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DEVELOPMENT REIMAGINED

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MAKING AFRICA'S PHARMACEUTICAL AMBITIONS A REALITY:

LESSONS FROM CHINA AND INDIA

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2. INTRODUCTION

Low- and middle-income countries are often dissimilar, given the wide variation in continents and states under this term; however, there is much a developing region can learn from others.

China and India are among the world's fastest-growing countries, averaging at least 8% growth in 2021, compared to Africa's 4%. The consolidated value of both middle-income economies is estimated at US$17.7 trillion and US$3.1 trillion. In addition to their considerable industrialisation, expanding middle classes, and an estimated 1.4 billion population each, respectively, to Africa's 1.3, these factors position both countries favourably in the global pharmaceutical market.

Ranked as 2nd and 6th in terms of GDP in 2021, China and India account for approximately 17% and 3% of global GDP, respectively, with a World Bank estimate of their purchasing power parity (PPP) standing at US$27.3 trillion (China) and US$10.2 trillion (India), in contrast to Africa's collective 3% of global GDP (PPP) at US$4.82 trillion. However, China and India are still in their developmental stage, much like African countries: this includes all the attendant difficulties with building the necessary sectors and regulations to sustain growth, such as in their pharmaceutical sectors.

The pharmaceutical markets in China and India currently represent the world's 18th and 10th largest by export volume as of 2021 and were valued up to an estimated US$154 billion and US$42 billion, respectively. Both countries are anticipated to continue a growth trajectory in this industry yet are faced with several challenges: competition for market share and transitioning to an R&D focus with shifting government aims/policy, among other issues.

Learning from other low- and middle-income nations' growth paths will be crucial to expediting Africa's pharmaceutical development. Avoiding noted pitfalls and adapting tested methods will be essential to Africa in harnessing its full potential and taking its place in the global market of pharmaceuticals and self-sufficiency for medicines – a goal that has become more pressing in the wake of the COVID-19 pandemic and the undeniable inequity experienced by the continent in accessing much-needed vaccines.

This report encapsulates the second and third papers in a three-part series of Development Reimagined reports on the pharmaceutical industry, intended to offer insights into – and provide actionable recommendations for – the decolonisation and sustainable improvement of Africa's pharmaceutical sector.

The report, split into a two-part focus on China and India, assesses each country's pharmaceutical sector from a historical standpoint, highlighting the history, progress, challenges, and opportunities – from the role of early government in supporting the sector, international market entry, and homegrown innovation, to the current state of pharmaceutical sectors and what these insights could mean for the African industry.

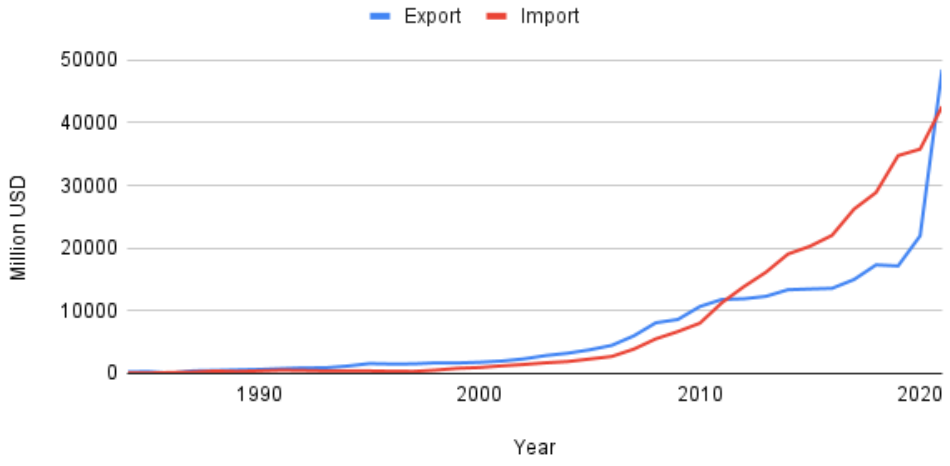
The bulk of this report draws from desk research, including but not limited to a combined quantitative and qualitative research approach by Development Reimagined, as well as white papers by international organisations and news publications. This report is written to be read and understood by pharmaceutical sector experts worldwide in African countries, China, and India, including manufacturers, researchers, investors, boards of regulatory bodies, local and international organisations in the sector, and state leaders, among others.

