BIO Collaborate

Bio Tianfu

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内部资料 仅供交流

我国在疫苗行业的政策导向明确而具体。“健康中国2030”规划纲要及《“十三五”卫生与健康规划》都明确提出了要坚持贯彻预防为主的方针政策，其中疫苗接种是预防传染病最有效的公共卫生手段。做好预防接种对实现健康中国战略意义重大，国内疫苗行业也将颇多获益。

China has very explicit and concrete policy orientation in the vaccine industry. Both the “Healthy China 2030” Planning Outline and the Plan for Health in the 13th Five-year Plan Period have explicitly proposed the policies and guidelines that put prevention first, among which, vaccination is the most effective means of public health in the prevention of infectious disease. Protective vaccination is of critical importance to implement the Healthy China Strategy. In addition, domestic vaccine industries will benefit a great deal.

疫苗：防控传染病的最有效手段

Vaccine is the most effective method to prevent and control the infectious disease.

天府生命科技园
Tianfu Life Science Park

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01
创新前行
Advance with Innovation

助推科研成果就地转化 助力国家中心城市建设
Promote the Quick Transformation of Technological Achievements, and Help the Construction of a National Central City

看校地合作的成都前沿医学中心实践
School-Government Cooperation Project-Chengdu Advanced Medical Science Center in Action

医药健康产业被誉为 21 世纪的朝阳产业。作为最具创新活力的新兴产业，医药健康产业在推动经济向高质量发展过程中，发挥着十分重要的作用，亦是成都构建具有国际竞争力和区域带动力的现代产业体系的重要支撑。

The medical and health industry is known as the sunrise industry in the 21st century. As the most innovative and active emerging industry, the medical and health industry plays a very important role in promoting the high-quality economy development. It is also an important support for Chengdu to build a modern industrial system with international competitiveness and regional momentum.

作为成都生物医药产业的主阵地，成都高新区生物产业发展基础良好，近年来更是发展势头强劲。在 2019 年中国生物医药园区竞争力排行榜中，成都高新区排名第六。成都高新区也在加快生物产业功能区建设，积极构建产业生态圈，打造生物产业特色产业链和校地合作利益共同体。

As the main base of Chengdu's biopharmaceutical industry, Chengdu Hi-tech Zone has laid a solid base for biological development, with a strong momentum especially in recent years. In the 2019 China Biomedicine Park Competitiveness Ranking, Chengdu High-tech Zone ranked sixth. Chengdu Hi-tech Zone is also accelerating the construction of bio-industry functional zones, building an industrial ecosystem, and creating a bio-industry characteristic industrial chain and a community of common interest through school-government cooperation.

在此背景下，承载校地合作重任，成都前沿医学中心（以下简称“中心”）应势而生。2018 年 6 月 13 日，成都市人民政府与四川大学签署协议，将在前沿医学研究中心、技术交叉与转化中心以及大型综合博物馆三方面深化合作，共建世界一流大学，助推国家中心城市建设。其中作为市校合作在医药健康领域重要布局的成都前沿医学中心由“研究极”和“产业极”载体组成，“研究极”载体包括成都高新区生物医药创新孵化园（天府生命科技园二期）创新研发中心和四川大学华西校区将建设的“研究极”大楼；“产业极”载体则包括新川创新科技园孵化加速中心和成都天府国际生物城的产业转化中心。

In this context, Chengdu Advanced Medical Science Center (hereinafter referred to as the "CFMC") was born in response to the important task of school-government cooperation. On June 13, 2018, the Chengdu Municipal People's Government and Sichuan University signed an agreement to deepen cooperation in three areas: Advanced Medical Science Center, Technology Intersection and Transformation Center, and a large comprehensive museum, where they will jointly build a world-class university and promote the construction of a national central city. Among them, the Chengdu Advanced Medical Science Center, which is an important part of the city-school cooperation in medicine and health, is composed of the carriers of "research pole" and "industrial pole". The "research pole" carrier includes the Innovation R&D Center in Chengdu High-tech Zone Biomedical Innovation Incubation Park (Tianfu Life Science Park Phase II) and a “research pole” building to be constructed in West China Medical School campus of Sichuan University; the “Industrial Pole” carrier includes the Incubation Acceleration Center of Singapore-Sichuan Hi-Tech Innovation Park and the Industrial Transformation Center of Chengdu Tianfu International Bio-town.

作为承载这一重要任务的主战场，成都高新区及天府生命科技园二期将如何与一流高校碰撞出火花？如何打造校地合作新模式？

As the main battlefield for carrying out this important task, how will Chengdu Hi-tech Zone and Tianfu Life Science Park Phase II work with a first-class university to produce satisfactory results? How can they create a new model of school-government cooperation?

01
政府建载体，川大引团队
The Government Builds the Carrier While Sichuan University Provides the Team

2019 年 9 月 12 日，成都前沿医学中心首批载体交付仪式举行，位于天府生命科技园二期内首批完成装修的 9000 平米研究极载体、8500 平米产业极载体分别交付给了四川大学华西医院、华西第二医院、华西口腔医院以及首批签约的创业教授们。首批载体交付，标志着成都前沿医学中心项目导入进入实质阶段。

On September 12, 2019, the first batch of carriers handover ceremony for Chengdu Advanced Medical Science Center was held. The first batch of 9,000 square meters of research pole carriers and 8,500 square meters of industrial pole carriers with fittings completed in the second phase of Tianfu Life Science Park were handed over to West China Hospital of Sichuan University, West China Second University Hospital, West China Hospital of Stomatology and the first batch of signed entrepreneurial professors. The handover of the first batch of carriers marked the project inauguration at Chengdu Advanced Medical Science Center.

在四川大学与成都高新区双方共同的推动下，2019 年底已有 10 个由四川大学教授创办的公司确定入驻天府生命科技园二期。

With the joint efforts of Sichuan University and Chengdu High-tech Zone, at the end of 2019, 10 companies founded by professors from Sichuan University confirmed their settlement in the second phase of Tianfu Life Science Park.

而成都高新区则给出了实打实的“大礼包”：专业化载体及装修补贴，天府生命科技园二期的一流建筑设计及完善的配套服务，让创业教授们享受“拎包入驻”的便利；入驻咨询、工商注册、环评办理等贴心服务，帮助教授们迅速从专家学者向企业家转型。

Chengdu High-tech Zone provides a substantial "gift package": professional carriers and fitting subsidies, first-class architectural design and perfect supporting services in the second phase of Tianfu Life Science Park. Therefore entrepreneurial professors can enjoy their fully furnished space. Park services such as settlement consulting, industrial and commercial registration, and environmental assessment management can help professors quickly transform from academic experts and scholars to entrepreneurs.

02

事业合伙人 利益共同体

Business Partner and Community of Common Interests

针对以往科技成果本地转化率不高、校地合作单方向不持续等问题，对标波士顿生物医药创新生态，成都高新区与四川大学以共建成都前沿医学中心为契机，以转化医学为创新靶标、以市场应用为价值导向，在全国首创科技成果确权校地分享“事业合伙人”模式，紧紧抓住“科技创新 - 孵化创新 - 促进产业发展”这条主线，通过校地双方优质资源整合和成果确权分享的方式，将政府与大学建成利益共同体，实现创新能力集成提升、科技成果就地转化。

In view of the issues of low local transformation rate of scientific and technological achievements in the past and unsustainable school-campus cooperation caused by unpredictable changes from either party, with reference to the biopharmaceutical innovation ecology in Boston, Chengdu High-tech Zone and Sichuan University took the opportunity in the construction of the Advanced Medical Science Center for a solution. Targeting for medical transformation and innovation and orientated with market application value, it takes the lead to set up the “business partner” model in China with confirmed rights and interests of technological achievements between the school and the government. Centering on the developing route of “technological innovation—incubation innovation — promotion of industrial development”, and through high-quality resources integration and the confirmation of rights and interests of technological achievements, it aims to build a community of common interests between the government and a university, and to realize integrated improvement of innovation capabilities and localized transformation of technological achievements.

双方共同设立工作小组，负责中心工作整体设计、战略规划、协调推进。共同成立由中国科学院院士、四川大学华西医院生物治疗国家重点实验室主任魏于全在内的 76 位专家组成的学术委员会，负责成都前沿医学中心入驻项目的导入标准、项目筛选、团队引入、考核评估等工作。

The two parties will jointly set up a working group to take charge of the overall design, strategic planning, and work coordination of the center. They will Jointly establish an academic committee composed of 76 experts including Wei Yuquan, an academician of the Chinese Academy of Sciences and Director of the State Key Laboratory of Biotherapy of West China Hospital, Sichuan University, which will be responsible for the standards formulation for project settlement, project selection, team introduction, assessment and evaluation of Chengdu Advanced Medical Science Center.

“事业合伙人”模式同时也体现在企业全生命周期中。企业成长中，政府引导基金优先入股；专利确权时，四川大学以科技成果转化确权后校方所得部分与成都高新区分享，作为高新区支持创新的回报；企业成熟后，总部在高新，转化在市州。

The "business partner" model is also reflected in the full life cycle of the enterprise. During the growth of the enterprise, fund under government guidance will be given priority to shareholding. In patent right confirmation, Sichuan University will share its confirmed rights upon technological achievement transformation with Chengdu High-tech Zone as the return of the support for innovation from High-tech Zone. When the enterprise grows to maturity, it shall be headquartered in Hi-tech Zone with achievement transformation to be carried out in cities or prefectures as appropriate.

KNOWLEDGE
CHANGE PRODUCT

03

知识变产品 教授做股东

Knowledge Transformed to Products, and Professors Transformed to Shareholders

成都前沿医学中心载体面积约 12.5 万㎡，其中研究极部分，入驻四川大学高水平研究团队。

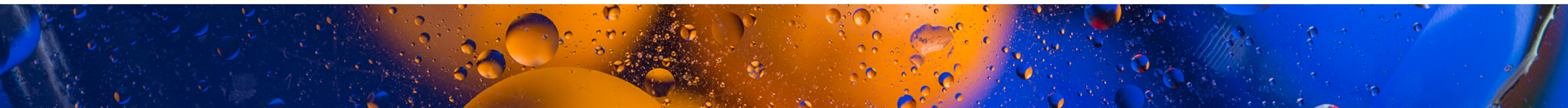
The carrier of Chengdu Advanced Medical Science Center covers an area of about 125,000 square meters, of which the research pole is settled in by a high-level research team from Sichuan University.

目前，研究极共引入 8 个研究平台，这里面就包括四川大学华西临床医学院 / 华西医院院长李为民担任负责人的疾病分子网络前沿科学中心，四川大学华西医院党委书记、华西生物医学大数据中心主任担任负责人的医学大数据中心，国家口腔临床医学研究中心负责人、长江学者特聘教授陈谦明担任负责人的口腔医学 + 前沿创新转化平台，以及四川大学华西基础医学与法医学院院长黄灿华担任负责人的应激医学前沿研究中心等等。研究极平台水准，可见一斑。

At present, eight high-level technological innovation platforms are about to settle in, which include the Advanced Science Center for Disease Molecular Networks headed by Li Weimin, President of West China School of Medicine/West China Hospital of Sichuan University, a big data center headed by Secretary of the Party Committee of West China Hospital of Sichuan University, and Director of the big data center of West China Biomedicine, a stomatology + cutting-edge innovation transformation platform headed by Chen Qianming, head of the National Clinical Research Center for Oral Diseases, and Changjiang Distinguished Professor, and Huang Canhua, advanced research center of stress medicine headed by Huang Chanhua, dean of West China School of Basic Medical Sciences & Forensic Medicine, Sichuan University, etc. It can be seen that the platforms of the research pole are of high expertise.

而产业极部分，入驻四川大学教授创办企业，现已入驻赜灵生物、贝斯迪生物、川康金格、分迪药业等 4 家企业，其余项目入驻正有序推进中。

As for the industrial pole, enterprises founded by professors from Sichuan University such as Zeling Biotech,ChuanKangJinGe,BSD Co.,Ltd,and FenDi Pharm have settled here,more enterprises are settling orderly.



