology from the Institute of Medical Biology, Chinese Academy of Medical Sciences. The inactivated hepatitis A vaccine is based on the use of L 8 strain, which is multiplied in human diploid cell KMB17, the virus is harvested after multiplication, and then purified, inactivated, and adsorbed on aluminum hydroxide. AMY KANG JIANGSU BIO is situated in the Taizhou City of Jiangsu Province, China in an area of about 170 acres and with a total construction area of about 60,000 m<sup>2</sup>.
2. Beijing Minhai Biotechnology (BEIJING MINHA BIO)<sup>[3,4]</sup> was founded in June 2004, with a registered capital of 200 million RMB at the Bio-medicine Industry Park in Daxing District, Beijing. The company has an elaborate R&D center to develop various kinds of human vaccine. BEIJING MINHA BIO has multiple Current Good Manufacturing Practice (CGMP)-compliant facilities in an area of nearly 60,000 m<sup>2</sup>. It has been selling Hib conjugate vaccine (conjugated with tetanus toxoids), live measles and rubella (MR) vaccine and DTaP-Hib vaccine, the technologies of which were developed by the company. There are over 20 other vaccines in the company's developmental pipeline, which include human diploid cell (HDCV)—grown rabies vaccine, Sabin IPV, and meningitis conjugate vaccine. Since 2013, BEIJING MINHA BIO had initiated the registration of the above three vaccines (which are in production) in more than 10 countries and also had initiated the World Health Organization (WHO) prequalification process.
3. Beijing Vigoo Biological (BEIJING VIGOO BIO),<sup>[5]</sup> China, is a part of the China National Biotec Group, Beijing Tiantan Biological Products Corp, Beijing Biological Products Research Institute, and the Chinese Disease Prevention and Control Center. BEIJING VIGOO BIO is a government-owned company. Inadvertently, the company's profile was not described in Part I. BEIJING VIGOO BIO is engaged in high-class R&D for the development of biological processes for multiple products including vaccines; it had built its new Vaccine National Engineering Research Center in the Beijing Economic-Technological Development Area, China; the facilities created included five pilot-scale production lines, laboratories, and support facilities. BEIJING VIGOO BIO and two other Chinese establishments, namely Sinovac Biotech (SINOVAC BIO), and the Institute of Medical Biology (INSTITUTE M BIO), Chinese Academy of Medical Sciences (Kunming Institute), China, had made substantial progress in developing inactivated enterovirus 71 (EV71) vaccine<sup>[6]</sup> technology in China. EV71 viral vaccines are new tools to control outbreaks of hand, foot, and mouth disease (HFMD). HFMD is caused by enteroviruses, which belong to the species Enterovirus A (serotypes coxsackievirus A 2–8, 10, 12, 14, 16, and enterovirus 71, 76, and 89–92), and sometimes by Enterovirus B (though rarely), with CA16 and EV71 as the main agents for the disease (HFMD). Vaccines from the three establishments, namely BEIJING VIGOO BIO, INSTITUTE M BIO, and SINOVAC BIO, have later been approved for use in China.
4. Can Sino Biologics (CAN SINO BIO) Tianjin, China, is engaged<sup>[7]</sup> in the activities to develop processes for the manufacture and sale of human vaccines. CAN SINO BIO was founded in 2009. The vaccines the company is working on include quadrivalent (ACYW135) meningococcal conjugate vaccine, pneumococcal polysaccharide, and conjugate vaccines as well as diphtheria, tetanus, and whole-cell pertussis (DTcP)—based combination vaccines. The R&D focus of the company includes the discovery of the right antigen for a candidate vaccine, devise methods and expression hosts to magnify the antigen/s by overexpression and purification, followed by preclinical evaluation further followed by the development of commercial processes and proper assaying methods required in the vaccine development. The company has developed a team that has expertise in microbiology, molecular cell biology, immunology, and biochemistry. A number of products of the company are in various stages of development, including adenovirus-based recombinant tuberculosis (TB) vaccines, recombinant protein-based pneumococcal vaccines, and certain polyvalent-conjugate vaccines. CAN SINO BIO is stated to have already developed an Ebola virus vaccine using adenovirus (Ad 5)-based vector. Their Ebola virus vaccine is approved in China for emergency use and stockpiling.