3. PART 1: LESSONS FROM CHINA

China is the second-largest pharmaceutical market in the world and was worth US$137 billion in 2018.[1] [2] China's pharmaceuticals industry is expected to reach US$161.8 billion by 2023 and accounts for a 30% global market share.[3]

China currently exports pharmaceutical products to more than 160 countries worldwide, with US$73.83 billion exported in 2019.[4] China's pharmaceutical exports were mainly active pharmaceutical ingredients (APIs). Indeed, it has been the largest manufacturer of APIs since 2010, accounting for one-third of the world's APIs production.[5] The USA, India, Japan, Germany, and South Korea are the top five export destinations for China's pharmaceutical products.

Figure 1: Export-Import of Pharmaceutical Products (1984 – 2021)



But how did China get here?

In five major stages, most determined domestically, but some also internationally.

For purposes of this report, to describe these stages, we begin with the end of World War II and the establishment of the People's Republic of China (PRC), where China's modern "development" story started.

[1] China Daily. *Fast growth in China's pharmaceutical market to benefit foreign firms: Report.* https://www.chinadaily.com.cn/a/201909/29/WS5d901f4ca310cf3e3556e1cc.html
[2] Development Reimagined. *21 Country Profiles: An Introduction to Local Pharmaceutical Production Opportunities in Africa.* https://usercontent.one/wp/developmentreimagined.com/wp-content/uploads/2019/01/unaids-report-new_english_webversion.pdf
[3] Daxue Consulting. *China's pharmaceutical industry will be the world's largest in less than 10 years.* https://daxueconsulting.com/pharmaceutical-industry-china/
[4] CCCMHPIE. Blue Book on the Internationalization of China's Healthcare Industry 2020.
[5] Ibid

3.1 Stage 1: 1945-1978: A poor Pharmaceutical Industry

When World War II ended in 1945, an influx of medicines used to treat combatants flooded the Chinese pharmaceutical market. The domestic bureaucratic capital took the opportunity to advocate for importing Western drugs, resulting in 80% of imported medicines. Since 1949 and the establishment of the People's Republic of China (PRC), the early stages of China's pharmaceutical industry were wholly coordinated and managed by the state government. The government allocated funds to strengthen the pharmaceutical industry infrastructure and implemented a strict regulatory plan for its production, supply, and marketing.[6]

China's pharmaceutical industry development aligns with the government policy plans and reforms. China issued its first national economic and social development five-year plan in 1953 – such a five-year planning process has typified China's method of reviewing the progress and changing the direction of different parts of the economy and industry. The main policies set up in the first five-year plan related to the pharmaceutical industry were to develop active pharmaceutical ingredients (APIs), antibiotics, sulfonamides, and other epidemic drugs. At the time, however, China relied on importing antibiotics.[7] It was not until the Tenth Five-Year Plan (2001-2005) that China designed a separate five-year development plan for its pharmaceutical industry.[8]

In the early 1960s, due to the fragmentation of China's industrial production system, small-scale factories, low level of technology, and slow economic growth, China introduced the reform of the state's industrial management system by establishing the Trusts "托拉斯". This reform implemented the central government's unified management strategy of people, finances, and materials. Specifically, the Trust, an independent planning unit, was guided by the central government and was responsible for overseeing the state plan. It received financial support from the state and operated and managed its branches, plants, scientific research, and other units in a unified manner.[9]

The Trusts were established in key industrial sectors across the country, including in the pharmaceutical industry. In 1964, China approved the "*Report on the Pharmaceutical Industry to Implement the Centralized and Unified Management of the Trust*", and in August of the same year, the China Pharmaceutical Industry Corporation (the Pharmaceutical Trust) was established.[10]

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[6] China Pharmaceutical Enterprise Management Association. (2009). China Pharmaceutical Industry Report (1949-2009) 中国医药产业发展报告(1949-2009). Beijing: Chemical Industry Press.