04

全生命周期企业服务 助推产业生态圈建设

Full Life Cycle Enterprise Services to Promote the Construction of Industrial Ecosystem

天府生命科技园二期载体面积约 29.4 万㎡，在成都前沿医学中心之外，园区内还将陆续入驻由高新区自主招商企业。为了与成都前沿医学中心形成交流互动，按照高新区管委会要求，自主招商入驻的企业需能为成都前沿医学中心项目提供应用场景，实现与成都前沿医学中心项目的创新协作协同。截至 7 月底，互动极已有珀金埃尔默、华曙图灵、北科生物等 5 家企业入驻，倍特药业、世联康健、疆域医疗等 3 家企业正在装修中。

The carrier of the second phase of Tianfu Life Science Park covers an area of about 294,000 square meters. Besides Chengdu Advanced Medical Science Center, companies to be independently introduced by High-Tech Zone will also settle in the park. For interactions with the Chengdu Advanced Medical Science Center, based on the requirements of the High-tech Zone Management Committee, enterprises independently introduced need to be able to provide application scenarios for the projects of Chengdu Advanced Medical Science Center and achieve innovative collaboration with Chengdu Advanced Medical Science Center. As of the end of July,2020,five enterprises, include PerkinElmer,Huashu Turing,BeiKe BioTech,have settled in interactive pole,and 3 other enterprises are decorating now.

实现区域产业发展，除了企业独立奋进和政府的支持引导外，也离不开载体运营单位的服务。总结多年园区运营管理经验，在服务天府生命科技园一期现有 170 余家企业基础之上，成都高投生物医药园区管理有限公司（以下简称“高投生物园公司”）已建立覆盖企业全生命周期的服务体系助推生物企业发展。涵盖向生物医药企业和创业团队提供创业指导、公共技术平台、安全环保、人力资源、品牌策划与推广、后勤保障等多项服务，让企业在入园前、入园时、入园后的不同阶段，都能享受到园区提供的涵盖企业全生命周期的各类创业孵化服务。

To realize regional industrial development, apart from the efforts of enterprises and the support and guidance of the government, services provided by carrier operating institutions also play an inseparable role. Based on many years of experience in the operation and management of industrial parks, after serving more than 170 enterprises in the first phase of Tianfu Life Science Park, CDHT Investment Biomedicine Park Management Co., Ltd. (hereinafter referred to as "CDHTIBPM") has established a service system covering the full life cycle of the enterprise. It provides services for biopharmaceutical companies and entrepreneurial teams such as entrepreneurship guidance, public technology platforms, security, environmental protection, human resources, brand planning and promotion, logistics, etc., so that enterprises can enjoy incubation services covering the full life cycle of enterprises before, during and after their settlement in the park.

05

扎实推进 未来可期

Stable Progression with a Foreseeable Future

天府生命科技园二期不仅是一座现代化生物医药产业园区，更拥有人文、产业、生态高度融合的、公园化的配套设施。为了保障成都前沿医学中心的生活配套，高投生物园公司积极推动天府生命科技园二期配套项目落地，目前已完成园区文化氛围打造，展厅、会议中心、便利店、食堂、文印店已对外营业，咖啡厅、健身房、药店等正在招引中。未来，这里将是高新南区“人城产”融合发展的典范。

The second phase of Tianfu Life Science Park is not only a modern biomedical industrial park, but is also facilitated with high integration of humanities, industries and ecology with park characteristics. In order to ensure the living facilities of Chengdu Advanced Medical Science Center, CDHTIBPM endeavors to provide full facilities for the second phase of the Tianfu Life Science Park. At present, the cultural-related facilities of the park have been completed. The conference center and convenience store are open for business. The cafeteria and printing stores will be open soon. The hotel and exhibition hall will soon undergo fittings. In the future, this will become a model for the integrated development of the "human—urban life—business" in the south of High-tech Zone.

目前，在生物医药领域，成都高新区和四川大学聚集了长江学者、杰出青年等 100 余位；诺贝尔奖团队 5 个、国家级院士团队 4 个、高层次人才团队 51 个，通过产业人才和科研人才的交流碰撞，为医药科技创新提供了无穷的驱动力。预计 2025 年，成都前沿医学中心将带动成都生物医药产值超过 500 亿元，并力争引进 15 个院士级，50 个长江、杰青级创新人才，获得专利授权超过 200 项，孵化创新企业 100 家。

At present, Chengdu Hi-tech zone & Sichuan University has gathered more than 100 Changjiang Scholars and Excellent Young Scientists, 5 Nobel Prize Teams, 4 National Academician-level scientists and 51 High-level Talent teams.The communication between industrial talents and scientific talents brings endless driving forces for medical science innovation. It is expected that by 2025, Chengdu Advanced Medical Science Center will drive an output value of over 50 billion yuan in biomedicine in Chengdu, with the goal to introduce 15 academician-level talents, 50 Changjiang Scholars and Excellent Young Scientists, obtain more than 200 patent authorizations, and incubate 100 innovative enterprises.

当前，成都正提升创新引领能力，实施蓉城科技聚变计划，推进校院企地深度融合发展。成都前沿医学中心作为成都市与四川大学校地合作的核心项目，将承担起“打造成都前沿医学创新发展的新机核和策源地”使命，建设高水平合作平台，打造校地交流合作成功典范，助力成都打造成为全球生物医药创新创造中心。

Currently, Chengdu is improving its ability to lead innovation, implementing the technology aggregation plan, and promoting the deep integration of schools, academies, enterprises and local government. As the core project of school-government cooperation between Chengdu Municipal Government and Sichuan University, Chengdu Advanced Medical Science Center will undertake the mission of "creating a new core and source of innovation for advanced medical innovation in Chengdu", build a high-level cooperation platform, create a successful model for school-government exchange and cooperation, and help Chengdu become a global biomedical innovation and creation center.

02
行业洞察
Industry Insight

2-1

疫苗产业发展现状
Development of Vaccine Industry

2-1-1
疫苗产业特征
Characteristics of Vaccine Industry

疫苗产业是生物医药领域不可或缺的重要子领域，近年来由于国内外疫苗产品的代际差异逐渐缩窄、可及性大幅提升，驱动我国疫苗市场步入了新一轮扩容期，未来几年将维持高景气度，资本市场对于疫苗行业的关注度也日益升温。

The vaccine industry is an indispensable and important subfield of biomedicine. In recent years, due to the gradual narrowing of intergenerational differences between domestic and foreign vaccine products, China's vaccine market has entered a new round of expansion driven by substantial accessibility expansion. It is expected to maintain a high prosperity within the next few years with the capital market's increasing attention to the vaccine industry.

疫苗是将病原微生物（如细菌、病毒等）及其代谢产物，经过人工减毒、灭活或利用基因工程等方法制成的用于预防传染病的自动免疫制剂。疫苗保留了病原菌刺激动物体免疫系统的特性。当人体接触到这种不具伤害力的病原菌后，免疫系统便会产生一定的保护物质，如特异性抗体、免疫细胞、活性生理物质等。当人体再次接触到这种病原菌时，人体的免疫系统便会依循其原有的“记忆”，制造更多的保护物质来阻止病原菌的伤害。

Vaccines are automatic immune preparations used to prevent infectious diseases by using pathogenic microorganisms (such as bacteria, viruses, etc.) and their metabolites through artificial attenuation, inactivation, or genetic engineering. A vaccine retains the pathogenic bacteria's ability to stimulate the animal's immune system. When the human body comes into contact with such harmless pathogenic bacteria, the immune system will produce certain protective substances, such as specific antibodies, immune cells, active physiological substances etc. When the human body comes into contact with such pathogen again, the immune system will follow its original "memory" and produce more protective substances to prevent the harm from the pathogen bacteria.

疫苗所诱导的免疫效应物主要是 B 淋巴细胞产生的抗体，它能够与内毒素或者病原体特异性结合，进而引起保护性免疫。疫苗应具有很强的免疫原性，接种后能引起保护性抗体，使群体的抗感染能力增强。疫苗研发过程中针对有效性须考虑两个问题：一是保护性免疫是以体液免疫为主还是细胞免疫为主，或二者兼备；二是能否引起显著的免疫记忆，使保护性免疫长期维持。

The immune effectors induced by the vaccine are mainly antibodies produced by B lymphocytes, which can specifically bind to endotoxins or pathogens, thereby causing protective immunity. The vaccine needs to have strong immunogenicity, which can generate protective antibodies after inoculation, and thereby enhance the anti-infection ability of the population. In the vaccine development, two issues must be considered for effectiveness assessment: One is what is the focus of protective immunity, humoral or cellular imunity? Or both? The second is that whether it can generate significant immune memory and maintain the protective immunity for a long time.

在人类与疾病的抗争史上，疫苗被公认是传染病防控最经济、最有效的手段。由于疫苗的使用，天花从地球上消失，脊髓灰质炎也几近消失，麻疹、风疹、白喉等传染病得到了有效控制。此外，近半个世纪以来，人类的人均寿命得以大幅延长，除了清洁水的使用之外，很大程度上也得益于疫苗的普及。

In the history of humans combating diseases, vaccines have been recognized as the most economical and effective means of infectious disease prevention and control. Thanks to the use of vaccines, smallpox disappeared from the earth, poliomyelitis almost disappeared, and infectious diseases such as measles, rubella, and diphtheria are under effective control. In addition, in the past half a century, human life expectancy has been greatly extended due to two major changes: the use of clean water, and the wide use of vaccines.

疫苗可分为动物培养疫苗、鸡胚培养疫苗和细胞培养疫苗；根据物理性状，疫苗可分为液体疫苗和冻干疫苗；根据佐剂的有否，疫苗可分为佐剂疫苗和无佐剂疫苗；根据微生物是否完整，疫苗可分为全微生物疫苗和亚单位疫苗；根据免疫途径，疫苗可分为注射用疫苗、口服疫苗、气雾疫苗和皮肤划痕疫苗；根据生长繁殖力和残留毒力，疫苗可分为活疫苗（强毒疫苗、弱毒疫苗）和灭活疫苗（死疫苗）。

Vaccines can be divided into animal culture vaccines, chicken embryo culture vaccines and cell culture vaccines. In terms of physical properties, vaccines can be divided into liquid vaccines and lyophilized vaccines. In terms of the presence or absence of adjuvants, vaccines can be divided into adjuvant vaccines and non-adjuvant vaccines. In terms of microorganism completeness, vaccines can be divided into whole microorganism vaccines and subunit vaccines. In terms of the route of immunization, vaccines can be divided into injection vaccines, oral

vaccines, aerosol vaccine and skin scratch vaccines. In terms of growth and reproduction capacity and residual toxicity, vaccines can be divided into live vaccines (strengthened vaccines, attenuated vaccines) and inactivated vaccine (dead vaccines).

随着免疫学、生物化学、生物技术和分子微生物学的发展，20 世纪后半叶全球疫苗的研制进入快速发展阶段。从技术路径的角度来看，最开始的第一代传统疫苗，包括灭活疫苗、减毒疫苗等；发展到第二代疫苗，包括由微生物的天然成分及其产物制成的亚单位疫苗和将能激发免疫应答的成分基因重组而产生的重组蛋白疫苗；再到目前最新第三代，以 mRNA 疫苗、DNA 疫苗、重组载体疫苗为代表的基因疫苗。

With the development of immunology, biochemistry, biotechnology and molecular microbes, vaccines R&D was greatly accelerated in the second half of the 20th century. From the perspective of the technical path, it started with the first generation of traditional vaccines including inactivated vaccines, attenuated vaccines, etc., developed to the second generation of vaccines including subunit vaccines made from natural components of microbes and their products, and recombinant protein vaccines produced by the genetic recombination of components that can stimulate an immune response. Until today, it has developed to the third generation of genetic vaccines represented by mRNA vaccines, DNA vaccines, and recombinant vector vaccines.

目前全球上市的预防性疫苗种类约 70 种，可预防 37 种感染性疾病，针对大多数传染病的疫苗已经被研发上市成功。然而，截至目前，一方面仍有部分疫苗品种的研发尚未成功，如呼吸道合胞病毒疫苗、单纯疱疹病毒疫苗、巨细胞病毒疫苗、疟疾疫苗、艾滋病疫苗、诺如病毒疫苗、MERS（中东呼吸综合征）与 SARS（非典）等冠状病毒疫苗仍在研发当中。另一方面，流感疫苗、百日咳疫苗等仍存在新一代预防效果更好的产品研发需求。

At present, there are about 70 types of preventive vaccines on the market worldwide, which can prevent 37 infectious diseases. Vaccines for most infectious diseases have been successfully developed and marketed. However, as of now, some vaccine varieties have not been successfully developed yet, such as vaccines for respiratory syncytial virus, herpes simplex virus, cytomegalovirus, malaria, AIDS, norovirus, MERS, SARS, etc., which are still under development. On the other hand, there is still the need for a new generation of products of better prevention effects such as influenza vaccines and pertussis vaccines.