5. Changchun Baiké Biotechnology<sup>[8]</sup> (CHANGCHUN BAIKE BIO), China, was established in March 2004. The company produces lyophilized influenza live-attenuated vaccines. The technology was obtained from Russia and was subsequently modified at CHANGCHUN BAIKE BIO. The seed influenza virus is multiplied in specific pathogen-free (SPF) eggs. The cold-adapted strains of influenza virus were provided by the WHO. The formulation is a lyophilized live influenza vaccine, deployed as a nasal spray. The company also developed the technology for the manufacture of live-attenuated varicella vaccine where the viral strains are multiplied in SPF eggs. The finished vaccine has a shelf life of 36 months. CHANGCHUN BAIKE BIO is a high-tech enterprise integrating R&D, production, and sales of biological products and innovative drugs. The investment of CHANGCHUN BAIKE BIO was provided by Changchun High-tech Industry (Group), China.
6. Changchun BCHO Biotechnology (CHANGCHUN BCHO-BIO)<sup>[9-11]</sup> Changchun, China, is engaged in R&D, manufacture, and sale of biotechnology products and includes vaccines and innovative drugs. CHANGCHUN BCHO-BIO was established in 2004. The R&D facilities are created in an area of over 2000 m<sup>2</sup>; the facilities include a wide range of state-of-the-art instruments, clean rooms, dark rooms, polymerase chain reaction (PCR) rooms, and laboratories for synthesis, purification, fermentation, analysis, *in vitro* testing, and animal testing facilities. The pilot plants are established in an area over 3500 m<sup>2</sup> and have modern facilities for scaling up. About 70 researchers of their total staff members (numbering about 500) are pursuing university education or are undergoing postgraduate studies in multidisciplinary fields of chemistry, biology, and medicine. Most of them have been working in R&D projects and/or product manufacture in the biopharmaceutical industry for multiple years, thereby having considerable experience and expertise, both in theory and in applications. Certain members of the management team have been educated and/or having working experience in pharmaceutical companies in the United States and Europe. Their vaccine products include a human rabies vaccine (Vero cell based) in bulk (ready to fill bulk) and formulations. In addition, they have their lyophilized, live-attenuated varicella vaccine for sale in bulk (ready to fill bulk), and as finished formulations.
7. Changsheng Biotechnology (CHANG SHENG BIO)<sup>[12,13]</sup> China is a biotechnology company based in Changchun Jilin, China. It specializes in vaccine manufacturing. It was established in 1992 as a state-owned enterprise but became a family-owned private company in 2003 and thereafter. The company is engaged in R&D, manufacture, and sale of human vaccines. The main products of the company include a lyophilized live-attenuated hepatitis A vaccine, Vero cell-based human rabies vaccine, influenza split vaccine, influenza A H1N1 influenza virus split vaccine, adsorbed diphtheria, tetanus, and pertussis (DTaP) vaccine, and freeze-dried varicella live-attenuated vaccine. It was reported in October 2018 by Reuters<sup>[14]</sup> that the company was imposed with heavy penalties in a scandal over falsifying data for its rabies vaccine. It was also reported that the company had sold substandard DPT vaccines and was heavily fined. It appears that Shenzhen Stock Exchange regulators<sup>[15]</sup> had decided in October 2019 to delist the company from the Shenzhen Stock Exchange because of forging data on vaccines, a breach that was a “major” offense. The present status of the company is not known.
8. Chengdu Kanghua Biological Products (CHENGDU KANGHUA BIO)<sup>[16,17]</sup> Chengdu, China, is a company that specializes in the manufacturing and marketing of Group ACYW135 meningococcal polysaccharide vaccines and human diploid cell-based inactivated rabies vaccines. The production facilities comply with CGMP standards. The company sells its products mainly in China. CHENGDU KANGHUA BIO was set up in 2004. The company has its establishment set up in an area of 30,000 m<sup>2</sup> in the Chengdu Economic and Technological Development Zone of China. The infrastructure includes high-class equipment ready for experimentation of a wide range of biotechnological unit processes and unit operations. They also have SPF experimental animal center. Different kinds of bacterial and viral vaccines could be manufactured in their high-tech good manufacturing practice (GMP) production setups. Besides the two vaccines manufactured by the company, they are engaged in R&D and developmental work of other biological products such as the seasonal influenza vaccine without preservatives, the human H5N1 influenza vaccine (split virus) and certain other biological products. They also have skills to standardize high-density cell culture in bioreactors.
9. Changchun High & New Technology Industries<sup>[18]</sup> (Group) (CHANGCHUN HNTI BIO), Changchun City, Jilin, China, was established in June 1993. The company believes in the philosophy of technological innovation as a source of power. CHANGCHUN HNTI BIO is engaged in the production of lyophilized live varicella vaccines and rabies vaccines for human use. They also produce live influenza vaccines. They produce

certain other high-tech recombinant therapeutic proteins that are polyethylene glycol-based, such as human growth hormones and others. CHANGCHUN HNTI BIO has created CGMP facilities for the manufacture of biologicals aforementioned.