[7] Ibid

[8] Government of HangZhou City. (2009) *国家医药行业"十五"规划.* http://www.hangzhou.gov.cn/art/2009/7/15/art_1229541472_1883362.html

[9] 张宏志. (1993). *六十年代初我国试办工业、交通托拉斯的历史回顾.* https://www.dswxyjy.org.cn/n1/2019/0625/c427814-31187742.html

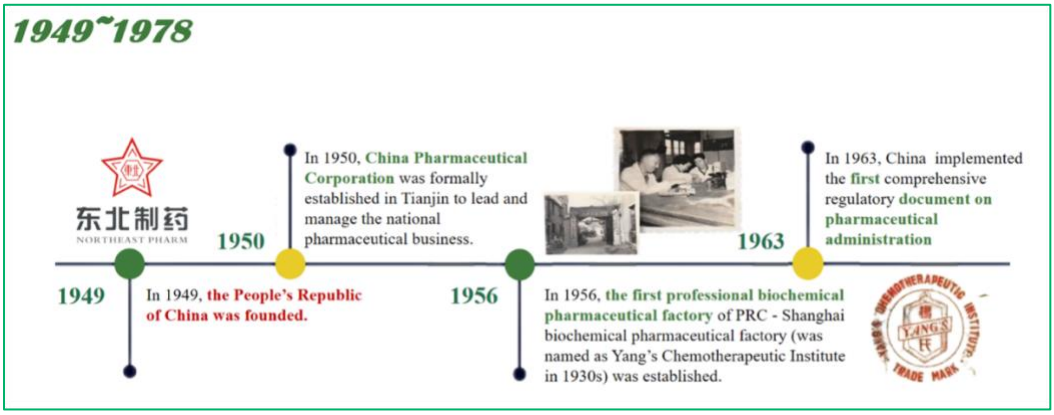
[10] China Pharmaceutical Enterprise Management Association. (2009). China Pharmaceutical Industry Report (1949-2009) 中国医药产业发展报告(1949-2009).

Before the establishment of the Pharmaceutical Trust, 297 pharmaceutical plants were operating in China in 1963. In 1965, the 297 pharmaceutical industry companies were reduced to 167, while the total production of six major APIs increased by 29% in the first quarter of 1965, compared with the same period of the previous year, with an increase in variety and quality improvement.[11]

As China was undergoing a planned economy during this time, the government exercised administrative planning control over all aspects of drug regulation, directly using planning targets to control supply, demand, and the structural balance between sectors. Consequently, drug prices were under complete state control. The government set the prices of medicines and distributed profits among pharmaceutical companies and hospitals through "ex-factory prices", "wholesale prices" and "prescription prices".[12]

Due to these regulations and reforms, China's domestic pharmaceutical industry experienced significant growth. As of 1967, the total value of China's pharmaceutical sector reached 7.2 billion RMB (US$2.9 billion).[13] But these development initiatives had been relatively limited and focused only on China's internal environment.

Figure 2: Timeline of China's Pharmaceutical Industry Development 1949-1978



There were four further key turning points to better understand how China has developed its pharmaceutical industry since 1949.

3.2 Stage 2: 1978 – The opening of China

The ten-year Cultural Revolution (1966–1976) halted China's industrial manufacturing industry, and the loss of national income amounted to 500 billion RMB (US$265.5 billion in 1976). School closure and the suspension of scientific research institutions further impacted China's education, science, technology, and culture sectors. These made China one of the poorest countries in the world in 1978. According to World Bank statistics,