2-1-2

疫苗产业化关键点

Key Links of Vaccine Industrialization

01

研发基础——菌株 / 毒株的获取

R&D Basis: Acquisition of Strains/Virus Strains

菌株 / 毒株获取是疫苗研发的基础。目前，研发疫苗所用的毒株仅有五个来源，分别是英国国家生物制品检定所（NIBSC）、澳大利亚药物管理局（TGA）、美国疾病控制中心（CDC）、美国 FDA 和世界卫生组织（WHO）。如果要进行产业化，上述毒株还需疫苗企业进行二次开发。

Strain/ virus strain acquisition is the basis of vaccine development. At present, only five sources of virus strains are used in the development of vaccines, namely, the National Institute for Biological Standards and Control(NIBSC) in Britain, the Therapeutic Goods Administration (TGA) in Australia, the Center for Disease Control (CDC) in the US, the US FDA and the World Health Organization (WHO). Where industrialization is needed, the above-mentioned strains need to be re-developed by vaccine companies.

上世纪 90 年代，在我国疫苗产业发展还相对滞后时，国际疫苗巨头应 WHO 要求，向我国捐赠了一批可直接产业化的毒株。21 世纪以来，我国疫苗企业通过“国际合作”的模式，引入一些新型疫苗的菌株 / 毒株用于产业化生产，但随着技术的发展仍然面临升级换代和技术受限。近年来，外资巨头对菌株 / 毒株的保护意识逐渐加强，尤其是针对创新疫苗（如 HPV 疫苗、肺炎疫苗）的毒株，几乎不可能转让。因此，对菌株 / 毒株的研发、获取和产业化转化，是考验疫苗企业研发能力的第一道技术门槛。

In the 1990s, when the vaccine industry in China was relatively backward, international vaccine giants donated a batch of virus strains that could be directly industrialized in China at the request of WHO. Since the beginning of the 21st century, vaccine companies in China have been introduced with some new vaccine strains/virus strains for industrial production through “international cooperation”. However, with the development of technology, they are still facing upgrading and technological bottlenecks. In recent years, foreign giants have gradually strengthened their awareness of strain/virus strain protection, especially for strains of innovative vaccines (such as HPV vaccines and pneumonia vaccines), where technological transfer is almost out of the question. Therefore, the R&D, acquisition and industrialization of strains/ virus strains are the first technical threshold to test the R&D capabilities of vaccine companies.

02

疫苗产品的大规模产业化

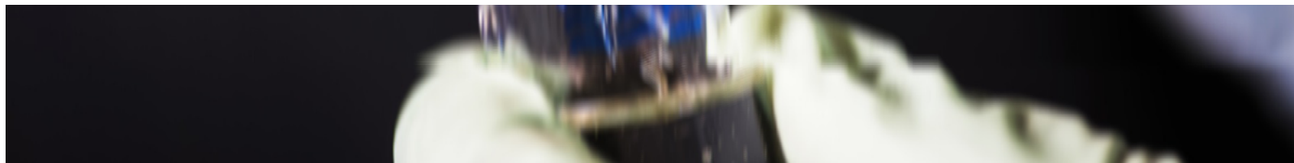
Large-scale Industrialization of Vaccine Products

疫苗的生产、检验及使用存在特殊性，主要表现在：1、起始材料菌株 / 毒株具有生物活性，分子结构复杂；2、生产过程复杂，生物材料具有高变异性和潜在内源性和外源性污染的危险，最终产品不能灭菌处理，需要采用无菌工艺；3、疫苗是复杂的大分子药物，可能有具有隐蔽性不良反应，需要经专业技术检验；4、疫苗生物学质量控制检测方法具有很大局限性，需要通过对样本进行破坏性抽检，以推测整批生产质量；5、疫苗的使用对象是健康人群，需要进行大规模免疫接种，产品质量直接影响整个公共卫生管理体系。因此必须对疫苗的生产和使用权过程进行控制，有效保证产品质量。

The production, inspection and use of vaccines have their particularities, which are mainly manifested in: 1) The strain/virus strain in the initial material contains biological activity with complex molecular structure. 2) The production is complex where biological materials have high variability with potential endogenous and exogenous pollution risks. The final product cannot be sterilized and therefore requires aseptic technology. 3) Vaccines are complex macromolecular drugs, which may cause hidden adverse reactions and require professional technical inspection. 4) There is great limitation on vaccine biology quality control testing methods, and destructive sampling of samples is required to infer the quality of the entire batch. 5) The target of the vaccine is healthy people, where mass immunization is required. The quality of the product directly affects the entire public health management system. Therefore, it is necessary to control the vaccine production and use rights to effectively ensure product quality.

另外，疫苗行业的产能利用率较低，一条生产线通常只能生产一种配方的产品，导致生产的固定成本较大而产能有限。并且，根据《药品管理法》的规定，疫苗等特殊药品企业必须内部生产，不允许进行委托外包。新版《疫苗法》同样规定，疫苗上市许可持有人应当具备疫苗生产能力，所以对疫苗企业自身的产业化能力要求较高。

In addition, the capacity utilization rate of the vaccine industry is low, where one production line can usually make products of only one formula, which results in large fixed cost demand with limited production capacity. In addition, according to the Pharmaceutical Administration Law, special drugs such as vaccines must be conducted for in-house production and are not allowed for outsourcing. The new version of the Law on Vaccine Management also stipulates that vaccine marketing license holders should be capable of vaccine production, so there is a high requirement for vaccine companies' own industrialization capability.



03
严苛的疫苗监管要求——伤害的“无过错”赔偿原则
Stringent Vaccine Regulatory Requirements: the "No-Fault Principle" of Compensation for Injury

疫苗伤害一般分为两种情况：一种是由于疫苗本身安全性问题或接种环节失误而造成的伤害，一般各国都有明确的赔偿机制；另一种，伤害并不一定由疫苗本身或接种程序所致，即俗称“恶魔抽签”下的小概率疫苗伤害。欧美日等大部分发达国家都采取人性化的补偿机制，即“无过错原则”，并由生产企业、医保基金、商保等承担补偿，同时通过税负转嫁等方式，最终的承担主体仍然以疫苗生产企业为主。

Vaccine injuries are generally divided into two categories: One is the injury caused by the vaccine itself or the error in the vaccination, and generally speaking, all countries have their own compensation mechanisms. The other category is that the injury is not necessarily caused by the vaccine itself or the vaccination. Rather it is caused by small probability of vaccine injury under the chance commonly known "devil lottery". Most developed countries such as Europe, America and Japan adopt a humane compensation mechanism, that is, the "no-fault principle", where the compensation is borne by manufacturers, medical insurance funds, and commercial insurance companies. Tax transfer and other methods are also adopted, but responsibility bearer is still mainly the vaccine manufacturer.

德国在 1976 年制定了一部《药物伤害法》，其中规定“受伤害者请求赔偿无须证明接种者过失”。此后，欧美日等多数发达国家都放宽了对疫苗损害受害者获得赔偿 / 补偿的条件。美国国会于 1986 年通过了国家儿童疫苗伤害法案（National Childhood Vaccine Injury Act, NCVIA），基于“无过错原则”，只要怀疑自身在接种疫苗后受到伤害，则可以申请疫苗救济，为此疫苗生产企业每售出 1 个接种剂量要交纳 0.75 美元税收，美国联邦政府建立一套疫苗不良反应系统 (VAERS) 用以检测接种疫苗后的不良反应。2019 年 6 月 29 日，最新《中华人民共和国疫苗管理法》表决通过，开始与国际接轨，同样接纳“无过错原则”，规定只要“不能排除”属于异常反应，疫苗生产企业或保险制度就“予以补偿”。

For example, Germany enacted a Law on Drug Injury in 1976, which stipulates that "the injured does not need to prove the negligence of the vaccinator for compensation." Since then, most developed countries such as Europe, America and Japan have relaxed the conditions for compensation/subsidy for victims of vaccine injury. The US Congress passed the National Childhood Vaccine Injury Act (NCVIA) in 1986. Based on the "no-fault principle", those who suspect that they have been injured after vaccination can apply for vaccine relief. For this reason, vaccine manufacturer needs to pay tax of US$0.75 for each dose of vaccination sold. The US Federal Government has established a Vaccine Adverse Event Reporting System (VAERS) to detect adverse reactions after vaccination. On June 29, 2019, the latest Law on Vaccine Management of the People's Republic of China was passed, which started to match international standards. It also adopts the "no-fault principle", stipulating that as long as "it cannot be ruled out" it is an abnormal reaction, vaccine manufacturers or insurance systems are held for compensation".

2-2

热点疫苗产业概览
Overview of Prevailing Vaccine Industries

2-2-1
HPV 疫苗
HPV Vaccine

宫颈癌症是全球女性第四大最常见的癌症。全球每年约有 50 万妇女被新诊断为宫颈癌，每年约有 28 万患者死亡。在我国，每年新增宫颈癌病例约 13.5 万，约有 5 万人因此死亡。感染人乳头瘤病毒（HPV）是宫颈癌的主要诱因，目前已知 HPV 亚型中至少有 14 种基因型为高危型，包括 16、18 和 31、33、45、52、58 型。庆幸的是，宫颈癌是目前为止唯一能够通过接种疫苗预防的癌症。

Cervical cancer is the fourth most common cancer among women worldwide. About 500,000 women worldwide are newly diagnosed with cervical cancer every year, and about 280,000 patients die of it every year. In China, there are about 135,000 new cases of cervical cancer every year, and about 50,000 people die of it. Infection with human papillomavirus (HPV) is the main cause of cervical cancer. At present, at least 14 genotypes of HPV subtypes are known to be high-risk types, including type 16, 18 and 31, 33, 45, 52 and 58. Fortunately, cervical cancer is by far the only cancer that can be prevented by vaccination.

01
全球疫苗市场概况
Overview of the Global Vaccine Market

目前，全球已上市销售的 HPV 疫苗包括英国葛兰素史克（GSK）的二价 HPV 疫苗 Cervarix、美国默沙东（MSD）的四价 HPV 疫苗 Gardasil4 和九价 HPV 疫苗 Gardasil9，以及我国厦门万泰沧海（INNOVAX）的二价 HPV 疫苗 Cecolin。Cervarix 和 Gardasil 可预防 HPV16 和 HPV18 感染引发的宫颈癌，Gardasil 还可预防 HPV6 和 11 的感染，Gardasil9 所预防的病种包括由 HPV6、11、16、18、31、33、45、52 及 58 感染引起的宫颈癌等，具有更高的病毒型覆盖率。根据葛兰素史克和默沙东的年报，2019 年 HPV 系列疫苗全球销售额合计约 38 亿美元。厦门万泰的 2 价 HPV 疫苗 Cecolin 于 2019 年 12 月 31 日正式生产批签，针对 HPV16、18 型，适用于 9~45 岁的女性，打破了外国制药巨头的品种垄断，大大缓解了 HPV 疫苗价格高、供给少的问题。

At present, the global HPV vaccines include Cervarix, a bivalent HPV vaccine from GSK in the United Kingdom, Gardasil4, a tetravalent HPV vaccine, and Gardasil9, a 9-avalent HPV vaccine from Merck in USA, and Cecolin, a bivalent HPV vaccine from Xiamen Innovax Biotech. Cervarix and Gardasil can prevent cervical cancer caused by HPV16 and HPV18 infections. Gardasil can prevent HPV6 and HPV11 infections. The diseases that Gardasil9 can prevent include cervical cancer caused by infections of HPV6, 11, 16, 18, 31, 33, 45, 52 and 58, with a wider viral coverage.

According to the annual reports of GSK and Merck, global sales of HPV vaccines totaled approximately 3.8 billion US dollars in 2019. Xiamen Innovax's bivalent HPV vaccine Cecolin was officially approved for production on December 31, 2019, which targets HPV16 and 18 for women aged from 9 to 45. Its emergence breaks up the monopoly of foreign pharmaceutical giants and greatly eases the high prices and low supply of HPV vaccines.

02
国内在研及上市 HPV 疫苗分析
Analysis of Domestic HPV Vaccines under Research and Marketed

近年来，我国 HPV 疫苗供不应求，国内销售市场规模已接近 100 亿元，是目前国内批签货值最大的疫苗大类，引领了整个二类疫苗市场的增长。

In recent years, the supply of HPV vaccines in China is in short supply, with a domestic sales demand close to 10 billion yuan. It is currently the largest vaccine category approved in China, leading the growth of the Type II vaccine market.