10. Chongqing Zhifei Biological Products (CHONGQING ZHIFEI BIO)<sup>[19]</sup> Changchun City, Jilin, China, is a company that is principally engaged in the R&D, production, sale, and distribution of vaccines. The company was founded in 2001. The main products include among the bacterial products, vaccines for the prevention of meningitis and pneumonia and biological products for the prevention and treatment of tuberculosis; among the viral products, the vaccines for the prevention of rabies virus and influenza virus; general drugs; and certain other biological products. For the prevention of bacterial pneumonia, they offer meningococcal (Group A and C conjugate vaccine) as well as meningococcal polysaccharide vaccine. To treat tuberculosis, the company offers deactivated *Mycobacterium vaccae* injection, which is an immunomodulator for treating certain kinds of tuberculosis. They also produce *Haemophilus influenzae* type b conjugate vaccine for the prevention of invasive disease caused by the bacteria *Haemophilus influenzae* type b. The company is also involved in the agency's sale of vaccines. They are agents for hepatitis A vaccine, pneumococcal vaccine, human papillomavirus (HPV) quadrivalent vaccine, and HPV 9-valent vaccine for the prevention of cervical cancer, grade 1/2/3 cervical intraepithelial neoplasia, and cervical adenocarcinoma *in situ* caused by HPV, and pentavalent rotavirus vaccine for the prevention of rotavirus gastroenteritis in infants caused by the serotypes. The company has teamed up with Merck & Co., Kenilworth, New Jersey, for the authorized sale of Merck's aforementioned products. The company distributes its products in domestic market and to overseas markets, with Central China as its main business domain.
11. Dalian Aleph Biomedical (DALIAN ALEPH BIO),<sup>[20]</sup> Dalian, Liaoning, China, is essentially a consultation company, which provides consultancy services in biomedical projects including vaccines. The company is headquartered in Dalian, China. It has an interest in the distribution of biomedical products. Further, the company has an interest in the production of vaccines and introduced its Vero cell-based human rabies vaccine in 2016, produced in its CGMP compliant facilities. DALIAN ALEPH BIO also offers an inactivated influenza vaccine. The company has been acquired by Shanghai Fosun Pharmaceutical Group, China; Fosun<sup>[21]</sup> manufactures various pharmaceutical products, including generic medicines, Chinese traditional medicines, diagnostic products, reagents, and other substances.
12. Dalian Yalifeng Biological Pharmaceutical (DALIAN YALIFENG BIO)<sup>[22]</sup> is a pharmaceutical company, which specializes in the development of biomedical products and processes focusing attention on those linked to infectious diseases. The company was established in 2002 at Middle Road, Dalian Economic and Technological Development Zone in an area of 27,662 m<sup>2</sup>. DALIAN YALIFENG BIO specializes in the production of influenza virus split vaccine and Vero cell-based human rabies vaccine. The influenza vaccine is presented in vials and in prefilled syringes. The manufacturing premises comply with CGMP standards of China. Vero cells are multiplied into bioreactors and infected with the rabies CTN-1V strain, a production strain isolated in China. The production capacity of Vero rabies vaccine is about 3 million doses per year and the split influenza vaccine is about 4 million doses per annum. The company is stated to have invested a registered capital of 52 million Yuan. DALIAN YALIFENG BIO is a wholly owned subsidiary of Shanghai Fosun Pharmaceuticals (Group);<sup>[21]</sup> it serves as a platform for the high-tech vaccine industry under Shanghai Fosun Pharmaceutical Group.
13. Huabei Pharmaceutical Jintan Biotechnology (HUABEI JITAN-BIO)<sup>[23]</sup> (also known as North China Pharmaceutical Jintan Biotechnology), Hebei, China, is a biotech company and is stated to be a joint venture formed between North China Pharmaceutical Group and British Maoye Biotechnology Development. HUABEI JITAN-BIO was established in May 1997. It was established as a modernized modular biotechnology product industry based in China. The facilities can be utilized by others by teaming up on agreed commercial terms. The facilities are utilizable for R&D and manufacture of value-added biotech drugs and pharmaceuticals. The facilities were established in Shijiazhuang National High-tech Industrial Development Zone, covering an area of 40 acres. The main current products of the company are CHO cell line-based hepatitis B vaccine, recombinant human granulocyte-macrophage colony-stimulating factor, and recombinant human erythropoietin.
14. Hualon Biological Engineering (HUALON BIO),<sup>[24-26]</sup> Henan, China, is a Chinese biotech company, which is engaged in R&D, manufacture, and sale of a varied range of biological products, including human albumin, human immunoglobulin, human coagulation