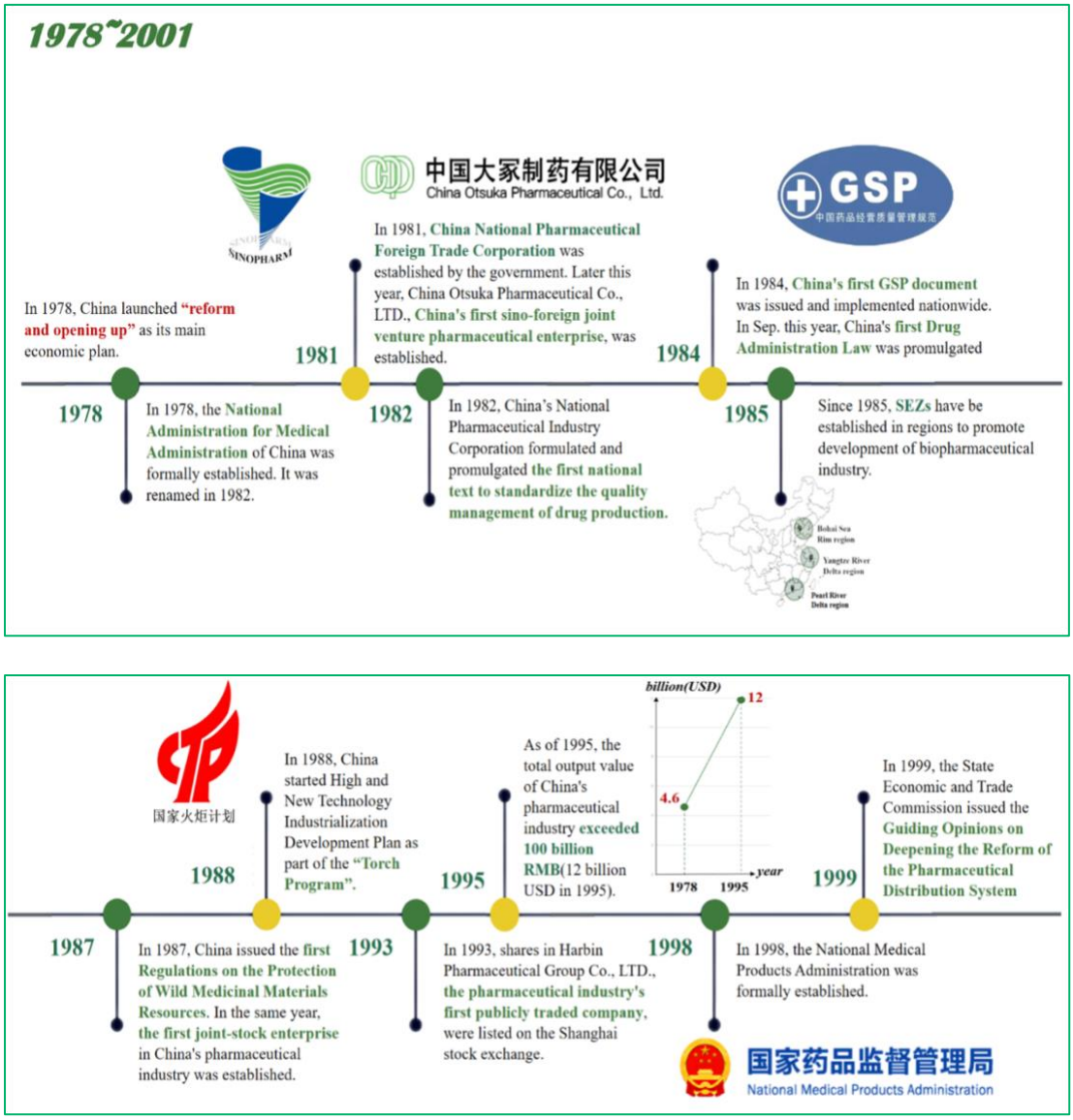
[11] 张宏志. (1993). *六十年代初我国试办工业、交通托拉斯的历史回顾*. https://www.dswxyjy.org.cn/n1/2019/0625/c427814-31187742.html

[12] 胡敏,陈文,蒋虹丽 & 乔楠. (2009).*我国药品监管体系发展和改革历程*. 中国卫生经济(08),71-74.

[13] Yaozhi News. https://news.yaozh.com/archive/34356.html

China's gross domestic product (GDP) per capita was only US$156, compared with the average GDP per capita of the poorest African countries at US$490. China had a huge population of 1 billion people at the end of 1978, with 81% of peasants with low literacy levels and 84% living below the international poverty line of US$1.25 per person per day.[14]

Figure 3: Timeline of China's Pharmaceutical Industry Development 1978-2001



In 1978, China launched "reform and opening up" as the leading economic plan to recover the stagnant economy. The reforms began to open China's market to foreign capital, resources, technology, and talent. They also involved the privatisation and contracting out of many state-owned industries. As a result, there was a boom in pharmaceutical joint ventures that necessitated the establishment of the China National Pharmaceutical

[14] Xinhua News. (2018). *著名经济学家林毅夫：改革开放创 40 年经济增长奇迹.* https://web.archive.org/web/20191101180412/http://www.xinhuanet.com/fortune/2018-05/02/c_1122769552.htm

Foreign Trade Corporation in 1981[15], which fell directly under the supervisor of the State Pharmaceutical Administration Committee, to actively engage in international economic and technological cooperation, international trade, and domestic sales of pharmaceuticals and related products.