2017 年 5 月，默沙东 4 价 HPV 疫苗经原 CFDA 批准在国内上市；2018 年 4 月，9 价 HPV 疫苗在我国获批上市，这两款 HPV 疫苗产品均由智飞生物独家代理销售。默沙东凭借两款产品占据了国内 HPV 疫苗市场的主要份额；葛兰素史克的 2 价 HPV 疫苗 2019 年批签与 2018 年基本持平，维持在 200 万剂左右。2016-2018 年国内市场呈现明显的产品迭代趋势：4 价、9 价 HPV 替代 2 价 HPV 疫苗。Gardasil9 在我国上市后，即刻占领我国 HPV 疫苗市场的全部份额，市场渗透率快速增长，市场出现极度紧缺的局面，需要摇号或者排队预约。

In May 2017, Merck's tetravalent HPV vaccine was approved for marketing in China by the CFDA. In April 2018, 9-valent HPV vaccine was approved for marketing in China, and both HPV vaccine products were sold by Zhifei Biological as an exclusive agent. With these two products, Merck takes up a major share of the domestic HPV vaccine market. GSK's bivalent HPV vaccine approval amount in 2019 remained basically the same as in 2018, maintaining at about two million doses. From 2016 to 2018, the domestic market showed an obvious product replacement: Tetravalent and 9-valent HPV vaccines replaced bivalent HPV vaccines. GARDASIL9 immediately occupied the entire market of HPV vaccines upon its marketing in China. With the rapid market penetration rate, there was once an extreme short of products needing lottery or reservation.

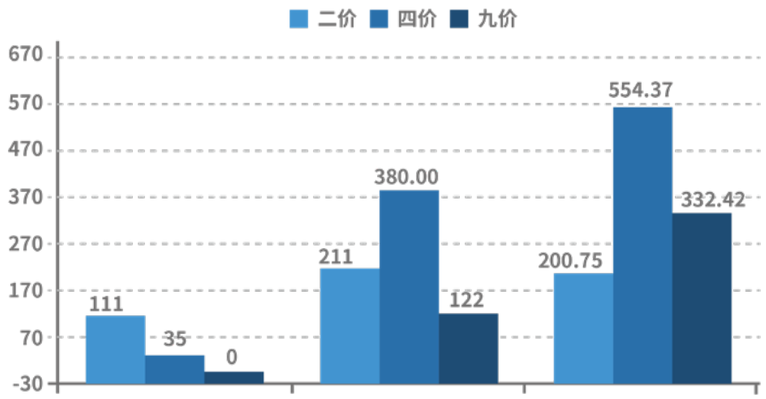


图 1 2017—2019 年我国 HPV 疫苗批签发量统计（万支）

Figure 1 Statistics of the number of HPV vaccines approved in China from 2017 to 2019 (Unit: 10,000 doses)

国内企业奋起直追，争抢国内庞大的 HPV 疫苗市场，在研 HPV 疫苗较多。2 阶疫苗方面，去年年底，厦门万泰沧海生物技术有限公司的馨可宁（Cecolin）作为首个国产 2 价 HPV 疫苗获批上市；2020 年 6 月 15 日，沃森生物控股子公司上海泽润生物提交的重组人乳头瘤病毒双价（16/18 型）疫苗（酵母）上市申请获得国家药监局受理；3 价 HPV 方面，康乐卫士已完成 II 期临床；9 价 HPV 疫苗临床企业较多，博唯于 2020 年 4 月进入 III 期临床，厦门万泰和康乐卫士进入临床II期，沃森生物正在进行I期临床试验；成都生物制品研究所等联合申报的 11 价 HPV 疫苗也已开始临床试验。2020 年 6 月 8 日，厦门大学国家传染病诊断试剂与疫苗工程技术研究中心夏宁邵、李少伟团队构建了一种能够针对多种型别人乳头瘤病毒同时产生保护效果的“杂合病毒样颗粒”，有望研制出对 200 多种型别 HPV 全覆盖的新型多价 HPV 疫苗，对宫颈癌、皮肤疣的预防效能进一步向 100% 迈进。

Domestic companies are endeavoring to catch up and compete for the huge HPV vaccine market in China, and many HPV vaccines are under development in China. Regarding second-tier vaccines, at the end of last year, Cecolin developed by Xiamen INNOVAX, as the first domestic second-tier vaccine was approved to be listed on the market.on June 15, 2020, the application for the marketing of the recombinant human papillomavirus bivalent (type 16/18) vaccine (yeast) submitted by Shanghai Zerun Biotechnology, a subsidiary of Walvax Biotechnology, was accepted by the National Medical Products Administration. Regarding trivalent HPV, Kangle Weishi has completed Phase II clinical trial. There are a large number of enterprises engaged in 9-valent HPV vaccine clinical trial. Bovax has entered the Phase III clinical trial in April 2020, Xiamen Innovax and Kangle Weishi have entered the Phase II clinical trial, and Walvax Biotechnology has entered the Phase 11 clinical trials. The 11-valent HPV vaccine jointly declared by Chengdu Institute of Biological Products and other institutions has also started clinical trials. On June 8, 2020, the team lead by Xia Ningshao and Li Shaowei from the Research Center for National Infectious Diseases Diagnostic Reagent and Vaccine Engineering Technology of Xiamen University constructed a "hybrid virus-like particle" that can combat multiple types of other papillomaviruses while producing some protective effects. It is expected to develop a new multivalent HPV vaccine that fully covers more than 200 types of HPV for the prevention of cervical cancer and skin warts with a final goal of 100% coverage.

2-2-2

新冠病毒疫苗

COVID-19 Vaccine

01 全球研发概况

Overview of Global R&D

根据世界卫生组织（WHO）的统计，新冠治疗药物与疫苗的研发数量与疫情在全球的扩散正相关。美国、英国和中国的新冠疫苗研发进展最快。

According to statistics from the World Health Organization (WHO), the number of R&D of new coronavirus therapeutic drugs and vaccines is positively correlated with the spread of the epidemic worldwide. The development of new coronavirus vaccines in the United States, the United Kingdom and China is taking the lead.

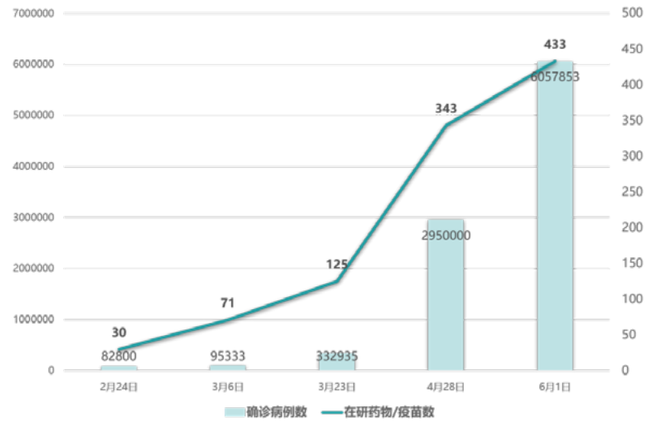


图 2 全球新冠疫情和在研药物与疫苗的增长

Figure 2 The global new coronavirus epidemic status and the growth of drugs and vaccines under development

在截至 6 月 1 日的 115 款在研新冠病毒疫苗中，有 13 款处于临床试验阶段，包括 2 款处于 II 期临床试验、3 款处于 I/II 期、8 种处于 I 期，其余的 101 款疫苗处于临床前研究或发现阶段。

Of the 115 COVID-19 vaccines under development as of June 1, 13 are in clinical trials, including two in phase II clinical trials, three in phase I/II, eight in phase I, and the remaining 101 in the pre-clinical research or discovery.

进度最快的候选疫苗处于 II 期临床试验，包括康希诺生物（CanSino）的 Ad5-nCoV 和 Moderna Therapeutics Inc 的 mRNA-1273。虽然大多数临床数据预计要到 2021 年才能获得，但康希诺生物的 Ad5-nCoV 和 BioNTech 公司处于 I/II 期的 BNT-162 应该会在 2020 年读出数据。

The fastest candidate vaccines in Phase II clinical trials include Ad5-nCoV from CanSino and mRNA-1273 from Moderna Therapeutics Inc. Although it is expected that most clinical data will not be available until 2021, Ad5-nCoV from CanSino and BNT-162 Phase I/II trials from BioNTech's should be able to generate readable data in 2020.

4 月 3 日，InovioPharmaceuticals Inc 的 INO-4800 进入 I 期临床试验，并计划在 2020 年夏季开始 II/III 期试验。其他处于 I 期试验的疫苗包括 Novavax 公司的 NVX-CoV2373、深圳市免疫基因治疗研究院的 aAPC 疫苗、科兴生物和 Dynavax Technologies 使用 CpG 1018 佐剂的一款疫苗，以及 Symvivo 公司的 bacTRL-Spike 疫苗。

On April 3, INO-4800 from Inovio Pharmaceuticals Inc. entered Phase I clinical trial, and it plans to start Phase II/III trials in the summer of 2020. Other vaccines in Phase I trials include NVX-CoV2373 from Novavax, aAPC vaccine from Shenzhen Geno-immune Medical Institute, a vaccine using CpG 1018 adjuvant adopted by Sinovac Biotech and Dynavax Technologies, and bacTRL-Spike vaccine from Symvivo.

Reithera Srl、Leukocare AG 和 Univercells SA 三方合作，计划在 2020 年 6 月使其腺病毒载体疫苗进入 I/II 期试验。其他接近临床的疫苗包括 Intellistem Technologies Inc 的 IPT-001，它将于 2020 年 9 月进入 I 期试验。赛诺菲和 GSK 的佐剂重组亚单位疫苗预计于 2020 年下半年进入 I 期试验。

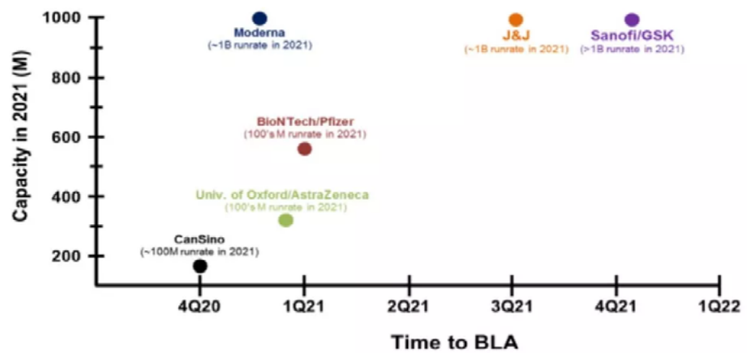


图 3 新冠病毒疫苗上市申请提交时间及产能预估

Figure 3 COVID-19 vaccine marketing application submission time and production capacity forecast

Reithera Srl, Leukocare AG and Univercells SA plan to jointly enter the Phase I/II trial of adenoviral vector vaccine in June 2020. Other close-to-clinical vaccines include IPT-001 from Intellistem Technologies Inc., which will enter phase I trials in September 2020. The adjuvant recombinant subunit vaccines of Sanofi and GSK are expected to enter Phase I trials in the second half of 2020.

02
NIH 推出 ACTIV 合作计划，加速研发速度
NIH Launches ACTIV Cooperation to Speed up R&D

美国 NIH 于 4 月启动了一个协调多种疫苗临床试验的合作项目，即 ACTIV（Accelerating COVID-19 Therapeutic Interventions and Vaccines）公私伙伴关系。该项目的内容包括使用共同的临床试验设计、相同的临床终点、标准化的免疫分析和共同的数据安全要求及监管委员会，以便能透明地评估每种疫苗的相对有效性。当前，美国疫苗的主要研发方向包括重组蛋白疫苗、病毒载体疫苗以及核酸疫苗等。

In April, NIH from US launched a collaborative project with the coordination of clinical trials of multiple vaccines, namely a public-private partnership called ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines). The project includes the use of common clinical trial designs, the same clinical endpoints, standardized immunoassays, and common data security requirements and regulatory committees, so that the relative effectiveness of each vaccine can be openly evaluated. At present, the main R&D directions of vaccines in the US include recombinant protein vaccines, viral vector vaccines and nucleic acid vaccines.