factors, human rabies immunoglobulin, human tetanus immunoglobulin, and certain human vaccines. The company was founded in 1992. Among the human vaccines in their product range are meningococcal polysaccharide vaccine Group ACYW135, inactivated influenza vaccine (split virion), influenza A (H1N1) vaccine (split, inactivated), H7N9-inactivated influenza vaccine, and recombinant hepatitis B vaccine (expressed in *Hansenula polymorpha*). The company claims to be the largest commercial manufacturer of influenza vaccines in Asia. The company has in its R&D pipeline another 10 vaccines, which are in various stages of preclinical and clinical studies. HUALAN-BIO entered into an alliance with the Chinese Academy of Sciences (CAS) in 2010 and through this alliance, it collaborates with multiple institutes for the discovery of innovative biological products.

15. Institute of Medical Biology (INSTITUTE M BIO)<sup>[27,28]</sup> produces multiple biological products and also offers biology research services in immunology, molecular biology, medical biotechnology, medical genetics, molecular epidemiology, and some more. The biological products that INSTITUTE M BIO produces include live-attenuated oral poliomyelitis vaccine (OPV), inactivated hepatitis A vaccine (HAV), and inactivated EV71 vaccines. The first inactivated EV71 whole-virus vaccine developed by the Institute of Medical Biology, Chinese Academy of Medical Science (CAMS) was approved<sup>[29]</sup> by the China Food and Drug Administration (CFDA) on December 3, 2015, for use among Chinese children. The vaccine is in production in China and is available to recipients. Two other Chinese companies are also producing and selling the inactivated EV71 whole-virus vaccine in China after taking approval from CFDA.
16. Jilin Maifeng Biopharmaceutical (JILIN MAIFENG BIO)<sup>[11]</sup> Erdao, Zhangchun, Changchun, Jilin, China, is a subsidiary of CHANGCHUM BCHT-BIO. JILIN MAIFENG BIO is devoted mostly to R&D in high-density cell culture technique and its application for large-scale production of biologicals. It has developed technology for the manufacture of human rabies vaccines using its microcarrier technology in bioreactors.
17. Liaoning Cheng Da Biotechnology (LIAONING CHENG DA BIO), China, is a holding subsidiary of Liaoning Cheng Da and Dalin (LIAONING CHENG DA DALIN)<sup>[30]</sup> China. LIAONING CHENG DA DALIN is a company, which is engaged principally in commodities trading business. It was founded in August of 1993. The company's business includes retailing and wholesale pharmaceuticals, trading in oil, coal and steel, among others. The biopharmaceutical company LIAONING CHENG DA BIO<sup>[31]</sup> was established in Shenyang, China, in June 2002. It has nearly 800 employees, and the production plant, which is located in the Hunnan National High-tech Park in Shenyang, covering an area of nearly 100 acres, has a constructed area of more than 50,000 m<sup>2</sup>. LIAONING CHENG DA BIO is engaged in R&D, manufacture, and marketing of vaccines for human and animals. Its main products are the human rabies vaccine and the inactivated Japanese encephalitis vaccine. Presently, the annual production capacity of human rabies vaccine is 10 million doses, and the annual production capacity of Japanese encephalitis vaccine is 20 million doses. The production facilities are CGMP compliant. The company has developed expertise in the handling of large-scale cell culture in bioreactors. The R&D work comprises development of bivalent renal syndrome hemorrhagic fever viral vaccine. The chosen virus seeds are multiplied on Vero cells under aseptic conditions, concentrated, deactivated, and formulated. Multiple families of RNA viruses can cause viral hemorrhagic fever such as arenaviruses, bunyaviruses, filoviruses, flaviviruses, and others. The company has not disclosed the diseases on which their work is progressing. It is also working on the development of viral vaccines against influenza, chickenpox, and hepatitis A. In the bacterial vaccine arena, they are presently working on the development of 23-valent pneumonia vaccines and other bacterial vaccines.
18. NCPC Genetech Biotechnology Development Company<sup>[32,33]</sup> (NCPC GENETECH BIO), China, operates by providing high-tech services in biotechnology research, product development, and manufacturing; it operates on a modular concept and its facilities can be utilized on proper terms for the manufacture of biologicals including vaccines by teaming up with the company. NCPC GENETECH BIO is a subsidiary company<sup>[34]</sup> of North China Pharmaceutical. North China Pharmaceutical Jintan Biotechnology was established in May 1997, by a joint venture between North China Pharmaceutical Group and British Maoye Biotechnology Development. The group manufactures<sup>[23]</sup> and markets its biotechnology products, which include recombinant human erythropoietin injection (CHO cell line based), recombinant human granulocyte-macrophage colony-stimulating factor injection, and CHO cell line-based recombinant hepatitis B vaccine. The facilities installed by the group in biotechnology include advanced in-