In 1980, the China National Pharmaceutical Foreign Trade Cooperation entered the pharmaceutical industry by providing therapeutics for the central nervous system, oncology, tuberculosis, ophthalmology, and nutraceutical.[16] In 1981, it established the China Otsuka Pharmaceutical Co., Ltd., the first joint venture pharmaceutical enterprise in China since 1949, with Japan Otsuka Pharmaceutical Corporation. Otsuka Pharmaceutical, one of the top pharmaceutical companies in Japan, was a manufacturer of chemical raw materials that began its infusion (intravenous solutions) business in 1946. In 1982, the China National Pharmaceutical Foreign Trade Cooperation established the Sino-American Shanghai Squibb Pharmaceutical Ltd., with Bristol-Myers Squibb Company, one of the largest pharmaceutical companies in the US, that manufactured pharmaceuticals for cancer, diabetes, hepatitis, cardiovascular diseases, and HIV/AIDS.[17] In China, it mainly produced I.V. products when the factory started operation in 1984.[18]

China enacted a series of regulatory laws and policies during this period. The Drug Administration Law, passed in 1984, is the major component of China's pharmaceutical regulatory legal framework. This law intended to strengthen the management of drugs, ensure their quality, and safeguard legitimate rights and interests of the public in the use of drugs. In adherence to international practices, in 1988, China also enacted its own 'Good Manufacture Practice of Medical Products' (GMP) process – to provide basic guidelines for drug production and quality management. These have been listed in stages, as shown in **Figure 4**.

Figure 4: Key legal frameworks of China's pharmaceutical industry

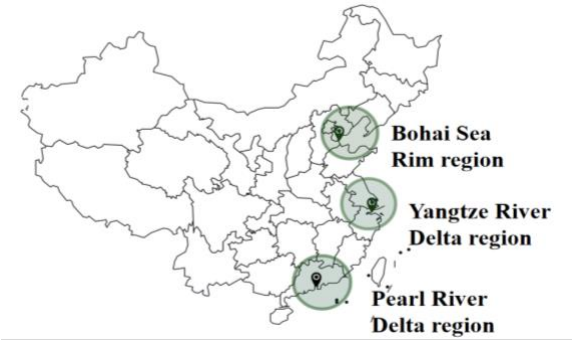
Year	Legal Framework
1984	Drug Administration Law
1988	Good Manufacture Practice of Medical Products (GMP)
1992	Patent Law
2020	Measures of the Supervision over and Administration of Pharmaceutical Production
2020	Drug Register Regulation

[15] Overview of SINOPHARM's Subsidiaries and Shareholding Companies. http://www.sinopharm.com/1399.html
[16] Otsuka Pharmaceutical. (2021). *Make Tomorrow, Otsuka Synergy.* https://www.otsuka.co.jp/en/company/pdf/CorporateBrochure_english.pdf
[17] B-M Squibb Expands China Pharma Plant (1992). https://www.thepharmaletter.com/article/b-m-squibb-expands-china-pharma-plant
[18] Otsuka Pharmaceutical. (2014). 1*st Foreign Joint Venture With China, Over 30 Years of Success.* https://www.otsuka.co.jp/en/company/global-topics/2014/20140516_vol46.html

Over this period, many private enterprises in the pharmaceutical industry were established in the wave of privatization. By 1995, the total output value of China's pharmaceutical industry exceeded 100 billion RMB (US$12 billion in 1995). There were 3,257 pharmaceutical enterprises, including 177 large enterprises, and 14 companies listed on the stock. The average annual growth rate of the pharmaceutical industry reached 17.5%, becoming one of the faster-growing industrial sectors of the national economy.[19]

Meanwhile, special economic zones (SEZs) were also a product of this period and played a crucial role in the development of China's pharmaceutical industry. These zones implemented preferential measures, such as tariff reduction and exemptions, as well as massive financial support from the government, to create a favourable investment environment, encouraging foreign investment and introducing advanced technology and scientific management methods to promote development. Since 1985, several SEZs have been established in the Yangtze River Delta region, Pearl River Delta region, and the Bohai Sea Rim region to promote the construction and development of the biopharmaceutical industry, as shown in **Figure 5.**