Moderna、BioNTech/Pfizer、CuraVac（基于 mRNA）和 Inovio（基于 DNA）等公司正在开发基于核酸的疫苗。此类疫苗可以在病毒序列的基础上快速生成，因而能够较快进入临床阶段。然而，尽管科学界在核酸疫苗临床早期阶段有较多的经验积累，但迄今暂无一种核酸疫苗获得大范围的使用许可。

Companies such as Moderna, BioNTech/Pfizer, CuraVac (based on mRNA) and Inovio (based on DNA) are developing nucleic acid-based vaccines. Such vaccines can be quickly generated on the basis of viral sequences, and thus they can enter the clinical stage quickly. However, despite the experience accumulation in the scientific community in the early clinical stage of nucleic acid vaccines, no nucleic acid vaccine has so far obtained a license for scaled use.

赛诺菲公司、Novavax 公司正在开发的疫苗采用传统重组蛋白技术表达刺突蛋白，虽然这种疫苗从研发至生产的时间较核酸疫苗长，但人们已从乙肝疫苗、带状疱疹疫苗和流感疫苗中积累了丰富的商业经验。不过，蛋白疫苗所需的某些佐剂可能供应不足。

The vaccines being developed by Sanofi and Novavax use traditional recombinant protein technology to express spike protein. Although it takes longer to develop this type of vaccine than nucleic acid vaccines, people have accumulated rich business experience from hepatitis B vaccine, herpes zoster vaccine and influenza vaccine. However, some adjuvants needed for protein vaccines may fall in short supply.

病毒载体疫苗将受关注的病毒基因编码装进几个具有良好表征的载体之一，包括腺病毒（Ad）和水泡型口炎病毒（VSV）。强生公司正在开发针对 COVID-19 的 rAd26。由牛津大学和阿斯利康公司开发的重组黑猩猩 Ad 载体（ChAdOx1）也进入了临床试验。

The viral vector vaccine encodes the viral gene code of interest into one of several well-characterized vectors, including adenovirus (Ad) and vesicular stomatitis virus (VSV). Johnson & Johnson is developing rAd26 for COVID-19. The recombinant chimpanzee Ad vector (ChAdOx1) developed by Oxford University and AstraZeneca has also entered clinical trials.

03
中国 5 条技术路线并进
Five Technical Routes under Parallel Development in China

根据 2020 年 6 月 18 日的消息，我国已有四种灭活疫苗和一种腺病毒载体疫苗获批开展临床试验。5 月 22 日，《柳叶刀》发表了军事医学研究院陈薇院士等研制的重组腺病毒 5 型载体新冠疫苗的人体试验临床数据结果，一期临床志愿者全部有显著的细胞免疫反应，这是世界首个新冠疫苗的人体临床数据。6 月 16 日，全球首个新冠灭活疫苗Ⅰ/Ⅱ期临床揭盲，中国生物武汉生物制品研究所研制疫苗的接种者均产生高滴度抗体，18-59 年龄组 0，28 天目标剂量两针接种阳转率 100%，且无严重不良反应。中国生物还率先建成了目前全球唯一符合生物安全和 GMP 标准、从数量上能够满足紧急接种需求的新冠疫苗生产车间。

According to the news released on June 18, 2020, four inactivated vaccines and one adenovirus vector vaccine have been approved for clinical trials in China. On May 22, The Lancet published the clinical data of human trials of a recombinant adenovirus Type 5 vector new coronavirus vaccine developed by Academician Chen Wei of Academy of Military Medical Sciences. There have been significant cellular immune responses among all clinical volunteers in the first phase. This is the first human clinical data of new coronavirus vaccine in the world. On June 16, the world's first new coronavirus inactivated vaccine phase Ⅰ/Ⅱ was disclosed. Vaccines developed by the Wuhan Institute of Biological Products in China all produced high-titer antibodies. The positive rate of two injections of target dose on day 0 and day 28 reached 100% for the 18-59 age group without serious adverse reactions. China National Biotech Group also took the lead in building the world's only new coronavirus vaccine production workshop that meets biosafety and GMP standards and the needs of emergency vaccination in large quantity.

厦门大学、四川大学、清华大学、北京大学、复旦大学等高校科研团队，重点从流感病毒载体疫苗、重组蛋白疫苗、核酸疫苗三条技术路线并行推进，协同加快开展新冠肺炎疫苗攻关。

Scientific research teams from Xiamen University, Sichuan University, Tsinghua University, Peking University, Fudan University and other universities presently focus on the parallel advancement of three technical routes, including influenza virus vector vaccine, recombinant protein vaccine, and nucleic acid vaccine, and jointly accelerate the development of new coronavirus vaccine.

2-3

疫苗领域企业概览
Overview of Vaccine Companies

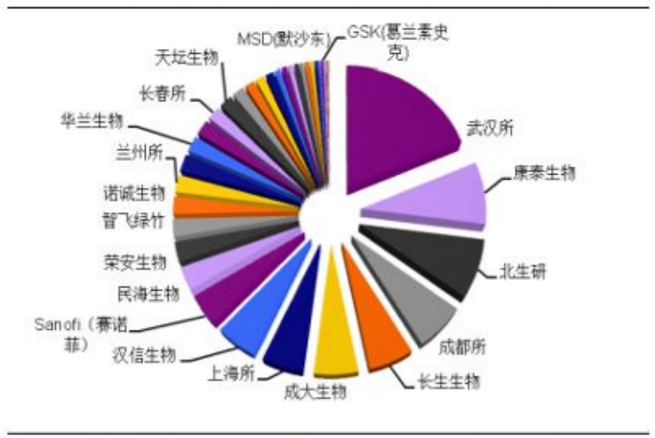
2-3-1
国内
Domestic Companies

与国际上疫苗产业 CR4（CR4 是行业前四名份额集中度指标，可以对产业的竞争和垄断程度分类研究）高达 90% 形成鲜明对比，截止 2018 年中国有疫苗批签发记录的企业共 59 家，格局非常分散。这与中国疫苗产业进入市场化阶段仅短短 20 年时间有关。

In stark contrast to the CR4(CR4 are the top four indicators of share concentration in the industry, which can be used to classify the degree of competition and monopoly) as high as 90% in the international vaccine industry, as of 2018, there were a total of 59 companies that had a record of vaccine approval in China. This is due to the fact that it was only the 20th year since Chinese vaccine industry first joined the market economy.

资本放开后，民营企业纷纷涉足疫苗领域，2000-2010 年间，中国疫苗企业的数量从不到 10 家猛增到 46 家，尤其 2012-2013 年左右，21 世纪整个世纪进入的民企获得的产品批文、行业批签发数量激增，但大部分企业只有单一产品的批签发，重复生产的情况严重。

Upon the market's opening to capital, private companies got involved in the development of vaccines. From 2000 to 2010, the number of Chinese vaccine companies increased from less than 10 to 46. Especially around 2012 and 2013, the number of private companies set up after year 2000 which obtained product approvals and industry approvals increased sharply. However, most companies only obtained single product approval, and repeated production was very serious.

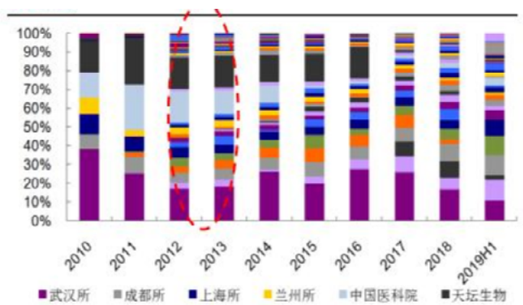


资料来源：中检院，光大证券研究所

图 4 2018 年中国疫苗市场格局
Figure 4 China's vaccine market structure in 2018

国内一类苗生产商主要以国企为主，中国生物下属七大所（北京、上海、武汉、成都、长春、兰州、昆明）占据国内超过 70% 的份额，垄断着全国疫苗的供应体系，主要以卡介苗、脊髓灰质炎疫苗、百白破疫苗、麻疹疫苗为主。二类苗市场中，民营企业是主力军，占据约 65% 的市场份额。水痘疫苗和狂犬疫苗等大品种的市场均由民企主导。

The domestic Type I vaccines are mainly produced in state-owned enterprises, and the seven major institutes under China National Biotech Group (Beijing, Shanghai, Wuhan, Chengdu, Changchun, Lanzhou, Kunming) accounted for more than 70% of the domestic share, monopolizing the national vaccine supply system, with main products of BCG vaccine, polio vaccine, DPT vaccine, and measles vaccine. In the Type II vaccine market, private enterprises are the main force, accounting for about 65% of the market. The market for major varieties such as chickenpox vaccine and rabies vaccine is dominated by private enterprises.



资料来源：中检院，光大证券研究所（共 59 家，家数较多，仅列举 2010 年前 6 家）

图 5 2010-2019H1 国内疫苗企业竞争格局（按批签发数量）

Figure 5 Competition of domestic vaccine companies from 2010 to 2019H1 (based on the number approved)

研发储备丰富的平台型疫苗龙头企业，或具有较强创新实力、专注于护城河更高的国内创新疫苗企业如下：

The leading vaccine platform companies with rich R&D capacity, or domestic innovative vaccine companies with strong innovation strength and with focus on high moat are as follows:

中国生物技术股份有限公司——一类疫苗龙头企业

China National Biotech Group Co., Ltd. – a Type I Leading Vaccine Enterprise

中国生物技术股份有限公司为卫生部直属，现为世界 500 强中国医药集团有限公司的重要成员企业。中国生物下辖 11 个二级子公司和 69 家二级以下子公司，员工 10663 人。公司拥有丰富的产品线，覆盖人用疫苗、血液制品、医学美容、动物保健、抗体药物、医学诊断六大生物制品领域。

China National Biotech Group Co., Ltd. is an important member enterprise of China National Pharmaceutical Group Co., Ltd. (Sinopharm), a China top 500 company directly under the Ministry of Health. There are 11 secondary subsidiaries and 69 sub-secondary subsidiaries under China National Biotech Group, with 10,663 employees. The company has complete product lines covering six major biological products, including human vaccines, blood products, medical cosmetology, animal healthcare, antibody drugs, and diagnosis.

智飞生物——自主微卡即将上市，代理护城河极高

Zhifei Biological-The self-owned mycobacterium vaccae vaccine to be marketed soon with extremely high agent moat

智飞生物成立于 1995 年，在 2002 年进入生物制品行业，并于 2010 年登陆创业板，是国内首家在创业板上市的民营疫苗企业。公司自产 + 代理双轮驱动，重磅产品推升业绩高速增长；HPV 疫苗终端供销两旺，市场空间有望超 300 亿；最强学术推广渠道构建公司核心优势，公司多年来始终重视自主销售队伍的建设，是国内唯一拥有自建学术推广团队的疫苗企业；预防用微卡、EV71、15 价肺炎疫苗等自研重磅新品有望接力。

Founded in 1995, Zhifei Biological entered the biological products industry in 2002 and was listed on GEM (Growth Enterprises Market) in 2010. It is the first private vaccine company listed on GEM in China. The company has a dual drive of self-production + agent, and it blockbuster products promote its rapid growth of performances. With the booming both on the supply and sales terminals in HPV vaccines, it is expected with a trade volume over 30 billion yuan. The company’s core advantage lies in its strongest academic promotion channels. For many years, the company has attached importance to the construction of its independent sales team, and it is the only domestic vaccine company with a self-built academic promotion team. Its self-developed major new products such as preventative mycobacterium vaccae vaccine, EV71, and 15-valent pneumonia vaccine are expected to be launched one after another.

康希诺生物——全球视野、中国创新的疫苗新秀

CanSino - China's Innovative Vaccine Rookie with a Global Vision

康希诺是一家集研发、生产和商业化为一体的，高质量、创新型疫苗企业，公司创始于 2009 年，2019 年 3 月在港股上市。重磅创新疫苗埃博拉病毒疫苗受瞩目，在研创新疫苗 15 种。公司的明星产品是埃博拉病毒疫苗，该产品是我国独立研发、具有完全自主知识产权的重磅创新性重组疫苗，于 2017 年 10 月在中国获批上市。除此以外，公司在肺炎、结核病、埃博拉病毒病、脑膜炎、百白破等 12 个疾病领域在研 15 种疫苗产品。

CanSino is a high-quality innovative vaccine enterprise integrating R&D, production and commercialization. The company was founded in 2009 and was listed on Hong Kong stocks in March, 2019. Its blockbuster innovative vaccine for Ebola virus has attracted wide attention, and 15 innovative vaccines are under development in the company. The company's star product is the Ebola virus vaccine, which is a blockbuster innovative recombinant vaccine independently developed in China with complete independent intellectual property rights, which was approved for marketing in China in October, 2017. In addition, the company is working on 15 vaccine products in 12 disease areas including pneumonia, tuberculosis, Ebola virus disease, meningitis, and DPT.