place cleaning and in-place sterilization functions, and using high-quality 316-L stainless steel equipment and piping to avoid any possibility of contamination. To extend its high-tech services, the company has established SS 316L facilities that are sterilizable in-place. The inner and outer walls of the pipeline and the tank are polished. The equipment installed and the facilities created are claimed to be the standards of the European GMP requirements and comply with China's current GMP standards. The facilities have advanced in-place cleaning and in-place sterilization functions. The input materials generated in the manufacturing area include the production and availability of quality water of various kinds (softened water, reverse osmosis water, water for injection, and water for pure steam generation). The ventilation, air-conditioning, and supply of proper quality of air at various production areas are based on the best-in-class manufacturer of such systems; the entire ventilation and air-conditioning purification system is fully controlled by computer. All sterilization operations are carried out using pure steam. All the input materials are collected in appropriate boxes and sterilized from the preparation end. The boxes containing the input materials are automatically used. The electric sterilizing cabinet is a special type of oven with protection under laminar airflow. Steam sterilizers and electric sterilizers are strictly monitored to ensure sterility. The fermentation system uses the automatic fermentation tanks, and the cell culture system uses the cell culture tanks. The control systems installed can control and read various necessary process parameters. Fully automatic washing, sterilizing, filling, and sealing systems have been installed for the finished products. The facilities can be explored for the high-tech production of biologics, including vaccines. The description is provided in an enlarged manner so that persons skilled in the art, requiring such facilities for hiring may like to interact with the company.

19. Olymvax Biopharmaceuticals (OLYMVAX BIO), China, is a Chinese high-tech enterprise, focused on development, manufacture, and marketing of a wide range of human vaccines. OLYMVAX BIO was founded in December 2009. It is a national high-tech enterprise.<sup>[35]</sup> The name of the company was changed to Chengdu Enterprise Technology Center in March 2019. In web search, the name appears as Chengdu Oulin Biotechnology. In Part I of the paper, the company was not described inadvertently. Presently, the company produces and sells three human vaccines, namely a recombinant *Staphylococcus aureus* vaccine based on the antigens trans-genetically produced

in recombinant *Escherichia coli*. A major pathogenic bacterium that causes hospital infection and community infection is *Staphylococcus aureus* such as methicillin-resistant *Staphylococcus aureus* (MRSA). Presently, several antibiotics have been resistant to the *S. aureus*, and therefore one method to tackle the problem is to have a vaccine to treat such resistant cases. The vaccine is effective against Group A streptococcal bacteria. There are nearly 150 serotypes of Group A. The other two products are *H. influenzae* type b conjugate vaccine and tetanus-adsorbed vaccine. In the R&D pipeline, there are multiple products, which include *S. aureus*-specific immunoglobulins, 13-valent pneumococcal polysaccharide conjugate vaccine, and 23-valent pneumococcal polysaccharide vaccine.<sup>[36]</sup> OLYMVAX BIO is set up in an area of 52,666 m<sup>2</sup>, with 39,000 m<sup>2</sup> in construction. OLYMVAX BIO had 282 employees, among which, 19 had master's degree or above in November 2019.

20. Shenzhen Kangtai Biological Products<sup>[37,38]</sup> (SHENZHEN KANGTAI BIO) was established in September 1992. The company is located at No. 6, Kefa Road, Science and Technology Park, Nanshan District, Shenzhen, and was created with a registered capital of 634 million Yuan. The headquarters of the company is in Guangdong, China. SHENZHEN KANGTAI BIO is engaged in the R&D, manufacturing, and marketing of modern biological products. The full-time R&D personnel in the company are more than 100, and the expertise includes core technical personnel participating in multiple national key research projects. They have profound expertise in handling human blood and isolating blood products. The current product range includes *Saccharomyces cerevisiae* based recombinant hepatitis B vaccine (in three strengths, namely 10, 20, 60 µg), *H. influenzae* type b vaccine, *H. influenzae* type b conjugate vaccine, live-attenuated combined measles–rubella, and other products. SHENZHEN KANGTAI BIO received the rDNA-based hepatitis B vaccine technology from Merck. The company operates primarily in the domestic market of China.
21. Shenzhen Neptunus Interlong Bio-Technique<sup>[39,40]</sup> (SHENZHEN NEPTUNUS BIO) Shenzhen, Guangdong Province, China. It is a high-tech biotech enterprise, which is involved in R&D, manufacture, sales, and distribution of biological products. The company specializes in recombinant DNA products. Presently, the main products of the company are recombinant human interferon-α-2b for injection (rhIFN α-2b), recombinant human interleukin-2 for injection (rhIL-2), and subunit influenza vaccine. The