Figure 5: Special Economic Zones in Key Three Regions in China



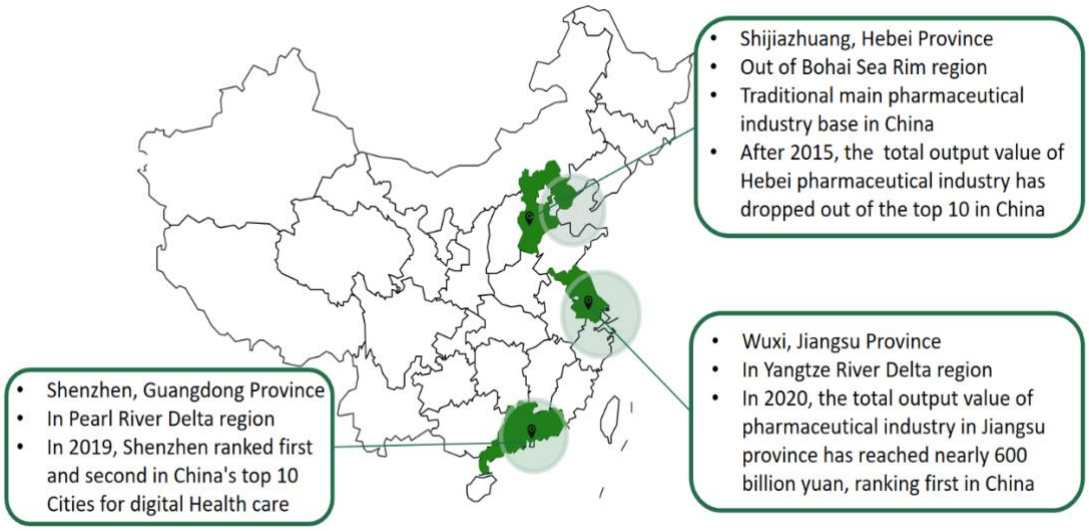
In August 1988, the State began implementation of the "*High and New Technology Industrialization Development Plan*" as part of the "Torch Program". This development plan proposed the creation of high-tech industrial development zones and entrepreneurial service centres and approved the establishment of national high-tech industrial development zones in 1991. The biopharmaceutical industrial park, also known as the pharmaceutical zone or high-tech zone, was established along with the national high-tech industrial development zone. In 2009, the first national pharmaceutical high-tech zone in China, Taizhou National Pharmaceutical High-tech Industrial Development Zone, was established.[20] Since the 1990s, China has approved the establishment of 168 national high-tech industrial parks, including 67 biopharmaceuticals (including medical devices) parks.[21]

[19] https://news.yaozh.com/archive/34356.html
[20] Forward Consulting. (2018). *我国生物医药产业园发展历程及特点分析*. https://f.qianzhan.com/yuanqu/detail/181123-946f9924.html
[21] 火石创造. (2018). *行业洞察：中国生物医药产业园发展历程*. https://www.cn-healthcare.com/articlewm/20181008/content-1035441.html

The Yangtze River Delta, Pearl River Delta, and Beijing-Tianjin-Hebei regions soon became the three most important areas for developing biopharmaceutical industrial parks and bio-industry – each with a different focus. For example, the Yangtze River Delta region has a significant economic scale, high output value of the pharmaceutical industry, increased sales of pharmaceutical enterprises, and a relatively complete industrial chain. The Pearl River Delta region has advantages in chemical pharmaceutical preparations, traditional Chinese medicine, biopharmaceuticals, and medical equipment. The Beijing-Tianjin-Hebei areas have solid foundations in the pharmaceutical industry and strengths in biotechnology.[22]

City case studies for each region are presented below to illustrate their importance and differences as per **Figure 6**.

Figure 6: Locations and Characteristics of the three (3) cities in the case studies



3.2.1 Case Study 1: Shijiazhuang

Shijiazhuang, the capital city of Heibei Province, is an excellent example of cities in the northern area of China that experienced rapid growth in the pharmaceutical industry in its early stages, but gradually became stagnant. Shijiazhuang was a major pharmaceutical manufacturing city in the 1950s. North China Pharmaceutical Group Co., Ltd, formerly known as North China Pharmaceutical Factory, was established in 1953 and operated in 1958. As once the largest antibiotic production plant in Asia, the Factory ended the history of China's dependence on imports of penicillin and streptomycin.[23] Shijiazhuang thus thrived

[22] The Central Government of China. (2006). *医药行业"十一五"发展指导意见*. http://www.gov.cn/govweb/jrzg/2006-08/31/content_374829.htm

[23] 华北制药. *华北制药集团简介*. http://www.ncpc.com/2021/jbqk_1020/2626.html

on pharmaceuticals and became one of China's largest pharmaceutical industry bases.