康泰生物——国内研发储备最为丰富的疫苗企业

Bio Kangtai-A Vaccine Company with the Richest R&D Reserves in China

康泰生物是我国疫苗龙头企业之一，也是国内最大的乙肝疫苗生产企业。现有默沙东引进的重组乙型肝炎疫苗，已成为我国最大的乙肝疫苗生产企业。在售产品包括乙肝疫苗、Hib 疫苗、麻风二联苗、四联苗，另外 23 价肺炎球菌多糖疫苗已获得生产批件，正在向中检院申请批签发。公司研管线包括人二倍体狂犬疫苗、13 价和 23 价肺炎多糖结合疫苗等近期即将上市的重磅品种。此外，在研品种中 EV71 疫苗市场潜力巨大，60μg 乙肝疫苗及新型佐剂乙肝疫苗有望占据一席之地。另外，公司正在进行 60μg 鼻腔喷雾型乙肝疫苗的临床前研究。

Bio Kangtai Biology is one of the leading vaccine companies in China and the largest hepatitis B vaccine manufacturer in China. With recombinant hepatitis B vaccine introduced from Merck, it has become the largest hepatitis B vaccine manufacturer in China. Presently, products available from the company include hepatitis B vaccine, Hib vaccine, combined and quadruple vaccines for leprosy, and its 23-valent pneumococcal polysaccharide vaccine has been approved for production, waiting for the marketing approval from National Institutes for Food and Drug Control. The company's research pipelines include human diploid rabies vaccine, 13-valent and 23-valent pneumonia polysaccharide conjugate vaccines and other blockbuster products to be launched in the near future. In addition, the market potential of EV71 vaccine, one of the company’s varieties under development, is expected with huge market potential, and its 60μg hepatitis B vaccine and new adjuvant hepatitis B vaccine are expected to take a considerable share in the market. Moreover, the company is conducting a preclinical study of 60 μg nasal spray hepatitis B vaccine.

沃森生物——多年研发积淀，大品种即将上市

Walvax Biotechnology-Years of R&D Achievements with Blockbuster Products Marketing Expected

沃森生物成立于 2001 年，于 2010 年 11 月在创业板上市。在以新型疫苗领域处于行业领先地位。公司主要上市销售产品包括 Hib 疫苗、AC 结合疫苗、AC 多糖疫苗、ACYW135 多糖疫苗、百白破疫苗以及 2017 年刚上市的 23 价肺炎疫苗。过去十年累计投入研发 17.27 亿元，两大重磅品种上市在即。公司是国产 13 价肺炎疫苗进展最快的厂家之一，有望成为国内第一家获批。2 价 HPV 同样也是国内进展最快的厂家。此外，公司还布局 9 价 HPV 疫苗、治疗用 HPV16 疫苗、EV71 疫苗、四价流感裂解疫苗等多个疫苗大品种。

Walvax Biotechnology was established in 2001 and listed on GEM in November, 2010. It plays a leading role in the industry in new vaccine development. The company's main products marketed for now include Hib vaccine, AC conjugate vaccine, AC polysaccharide vaccine, ACYW135 polysaccharide vaccine, DPT vaccine, and a 23-valent pneumonia vaccine launched in 2017. Over the past decade, it has invested a total of 1.727 billion yuan in R&D, and its two blockbuster products are expecting marketing soon. The company is one of the fastest growing manufacturers of domestic 13-valent pneumonia vaccine, and is expected to become the first domestic company of successful approval. It is also the fastest growing manufacturer in China for bivalent HPV. In addition, the company has planned a number of major vaccines such as 9-valent HPV vaccine, therapeutic HPV16 vaccine, EV71 vaccine, and tetravalent influenza split vaccine.

2-3-2

国外

Foreign Companies

全球疫苗市场经过多年整合，四大疫苗巨头葛兰素史克、默沙东、辉瑞和赛诺菲几乎垄断全球疫苗市场，行业集中度颇高。2017 年，葛兰素史克、默沙东、辉瑞、赛诺菲分别占据全球市场 24%、23.6%、21.7%、20.1% 的份额，合计垄断约 90% 的市场。尽管过去几年间，全球前四大疫苗企业之间的排名会随着新品种放量而略有变化，但总体上前 4 家地位长期稳固。

After years of integration in the global vaccine market, the four vaccine giants GlaxoSmithKline, Merck, Pfizer and Sanofi have almost monopolized the global vaccine market, leading to a high industry concentration. In 2017, GSK, Merck, Pfizer, and Sanofi accounted for 24%, 23.6%, 21.7%, and 20.1% of the global market respectively, monopolizing about 90% of the market. Although the ranking among the world's top four vaccine companies changed slightly with the increase of new products in the past few years, the top four as a whole have taken a lead for a long time.

在 2000 年之前，由于疫苗研发周期长、投入资金多、风险高，且不具有慢病治疗型药物长期使用的特点，大部分制药企业投资疫苗的积极性并不高。约在 2005 年以后，葛兰素史克、辉瑞、赛诺菲、强生、雅培等大型医药企业通过兼并收购等方式纷纷进入疫苗市场，从而推动了疫苗行业的新兴发展。

Prior to 2000, most pharmaceutical companies were not enthusiastic about investing in vaccines because of the long cycle of vaccine development, large investment, high risks, and the lack of long-term use like drugs for the treatment of chronic diseases. After about 2005, large pharmaceutical companies such as GSK, Pfizer, Sanofi, Johnson & Johnson, Abbott, etc. entered the vaccine market through mergers and acquisitions, which promoted the booming of vaccine industry.

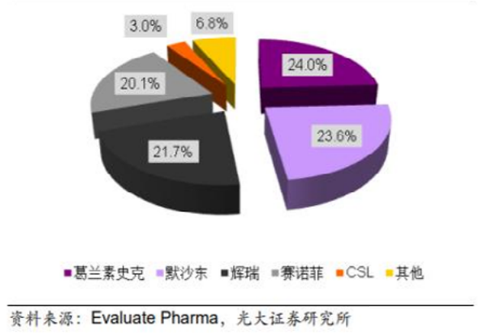


图 6 2017 年全球疫苗市场格局（销售额）
Figure 6 Global vaccine market structure in 2017 (sales volume)

疫苗新贵 CSL 最早是澳洲的本土制药企业，于 2015 年以 2.75 亿美元收购了诺华的流感疫苗业务，从而进入疫苗行业。2011 年诺华收购了浙江天元股权，以拓展中国疫苗市场。

Vaccine upstart CSL was the first local pharmaceutical company in Australia. In 2015, it acquired influenza vaccine business of Novartis for 275 million US dollars, which provided it with access to the vaccine industry. In 2011, Novartis acquired the equity of Zhejiang Tianyuan Co., Ltd. to expand its vaccine market share in China.

四大疫苗巨头在疫苗领域的简况如下：

The four vaccine giants in the vaccine can be briefed as follows:

01 葛兰素史克（GSK）

GlaxoSmithKline (GSK)

葛兰素史克是全球大疫苗公司之一，每年为 173 个国家提供疫苗超过 11 亿剂，帮助儿童和成人提供预防一系列的传染性疾病，如甲型和乙型肝炎、白百破、麻腮风、小儿麻痹、伤寒、流感和细菌性脑膜炎等，在中国上市的疫苗主用于预防甲肝、乙肝、水痘、麻腮风、流感、白百破等。

GSK is one of the world's largest vaccine companies, providing more than 1.1 billion doses of vaccines to 173 countries every year and helping children and adults to prevent a series of infectious diseases, such as hepatitis A and B, DPT, MMR, poliomyelitis, typhoid fever, influenza, bacterial meningitis, etc. Its vaccines marketed in China are mainly used to prevent hepatitis A, hepatitis B, chickenpox, MMR, influenza, DPT, etc.

02 默沙东（MSD）

Merck

默沙东享有“世界上最伟大的疫苗学家之家”美誉。其主要疫苗产品 HPV 疫苗加卫苗（Gardasil）每年给它带来 16-23 亿美元的收入，保持了第二畅销产品的地位。通过收购，在埃博拉病毒实验性疫苗、单克隆抗体和疫苗方面加大布局。同时，与贝勒医学院推动被忽略疾病的疫苗研发与生产。

Merck is known as "the home of the world's greatest vaccinologists". Its main vaccine product, an HPV vaccine called Gardasil, brings it 1.6 billion to 2.3 billion US dollars revenue each year, the second best-selling product in the world. Through acquisition, it enlarges it coverage in experimental vaccines and monoclonal antibodies and vaccines for Ebola virus. At the same time, it works with Baylor College of Medicine to promote the development and production of vaccines for neglected diseases.

03 辉瑞（Pfizer）

Pfizer

辉瑞疫苗产业管线的重要产品 Prevnar 13，是一款 13 价肺炎链球菌结合型疫苗，是 2009 年辉瑞在收购惠氏后将其收入囊中的，目前是全球最畅销的疫苗产品。辉瑞先后收购了 Baxter 公司和 Redvax GmbH 公司，获得 C 脑疫苗产品 Neis Vac-C、森林脑炎疫苗产品 Tico Vac 和 CMV 疫苗。2015 年 6 月，辉瑞以 1.15 亿欧元收购葛兰素史克旗下两大脑膜炎疫苗 Nimenrix 和 Mencevax，增强脑膜炎疫苗的产品线。

Prevnar 13, a major product of Pfizer's vaccine industry pipeline, is a 13-valent Streptococcus pneumoniae conjugate vaccine. It is included in Pfizer products upon acquisition of Wyeth in 2009 and is currently the world's best-selling vaccine product. Pfizer has successively acquired Baxter and Redvax GmbH, and obtained Neis Vac-C, a C brain vaccine product, Tico Vac, a forest encephalitis vaccine product, and CMV vaccine. In June 2015, Pfizer acquired two meningitis vaccines Nimenrix and Mencevax from GSK for 115 million euros to strengthen its meningitis vaccine product line.

04 赛诺菲（Sanofi）

Sanofi

赛诺菲旗下疫苗事业部赛诺菲巴斯德是世界领先的疫苗生产企业。赛诺菲巴斯德在预防流感、肺炎和儿童疾病等领域拥有创新的疫苗产品，积极参与并推进中国预防免疫事业的发展。赛诺菲于 2014 年与韩国 SK Chemical 公司合作共同开发肺炎球菌结合疫苗 (PCV)，掘金 40 亿美元的全球 PCV 市场。

Sanofi Pasteur, a vaccine branch under Sanofi, is the world's leading vaccine manufacturer. Sanofi Pasteur has innovative vaccine products in preventing influenza, pneumonia and childhood diseases, and it actively participates in and promotes China's preventive immunization. Sanofi cooperated with SK Chemical from South Korea in 2014 to jointly develop a pneumococcal conjugate vaccine (PCV), aiming for the global PCV market of four billion US dollars.

4-4

总结

Summary

疫苗研发成本不低于创新药。研发周期上，创新疫苗从概念到上市整个过程一般需要 8~12 年，与新药研发周期接近。临床数量上，疫苗临床研究规模要求在几千人甚至上万人，耗时和费用上比新药更高。研发投入上，随着已知机理的疫苗品种逐渐开发殆尽，未来新疫苗研发成本将越来越高。在此背景下，目前国内一类苗生产商主要以国企为主，中生集团下六大所和昆明所占据国内超过 70% 的份额。而二类苗市场中，民营企业是主力军，占据约 65% 的市场份额。未来，在对研发要求更高的二类疫苗领域，体制灵活、创新能力强的民营企业将更能体现优势，在成都创建中国疫苗谷的蓝图中，川内创新型疫苗研发企业将大放异彩。

The cost of vaccine R&D is no lower than that of innovative drugs. In the R&D of innovative vaccines, it usually takes 8 to 12 years from the concept formulation to actual marketing, which is close to the new drug R&D cycle. In terms of clinical quantity, vaccine clinical research requires a population of thousands or even tens of thousands of people, which is more time-consuming and costly than new drugs development. In terms of R&D investment, with the gradual exhaustion of vaccine varieties with known mechanisms, the cost of developing new vaccines will become higher and higher in the future. In this context, the current domestic Type I vaccine producers are mainly state-owned enterprises, and the six major institutes under China National Biotechnology Group and its Kunming branch take more than 70% of the domestic share. In the Type II vaccine market, private enterprises take the lead with about 65% of the market share. In the future, private companies with flexible systems and strong innovation capabilities will be able to give display to their advantages in Type II vaccines with higher requirements for R&D. In the blueprint for the creation of China's vaccine valley in Chengdu, innovative vaccine R&D companies in Sichuan are expecting a promising future.