R&D facilities of the company are equipped with modern facilities, and the pilot plant maintains CGMP standards and is approved by the Chinese authority as the Center for Vaccine Development. SHENZHEN NEPTUNUS BIO collaborates with many institutes for vaccine process development. The company has also put high emphasis on quality control, which also complies with the CGMP standards. The company was incorporated in July 2002. It has wide experience in management, and puts emphasis on staff selection, staff training, and staff motivation for the development of human resources, focused on sustained product development. The marketed products of the company are sold with the trademark of either “Neptunus” or “Interlong.” Both brands have a high reputation in the Chinese market. According to the company, its products have covered more than 20 provinces in China, and have served around 500 medical organizations around China. SHENZHEN NEPTUNUS BIO continues to upgrade its capability in R&D and expands its production facilities to extend its product lines with the utilization of more advanced techniques. It has also plans to enter the international markets.

22. Shenzhen Sanofi Pasteur Biological Products (SHENZHEH SANOFI BIO)<sup>[41-44]</sup> Shenzhen, China, is engaged in the development, manufacture, and sale of vaccines, antiviral drugs, and other biological products. The vaccine division of the Sanofi–Aventis Group known by the name Sanofi Pasteur created a new company by the name Shenzhen Sanofi Pasteur Biological Products (SHENZHEH SANOFI BIO) in Beijing in 1996 and later established certain manufacturing infrastructure in Shenzhen for the production of seasonal vaccines. Concurrently, Sanofi Pasteur started marketing a large number of their proprietary vaccines including Vaxigrip (influenza or flu vaccine), Act-Hib (vaccine against *H. influenzae* type b), Pneumo23 (pneumococcal vaccine), Verorab (rabies vaccine), and Meningo A + CA + C (bivalent meningococcal polysaccharide vaccines against A and C) in China. Sanofi Pasteur was holding the largest private market share of vaccines in China at one time.
23. Sinovac Biotech (SINOVAC BIO),<sup>[45,46]</sup> Beijing, China, is an innovative biopharmaceutical company. It is involved in the manufacture of vaccines against EV71, hepatitis A, hepatitis B, H5N1 pandemic influenza (avian flu), H1N1 influenza (swine flu), seasonal influenza, and mumps. The company focuses on research, development, manufacturing, and commercialization of vaccines against human infectious diseases. In their R&D, the company is trying to develop a number of products such as the Sabin strain–inactivated polio vaccine, pneumococcal polysaccharides vaccine, pneumococcal conjugate vaccine, and varicella vaccine. SINOVAC BIO markets its vaccines mainly in mainland China. It also exports some of its vaccines to the Philippines, Mongolia, and Nepal.
24. Walvax Biotechnology (WALVAX BIO),<sup>[47]</sup> Kunming, Yunnan, China, is a modern biological pharmaceutical enterprise. The company was founded in 2001. WALVAX BIO is engaged in the manufacture of biomedicinal products including vaccines, blood products, and certain others. It is an R&D intensive company. It employs more than 1000 people in various skills and cadres. Vaccines manufactured by the company include Group A and C meningococcal polysaccharide conjugate vaccine, freeze-dried Group A and C meningococcal polysaccharide vaccine, Group ACYW135 meningococcal polysaccharide vaccine, *H. influenzae* type b conjugate vaccine, *H. influenzae* type b conjugate vaccine in prefilled syringe, 23-valent pneumococcal polysaccharide vaccine, and diphtheria, tetanus, and a cellular pertussis combined vaccine adsorbed. In December 2019, WALVAX BIO received approval for the manufacture and sale of their pneumococcal 13-valent conjugate vaccine, which was similar to Pfizer’s Prevnar 13. The R&D center of WALVAX BIO is located in the high-tech zone of Kunming, covering an area of 2100 m<sup>2</sup>. The R&D has 10 departments, which include standard research laboratories, chemical coupling, and virus research labs and a few more. Their R&D work includes expertise in conjugating proteins to bacterial polysaccharide, large-scale fermentation, bacterial polysaccharide purification, bacterial endotoxin removal, virus separation, seed bank establishment, viral vaccine antigen purification, and many other core R&D technologies related to the development of vaccine technology.
25. Zhejiang Tianyuan Bio-Pharmaceutical (ZHEJIANG TANYUAN BIO),<sup>[48-50]</sup> Ningbo, Zhejiang, Hangzhou City, China, is one of the largest privately held vaccine companies in China. The company was incorporated in December 1986. ZHEJIANG TANYUAN BIO is also known in China as Tianyuan Biopharmaceutical. It is a rapidly developing enterprise. It operates in the biopharmaceutical area and integrates drug development, production, and sales. The company has a highly efficient R&D infrastructure and is committed to producing high-quality vaccine products for domestic and foreign markets. The company manufactures the influenza virus split vaccine, purified renal syndrome hemorrhagic fever vaccine, meningococcal