The pharmaceutical manufacturing industry had also become one of the leading industries in Shijiazhuang. Until the 1990s, the output value of Hebei's pharmaceutical sector ranked second in the country, and Shijiazhuang occupied 70% of the resources of Hebei's pharmaceutical industry. By 2000, Shijiazhuang's pharmaceutical industry achieved output value second only to Shanghai, ranking at the top of the provincial capital cities.[24] Shijiazhuang did not continue the glory of the past due to slow product upgrading, weak innovation capabilities, lack of human resources, and declining market competitiveness.[25]

3.2.2 Case Study 2: Wuxi

Wuxi, a city of Jiangsu Province in the Yangtze River Delta region, is a prime example of a city that has utilized foreign capital well. Wuxi is a manufacturing base that has gathered several multinational pharmaceutical companies, such as AstraZeneca and Nudicia.[26]

Notably, AstraZeneca is one of the key players in Wuxi's pharmaceutical industry. In 2001, AstraZeneca invested US$134 million to establish a manufacturing site in Wuxi.[27] Later in 2006, it invested an additional US$35 million in the Wuxi site to expand packaging capacity.

In 2015, AstraZeneca invested US$50 million in a new R&D manufacturing area adjacent to its existing Wuxi manufacturing site to develop innovative small molecule drugs discovered by AstraZeneca's Chinese and global R&D facilities. It is expected that the investment will be used to establish a third international drug formulation R&D centre in China, outside of the UK and Sweden, which will be staffed with up to 50 scientists in both Shanghai and Wuxi to support China's and global R&D needs.[28]

3.2.3 Case Study 3: Shenzhen

Shenzhen, which benefited from the "reform and opening-up" policy, was one of the first cities that established SEZs in China. As a seaside city in southern China, with its proximity to Hong Kong, Shenzhen, is a virtual channel for foreign trade

[24] Shobserver. *石家庄为何没能成为"药都"？专家：政府重视不够，体制改革落后.* https://export.shobserver.com/baijiahao/html/423956.html
[25] Ibid
[26] 无锡博报. (2021). *聚焦生物医药产业高质量发展 无锡跃起产业"龙头"链* http://www.wxrb.com/doc/2021/12/23/136161.shtml
[27] 经济日报. (2011). *阿斯利康在华建立新基地.* https://baike.baidu.com/reference/3890610/140exYZviLzY2GEDqfsm7Xs3qkJcQ2G72avGBVj-V4RHor1EZnCq5JnKsSBwXKuzKAmEEyu6l8YlHv_0Muj9vuxOY9wngLzc0CugncB_drXdH6Dykdbn
[28] 浦东时报. (2016). *阿斯利康全新商业模式更接地气"互联网+"战略惠及更多中国客户.* http://pudong-epaper.shmedia.tech/Article/index/aid/604804.html

and has become an important industrial cluster area for China's medical device industry. Shenzhen's medical device output value scale was forecasted to reach 67.286 billion RMB in 2020.[29] Another advantage of Shenzhen lies in its gene sequencing capability.