03
深度访谈
In-depth Interview

以新型佐剂助力国产创新疫苗研发
——专访疫苗研发专家陈德祥

Promote the R&D of Domestic Innovative Vaccines Through New Adjuvants
Interview with Chen Dexiang, an expert on vaccine R&D

01

专家简介
Expert Profile

陈德祥，成都迈科康生物科技有限公司创始人、董事长兼总经理。博士毕业于美国密西西比州立大学，先后在美国辉瑞、Powder Ject 和诺华等跨国公司和国际公共卫生机构 PATH 从事疫苗开发 25 年，主持和参与了 20 多种传染病疫苗产品开发工作，其中包括已经上市的肺炎疫苗、脑膜炎疫苗、轮状病毒疫苗、流感疫苗和儿童用多联苗。在科学（Science）和自然医学（Nature Medicine）等世界一流学术期刊上发表疫苗相关的学术论文 60 多篇。

Chen Dexiang is founder, president and general manager of Chengdu MaxHealth Biotech LLC. He graduated from Mississippi State University in the United States, and has been engaged in vaccine development for 25 years in multinational companies such as Pfizer, Powder Ject, and Novartis, as well as PATH, an international public health agency. He has led and participated in the development of more than 20 infectious disease vaccine products, including marketed products such as pneumonia vaccines, meningitis vaccines, rotavirus vaccines, influenza vaccines and polyvalent vaccines for children. He has published more than 60 vaccine-related academic papers in world-class academic journals such as Science and Nature Medicine.

疫苗的研发与应用是 20 世纪公共卫生领域最伟大的成就之一，它的出现为人类预防和控制传染性疾病提供了强有力的武器。疫苗产业也凭借其良好的社会效益和经济效益逐渐成为生物医药产业中的重要分支，凸显出商业发展上的强劲势头。近两年 HPV 疫苗“一针难求”的现象，今年新冠肺炎的暴发，都使疫苗研发备受关注，国内众多药企布局待发，力图打破进口疫苗垄断，加速国产疫苗崛起。本期，我们邀请到成都迈科康生物科技有限公司（下文简称“迈科康”）创始人陈德祥博士介绍国内外疫苗产业的发展差异、我国疫苗产业发展历程、研发瓶颈以及迈科康未来的发展布局。

The development and application of vaccines is one of the greatest achievements in public health in the 20th century. It provided a powerful weapon for humans to prevent and control infectious diseases. The vaccine industry gradually became an important branch of the biomedical industry with its positive social and economic benefits, and displayed strong momentum of commercial development. With the incredible shortage of HPV vaccines in the past two years and the outbreak of COVID-19 this year, vaccine R&D became a focus of the society. Many domestic pharmaceutical companies are preparing to break the monopoly of imported vaccines and accelerate the development of domestic vaccines. In this issue, we invited Dr. Chen Dexiang, founder of Chengdu MaxHealth Biotech LLC (hereinafter referred to as "MaxHealth") to introduce the differences between domestic and foreign vaccine R&D, the history of vaccine industry in China, its R&D bottleneck, and MaxHealth's development plan.

02

谈国内外疫苗研发的差异
On the Differences in Vaccine R&D at Home and Abroad

目前国产创新多联多价疫苗品种相对稀缺，与国外差距明显，但在国家政策支持下，13 价肺炎结合疫苗、HPV 疫苗、多联苗等创新品种有望加速上市。

At present, domestically produced innovative multi-vaccine and multivalent vaccine varieties are relatively scarce, obviously falling behind developed countries. However, with the support of national policies, innovative varieties such as 13-valent pneumonia conjugate vaccine, HPV vaccine, and multivalent vaccine are expected to be marketed quickly.

谈到与国外疫苗研发的差别，陈德祥表示，国外疫苗企业数量少，规模大，市场占有率高，如葛兰素史克、辉瑞、赛诺菲、默沙东四大巨头，其市场份额占据全球疫苗市场一半以上，且地位稳固。而国内疫苗企业数量多，规模小，涉及的领域较为分散。

Regarding the difference between domestic and foreign vaccine R&D, Chen Dexiang says that foreign vaccine companies are characterized with small number, large scale and high market share. For example, the four giants, GlaxoSmithKline, Pfizer, Sanofi, and Merck, have dominated more than half of the global vaccine market, and such domination will continue in the foreseeable future. On the contrary, there are quite a number of domestic vaccine companies of small scale in China with specialization in a variety of fields.

目前，国内有 45 家疫苗生产企业，其中之前有批签发的企业有 30 余家，且普遍研发资源不集中，资金投入无法与外企相比，受制于市场需求其长线布局缺乏战略眼光。此外，我国在疫苗领域具有自主研发能力的企业较少，同质化产品较多，管线布局不够深入。

At present, there are 45 vaccine manufacturers in China, of which more than 30 have received batch approval of vaccines. The R&D resources among these companies are not concentrated, and their investment is by no means comparable with foreign companies. Subject to market demand, they can hardly form strategies for long-term development. In addition, in China, there are very few companies with independent R&D capabilities in vaccines, accompanies by homogenized products and insufficient pipeline plan.

反观国外，新型疫苗研发成果往往诞生于研究院、高校等前沿机构，其独创性研究成果受资本青睐。因此，企业在进行此类成果转化时，不缺资金注入。而我国的投资环境与国外不同，这类创新型成果的独创性虽强，但投资伴随的风险也极大，难以吸引国内投资者的目光。

On the contrary, new vaccine R&D results in foreign countries are often born in frontier institutions such as academies and universities, where their original research results are favored by investment funds. Therefore, companies do not face the lack of funds when transforming such achievements. But the investment environment in China is different. Despite the competitive originality of some innovative achievements, the risks associated with investment are also extremely high, which make it hard to attract domestic investors.

03

谈国内疫苗产业的发展历程

On the Development of Domestic Vaccine Industry

陈德祥谈到，我国疫苗产业化发展从建国以来到现在主要经历了三个阶段。第一阶段，在国家计划经济的大环境下，经过政府布局，划分区域在全国范围内建有 6 家国营疫苗研究所，其职责是辐射辖区，解决免疫需求。我国的疫苗产业就此起步。第二阶段始于 80 年代后期，延伸至 2010 年左右。这一阶段，在原疫苗销售代理机构的资金支持下，大批民营医疗企业出现，以原国有疫苗企业的人才和技术为生产力，分割国内疫苗市场。2010 年后，我国步入第三阶段，也就是疫苗产业发展的黄金阶段，国内外许多具备疫苗研发能力的专家纷纷涌现，他们带领的疫苗研发团队不仅自身研发能力接轨国际，其丰富的研发经验和超前的发展理念都为国内疫苗产业注入了活力，缩小了我国与国际水平之间的差距。

Chen Dexiang says that the vaccine industrialization in China has mainly gone through three stages since the founding of the People's Republic of China. In the first stage, with national planned economy, government designated six state-owned vaccine research institutes in different areas in the country, and their responsibility was to serve the surround jurisdiction area with immunization needs. That was the beginning of the vaccine industry in China. The second stage started in the late 1980s and lasted to around 2010. At this stage, with the financial support to these vaccine agents, a large number of private medical companies emerged. Backed up by the talents and technology from the former state-owned vaccine companies, they took a considerable share of the domestic vaccine market. The third stage came after 2010, which is considered the golden stage of vaccine industry development. Experts who have been engaged in vaccine-related technology R&D abroad for many years return to China with world-leading research achievements. Vaccine R&D teams under their leadership not only match international standards in terms of R&D capacity, but also their rich R&D experience and advanced concepts inject vitality into the domestic vaccine industry and narrow the gap between China and developed countries.

统计数据显示，100 个疫苗项目从进入临床前阶段到获批上市，能研发成功的仅一两个。其中，进入临床阶段的项目成功率仅有 10%，在最关键的临床三期试验中，高达 50% 的项目遭遇失败。同时，疫苗从立项到产品进入市场的周期较长——平均不低于 10 年，成本高——平均资金投入不低于 5 亿人民币，可见疫苗研发难度巨大，考验着投资者的魄力和耐心。我国疫苗产业要真正接轨国际水平，仍需后劲十足地奋力追赶。国内疫苗管线中，肺炎结合疫苗在十余年前已有外企产品登陆市场，HPV 疫苗则出现在 10 年前，而国产产品时至近日才终于上市。

Statistics show that of 100 vaccine projects starting from preclinical stage, only one or two can be successfully approved for marketing. Among them, the success rate of projects entering the clinical stage is only 10%, and in the most critical Phase III clinical trials, up to 50% of the projects fail to pass. At the same time, the cycle from the establishment of the vaccine project to the actual marketing is long—no less than 10 years on average. In addition, it involves high cost—the average investment is no less than 500 million yuan, which shows that vaccine R&D is extremely difficult and it is a trial on the courage and patience of investors. It takes a lot of efforts and a long way for vaccine industry in China to catch up before it can truly conform to the international level. In the domestic vaccine pipelines, foreign-invested companies had their pneumonia-conjugated vaccines marketed more than ten years ago, HPV vaccines emerged 10 years ago, and domestic products in the true sense were not marketed until recent days.

国内外差距逐步在缩小。今年，GSK 的老年带状疱疹疫苗在国内获批上市，陈德祥预计，国产产品有望可在 5 年内投入市场。我国的疫苗研发能力一直在不断提升，追赶国际产品上市的步伐也从未松懈，陈德祥表示，未来国产产品和国外产品同步上市已不是奢望。

The gap between domestic and international development of vaccines is gradually narrowing. This year, GSK's old-age shingles vaccine was approved for marketing in China. Chen Dexiang predicts that domestic products are expected to be marketed within five years. The vaccine R&D capabilities in China have been continuously improving, and its pace of catching up with international product marketing has never slowed down. Chen Dexiang says that in the future, it should not be a surprise when domestic products and foreign products are concurrently marketed.

04

谈新型佐剂技术助力疫苗研发

On Promotion of Vaccine R&D Through New Adjuvant Technology

谈到目前疫苗研发的技术瓶颈时，“疫苗佐剂”这一术语反复出现在陈德祥口中。随着常规性疫苗技术的探究已足够深入，现在剩下的技术瓶颈都是难啃的骨头。疫苗佐剂是一种化学或生物的材料，作为辅料添加在疫苗中，对疫苗的有效性起着关键作用，如常用的氢氧化铝佐剂。

Regarding the current technical bottlenecks in vaccine R&D, the term "vaccine adjuvant" is repeated by Chen Dexiang. As the conventional vaccine technology has explored deep enough, the remaining technical bottlenecks are hard to break. Vaccine adjuvant is chemical or biological material, which is added as supplementary material to the vaccine and plays a key role in the effectiveness of the vaccine, such as the commonly used aluminum hydroxide adjuvant.

迈科康以新型佐剂为核心技术，开发了一款新冠肺炎疫苗佐剂，现已供给 8 家疫苗公司进行临床前评价。从实验结果来看，新型佐剂表现出两大优势：第一，佐剂的加入可以减少新冠病毒抗原的用量，大幅提升应急疫苗的产能；第二，新型佐剂的添加显著提升疫苗免疫效果，减少接种次数，对于新发突发传染病的控制至关重要。

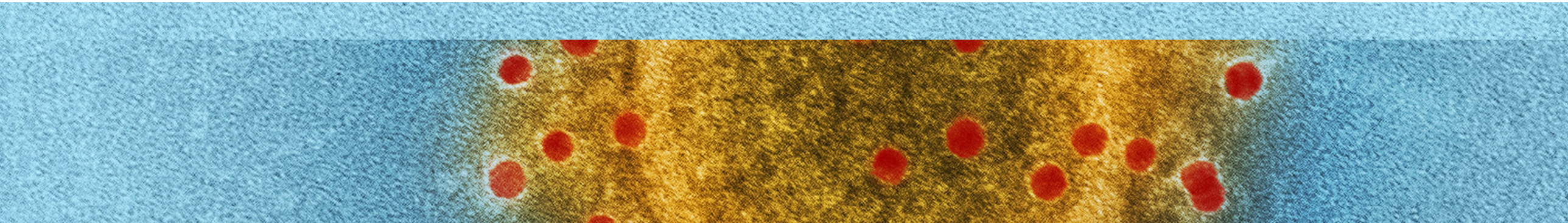
MaxHealth has developed a COVID-19 vaccine adjuvant based on its core technology of a new adjuvant, and has now provided eight vaccine companies for preclinical evaluation. Based on the experimental results, the new adjuvant shows two major advantages: First, the addition of adjuvants can reduce the amount of new coronavirus antigens and greatly increase the production capacity of emergency vaccines. Second, the addition of this new adjuvant can significantly improve the vaccine immunity effect and reduce the number of vaccinations, which is essential for the control of emerging and unexpected infectious diseases.