polysaccharide vaccines, purified Japanese encephalitis vaccine, and certain other biological products. Their products have been exported to Macau, Eastern Europe, South America, and India. Company's R&D projects are focused on the development of vaccines for treating vaccine-preventable viral and bacterial diseases. The company employs about 250 people and possesses CGMP-certified manufacturing facilities, certified by the State Food and Drug Administration (SFDA) of China. Novartis, Switzerland, a major vaccine manufacturer in the international market, was in the process of acquiring a majority stake<sup>[51]</sup> in ZHEJIANG TANYUAN BIO since 2009; Novartis had reached an agreement to acquire a 85% stake in ZHEJIANG TANYUAN BIO in 2011. This agreement was to combine the strength of Novartis to sell their own products in China as also to derive strength to use ZHEJIANG TANYUAN BIO's deep knowledge of the vaccine market in China to facilitate the delivery of a broad range of theirs and also of the Chinese company to the Chinese private market. ZHEJIANG TANYUAN BIO is presently a part of GSK, following the acquisition of the vaccine business of Novartis by GSK.

## 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), Chinese private companies (Part II of the paper), and the MNCs. In this paper, brief profiles of major Chinese market players operating in the private sector have been provided. Twenty-three private Chinese companies and two Chinese government companies have been identified as major players in the country. There are a few other private Chinese companies manufacturing vaccines; the share of production and supply of vaccines from such companies is small. For a few companies, no information was available on the net, although such companies have been mentioned in certain research papers, written by Chinese scholars.

The private companies supply about 50% of all vaccines presently available in China, whereas Chinese government companies supply the rest. The Chinese government has classified the 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 the

government-owned companies. The Category I vaccines in alphabetical order are anthrax vaccines, bacille Calmette–Guerin vaccine (BCG), diphtheria toxoid combined with tetanus and pertussis (DTwP), diphtheria-tetanus-pertussis acellular vaccine (DTaP), diphtheria and tetanus combined vaccine (DT), tetanus toxoid vaccine (TT), Group A meningococcal polysaccharide vaccine (Men A), Group A and C meningococcal polysaccharide vaccine (Men AC), hepatitis A live attenuated (Hep A-L), hepatitis B vaccine (Hep-B), hemorrhagic fever with renal syndrome (HFRS), Japanese encephalitis vaccine (inactivated) (JEV-I), Japanese encephalitis vaccine (live attenuated) (JEV-L), leptospirosis vaccine (*Leptospira*), measles–rubella vaccine (MR), measles mumps combined vaccine (MM), measles-mumps-rubella vaccine (MMR), measles vaccine (live attenuated) (MV-L), mumps vaccine (Mumps), rubella vaccine (Rubella), poliovirus vaccine—oral (OPV), polio vaccine—injectable (IPV), and pandemic influenza H1N1 vaccine (H1N1). All the other vaccines are Category II vaccines; the eligible recipients have to purchase these vaccines from the market. Most Chinese private companies as well as the MNCs operate in the Category II area. The government-owned companies producing Category II vaccines also sell their vaccines on the open market. The prices of Category II vaccines are high but are rationalized across the country due to market competition. By rationalization, it means that the ratio between the highest and the lowest unit prices of vaccines across the country is close to one. One study<sup>[52]</sup> has indicated that the variation was mostly within 5%. The variation was more for the proprietary vaccines obtained from exclusive supply sources; price variation for HPV vaccines available as bivalent and tetravalent categories was RBM 587–804 (US\$84.90–US\$116.40). The market prices of Category II vaccines when compared with United Nations Children's Fund (UNICEF) supply prices were much higher and even higher than the European prices. For example, although UNICEF charged RBM 23 (US\$3.30) for one dose of PVP-13 (13-valent pneumococcal conjugate vaccine), the retail market price at Shanghai GPO was RBM 704 (US\$102.00); for HPV vaccines available as bivalent and tetravalent vaccines, the UNICEF prices were between RBM 31–32 (US\$4.50–US\$4.60), the Shanghai GPO prices were RBM 586–804 (US\$84.90–US\$116.40), and the European prices were US\$53.97–US\$93.40. There is a need to have an in-depth study on how the retail market prices of Category II vaccines are charged by the suppliers and how these could be rationalized.

It is worthwhile to mention here that by using the Category I vaccines in the Chinese EPI program, the country has been able to eradicate polio, eliminate tetanus, control hepatitis B, and minimize measles infection.<sup>[53,54]</sup> The Chinese government has been able to implement its EPI program very effectively,



thereby ensuring vaccination of a high percentage of eligible children and pregnant mothers to comply with the program. Recent news<sup>[55]</sup> about the vaccination coverage of eligible children in China had been reported at 90%. Interestingly, the Chinese Category I vaccines also include vaccination against certain other diseases such as anthrax, leptospirosis, and HFRS, perhaps chosen by the government, taking into account the local needs.

It may be mentioned in this context that the WHO has recommended the deployment of several vaccines to the eligible population<sup>[56]</sup> of any country. Taking cognizance of the WHO list and having regard to the use of vaccines in developed countries as also in several other developing countries, it is prudent to mention that if the Chinese EPI would also have vaccines such as those against rabies, HPV, *H. influenzae* type b, and rotavirus in their Category I, list then the health of Chinese children shall further improve. No doubt, it would require more allocation of resources toward the EPI program. From the private industries “point of view,” the existing situation of Chinese EPI coverage through the deployment of the current Category I vaccines is an opportunity to develop and sell the Category II vaccines to the private market where the profit margin is lucrative.

Most of the Chinese private companies that manufacture vaccines were established in the decade of 1990 and thereafter. Local investors came forward to set up manufacturing facilities in an environment of China’s growing demand for human vaccines and for exports; therefore, many vaccine producers intensified their scale-up efforts in vaccine R&D with a view to introduce newer vaccines as fast as possible; many others had undertaken efforts to expand their existing capacity. The efforts of the Chinese investors resulted in the emergence of a large number of Chinese private companies. In 2020, the major private vaccine manufacturers were, in alphabetical order, the companies such as BEIJING MINHAI BIO, CAN SINO BIO, CHANGCHUN BCHT-BIO, CHANGCHUM HNTI BIO, CHONGQUING ZHIFEI BIO, DALIAN ALEPH BIO, HUALON BIO, LIAONING CHENG DA BIO, NCPC GENETECH BIO, SHENZHEN KANGTAI BIO, SHENZHEH SANOFI BIO, SINO VAC BIO, and WALVAX BIO.

The Chinese Vice Minister of Industry and Information Technology Mr. Wang Jiangping had mentioned during an inaugural function of the China Association for Vaccines,<sup>[57]</sup> in October 2019, that the turnover of the Chinese vaccine industry was about 25 billion Yuan (US\$3.50 billion). In one published estimate,<sup>[58]</sup> in 2019, the sales turnover of the vaccine industry in China was reported as 28.2 billion RMB,

which is equivalent to about US\$3.95 billion. The annual growth rate of Chinese vaccine industry was reported to expand annually at 11.7%, whereas the Category II vaccine’s growth rate was estimated at 12.7%. The Chinese vaccine industry turnover in 2019 can be taken between US\$3.50 and US\$3.95 billion dollars in 2019. The turnover of the Chinese Pharmaceutical Industry in 2018 was reported<sup>[59]</sup> at US\$127.9 billion, growing at a rate of 2.4% per annum. Therefore, the 2019 turnover of all pharmaceuticals was calculated at US\$130.97 billion. The pharmaceutical industry growth in China from 2017 to 2018 was registered at 6.3%. Therefore, the future growth is anticipated to be more than 2.4%. Nevertheless, going on a conservative estimate and taking the 2019 turnover at US\$130.97 billion, the Chinese vaccine industry turnover works out to about 2.7%–3.0% when compared to its pharmaceutical industry, in value terms. The vaccine industry even though very small in comparison with the whole pharmaceutical industry, its impact on the health care of the Chinese people is very high. Compared to the global human vaccine industry turnover<sup>[60]</sup> of US\$35.2 billion in 2019, the Chinese vaccine industry turnover worked out to about 9.9%–11.2%, which is sizable and significant.

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## Conflicts of interest

There are no conflicts of interest.

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