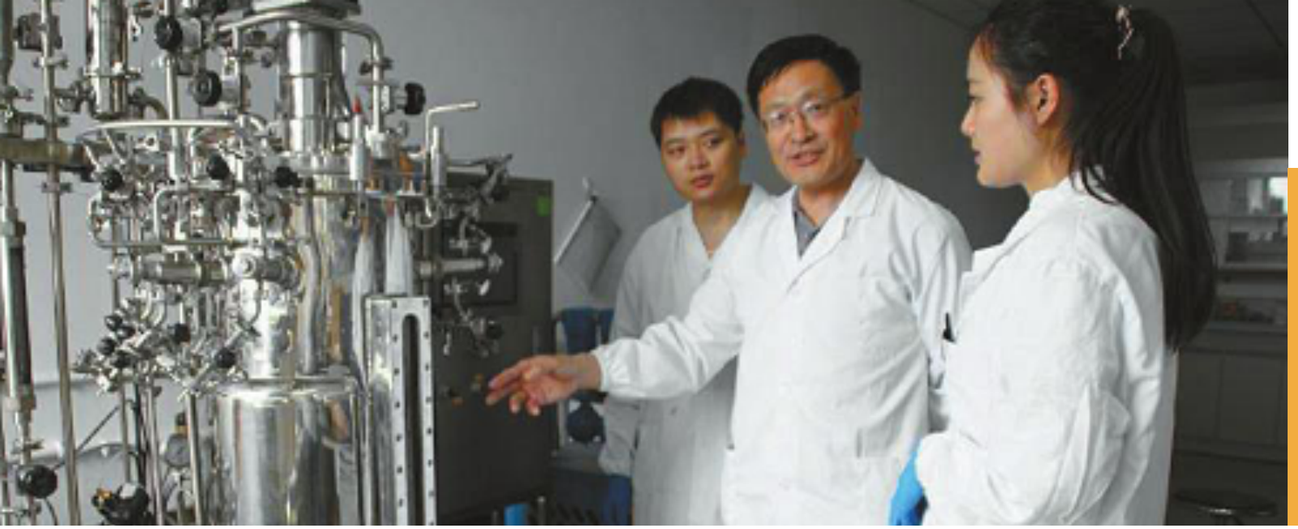
目前，国产疫苗鲜少使用新型佐剂，而在国外约有 10 种疫苗已使用新型佐剂。部分原因在于我国过去药监管理相对保守，未出台相应的指导和鼓励政策促进新型佐剂的开发和使用。并且，从事新型佐剂研发工作的企业在国内寥寥无几，产品市场几乎为空白。时至今日，国家开始鼓励基于新型佐剂的疫苗开发工作，目前已有新型佐剂疫苗申报临床试验成功。

At present, domestic vaccines rarely use new adjuvants, while about 10 vaccines abroad have adopted new adjuvants. Part of the reason is that the drug regulation in China was relatively conservative in the past, and corresponding guidance and incentive policies have not been issued to promote the development and use of new adjuvants. Moreover, there are very few companies engaged in the R&D of new adjuvants in China, and thus the market is almost blank. Today, China has begun to encourage the R&D of vaccines based on new adjuvants, with successful clinical trials of new adjuvant vaccines.

佐剂技术在助力创新疫苗的研发中，助力巨大，可作为带动创新和产业化潜力的平台。陈德祥对迈科康领先国内并接轨国际的核心佐剂技术信心十足，同时他也相当重视和川内企业的协作创新，如凡诺西、安特金等企业，希望以迈科康的佐剂核心技术，助力成都打造全国疫苗研发创新和产业化基地，促进国内疫苗行业的发展。

Adjuvant technology is a huge help in the R&D of innovative vaccines, and can be used as a platform to drive innovation and industrialization potential. Chen Dexiang has full confidence in the core adjuvant technology of MaxHealth for its domestic leading role and its conformity to international standards. He also attaches great importance to the collaborative innovation with enterprises in Sichuan such as FANXI Biopharma and Antejin Biotech. He hopes to help Chengdu build a national vaccine R&D innovation and industrialization base with MaxHealth's core adjuvant technology, and to promote the development of the domestic vaccine.





04
企业风采
Corporate Style

05

谈迈科康的发展布局
On the Development Plan of MaxHealth

2017 年，陈德祥先后在国内一二线城市进行了多次考察，最后选择将迈科康落户成都。在陈德祥看来，成都医药产业化的生态环境良好，成都高新区对创新型企业优渥的扶持政策也非常诱人。并且，成都疫苗相关的产业化人才也较为集聚，生活环境亦十分宜人。

In 2017, Chen Dexiang conducted many inspections in domestic first- and second-tier cities before he finally chose to settle MaxHealth in Chengdu. In Chen Dexiang's view, the environment for the industrialization of pharmaceutical industry in Chengdu is favorable, and Chengdu's excellent support policies for innovative enterprises are also very attractive. In addition, vaccine-related industrialization talents in Chengdu are also relatively concentrated, and it is a very livable city.

陈德祥在国外从事佐剂研发工作多年，对新型佐剂原材料的设计以及生产工艺都十分了解。自 2017 年底，陈德祥在天府生命科技园创办迈科康，如今已经拥有一支由 50 余名专业技术人员组成的优秀团队。谈到企业经营管理方面的经验，他表示在国外的三段工作经历都赋予自己了作为企业管理者的能力和自信。第一阶段，陈德祥在辉瑞担任疫苗相关的项目经理；第二阶段，任中层管理职务，从事包括研发、临床等相关的技术管理；第三阶段，在国际公共卫生机构 PATH 研究针对欠发达国家生物疫苗产品。作为疫苗研究领域的专家，陈德祥对不同的国家和地区的公共卫生需求了解的较为清楚，对全球用于疫苗开发的技术资源调研的较为透彻，并且对整个疫苗的开发过程十分熟悉。基于此，迈科康整合全球技术，自主创新，以佐剂这一核心平台技术和疫苗公司合作开发创新型疫苗，借助其产业化能力，铺开产品市场。未来，迈科康也将开发自主创新的疫苗产品，制定覆盖疫苗全价值链的管线布局。

Chen Dexiang has been engaged in adjuvant R&D abroad for many years with a deep understanding of the design and production of new adjuvant raw materials. Since the end of 2017 when Chen Dexiang founded MaxHealth in Tianfu Life Science Park, he has formed an excellent team composed of more than 50 professionals and technicians.

Speaking of experience in business management, he says that his three overseas work experiences have helped him build up the ability and confidence as a business manager. In the first experience, Chen Dexiang served as a vaccine-related project manager at Pfizer. In the second experience, he served as a middle-level manager responsible for related technical management including R&D and clinical studies. In the third experience, he worked in PATH, an international public health agency to study biological vaccine products for underdeveloped countries. As an expert in vaccine research, Chen Dexiang has a clear understanding of the public health needs of different countries and regions and a thorough insight of the global technical resources for vaccine development, and he is very familiar with the entire vaccine development process. Thus MaxHealth integrates global technology, makes innovation independently, develops innovative vaccines with vaccine companies through its core platform technology of adjuvants, and expands the market through its industrialization capabilities. In the future, MaxHealth will also independently develop its own innovative vaccine products and formulate a pipeline covering the entire value chain of vaccines.

迈科康成立以来已获得多轮融资，谈到公司吸引资本注入的因素时，陈德祥提到了三点：第一，疫苗产业的前景巨大，国家政策利好，发展迅速；第二，迈科康研发团队背景“接地气”，既具有国际疫苗产业化背景，又拥有丰富的国内疫苗产业化经验；第三，无论从技术领域还是市场角度来看，迈科康选择开发的产品具有市场前瞻性。目前，迈科康已在天府国际生物城建有 6000 平方米的生产和中试车间，预计 8 月底入驻。未来，迈科康将继续与高新区、天府国际生物城合作，启动疫苗产业化基地的建设，并计划 2021 年年初启动 a 轮融资，用于该基地的建设和项目临床试验的推进。

MaxHealth has received multiple rounds of financing since its establishment. When it comes to the fundraising factors, Chen Dexiang mentioned three aspects: First, the vaccine industry is making rapid development with great prospects backed up by favorable national policies. Second, MaxHealth's R&D team is deeply "grounded", with both an international vaccine industrialization background and rich domestic vaccines industrialization experience. Third, both in terms of technology and market, products under the development of MaxHealth are market-looking. At present, MaxHealth has built a plant of 6,000 square meters for production and pilot in Chengdu Tianfu International Bio-town, with a plan to settle in at the end of August. In the future, MaxHealth will continue to cooperate with the High-tech Zone and Tianfu International Bio-town to start the construction of a vaccine industrialization base, and it plans to start its “a” round of financing early next year for the construction of the base and the advancement of project clinical trials.

成都迈科康生物科技有限公司
Chengdu MaxHealth Biotech LLC (MaxHealth)

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Chengdu MaxHealth Biotech LLC

成都迈科康生物科技有限公司由国际创新疫苗研发的资深专家团队回国创立，专业从事创新疫苗及新型佐剂的研发、生产及销售。通过自主研发和国内外合作开发等多种模式，我们将为中国和世界公共卫生发展提供优质、安全和有效的疫苗产品。

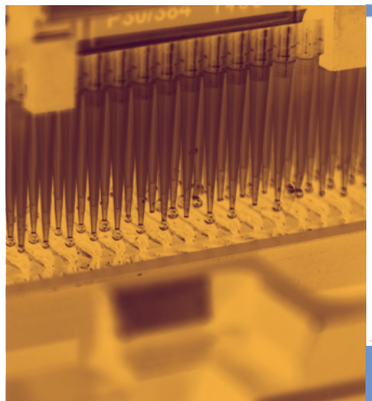
Chengdu MaxHealth Biotech LLC (hereinafter referred to as MaxHealth) was founded by a team of senior international experts in innovative vaccine R&D, and it is specialized in the development, production and sales of innovative vaccines and new adjuvants. It aims to provide high-quality, safe and effective vaccine products for the public health in China and the world through independent R&D, domestic and foreign cooperative development, and other approaches.

迈科康拥有多项国际领先、国内首创的佐剂技术，同时还建立了重组蛋白表达技术、新型佐剂评估技术和制剂技术等多项技术平台，拥有多项疫苗核心知识产权及专有技术，建立了针对多种创新疫苗产品的研发管线，涵盖了对轮状病毒、带状疱疹、新型冠状病毒肺炎、细菌性肺炎等一系列疾病的预防，以及乙型肝炎、过敏性疾病和癌症等疾病的治疗。公司计划将所有的产品通过世界卫生组织预认证，确保疫苗的质量，满足国内外市场的需求。

MaxHealth possesses a number of internationally leading and domestically pioneered adjuvant technologies. It has also established multiple technology platforms such as recombinant protein expression technology, new adjuvant evaluation technology and preparation technology. With multiple core vaccine intellectual property rights and proprietary technology, it has established a R&D pipeline for a variety of innovative vaccine products covering the prevention of diseases such as rotavirus, shingles, new coronavirus pneumonia, bacterial pneumonia, as well as the treatment of hepatitis B, allergic diseases, cancer, and other diseases. The company plans to apply for pre-certification of World Health Organization with all its products to ensure the quality of its vaccines and to meet the needs of the domestic and foreign markets.

公司拥有 50 多人的代表国际水平的疫苗研发团队，5 项疫苗产品和技术的发明专利，佐剂、疫苗的研发和生产的设备及场地，包括中试车间和生产车间。

The company has a vaccine R&D team of more than 50 people representing the international class, five invention patents for vaccine products and technologies, and equipment and sites for the development and production of adjuvants and vaccines, including pilot plants and production plants.



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