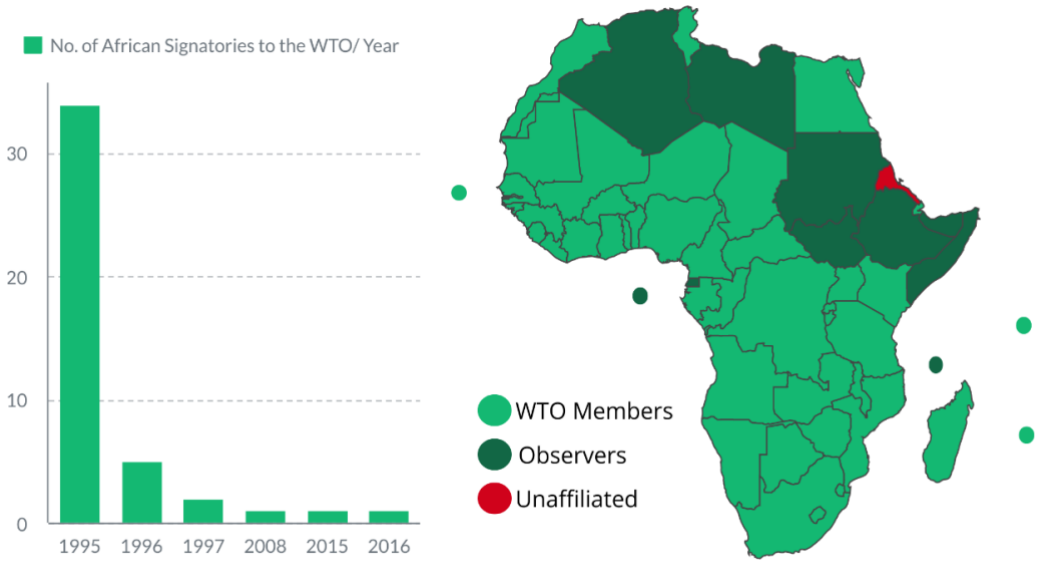
Shenzhen is home to the only **national gene bank** in China, **BGI** "华大基因", the world's largest genomic R&D and technology services company.[30]

Finally, as part of managing a rapidly developing pharmaceutical industry, China reformed its drug regulatory authority in 1998 and created the State Drug Administrative (SDA) as a separate entity from the Ministry of Health, to be directly managed by and accountable to the State Council. SDA is the primary regulatory authority in the sector conducting technical and administrative supervision over the industry.

3.3 Stage 3: 2001 – China's accession to the WTO

The World Trade Organization (WTO) is an international organization dealing with the rules of trade between nations. China became a member of the WTO in December 2001, behind many other African countries (from 1995) and India (1995), as seen in **Figure 7**.

Figure 7: African Signatories to the World Trade Organisation (WTO) (2020)[31]



[29] Sina. (2021). *超 50 家企业年产值过亿 深圳生物医药产业重点发展哪些领域.* *http://shenzhen.sina.com.cn/news/zh/2021-06-25/detail-ikqciyzk1840299.shtml*
[30] BGI. History. https://en.genomics.cn/en-history.html
[31] China's Model of Innovation: Are There Lessons for African Countries? (2021). https://www.cgdev.org/publication/chinas-model-innovation-are-there-lessons-african-countries

Regardless, this is seen as a significant milestone in China's participation in globalisation. China joining the WTO also significantly impacted the now well-established domestic pharmaceutical industry.

China's accession to the WTO in the pharmaceutical industry led to several major commitments:

- **First**, the protection of intellectual property (IP) rights of drugs
- **Second**, to reduce the import tariff of drugs (the drug import tariff rate declined from 14% in 1999 to 6% in 2003)
- **Third**, the abolition of administrative control of imports of large medical equipment in 2001
- **Fourth**, on January 1, 2003, China committed to opening the distribution of pharmaceutical services. This enabled foreign investors to engage in procurement, storage, transportation, distribution, wholesale, retail, and after-sales services in China
- **Fifth**, China started to allow foreign investors to open joint ventures in medical services, establish cooperative hospitals, and even hold a controlling stake in these (previously protected) parts of the pharmaceutical industry.[32]

Regarding the IP right of drugs, it is important to note that although China enacted a Patent Law in 1984, drug production was not included until the first law amendment in 1992. However, the most crucial amendment took place when China introduced the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) into its patent laws to meet the needs of its accession to the WTO. Key concepts, including the granting of pharmaceutical patents, compulsory licensing of patents, etc., were introduced at this time. With the newly amended Drug Administration Law and Measures for the Administration of Drug Registration introduced, China constructed a drug patent linkage system to support the transformation and innovation of China's pharmaceutical industry.

[32] 程艳霞,方勇,李秉桥. (2002). *加入 WTO 与我国医药企业发展对策研究.* 武汉理工大学学报(社会科学版) .02(2002):158-161.

After that, China also acceded to most of the multilateral international intellectual property treaties, such as the international multilateral treaties administered by WIPO, TRIPS, the International Convention for the Protection of New Varieties of Plants, the World Copyright Convention, etc.

These commitments had positive impacts on foreign companies and the domestic sales market. First, several multinational pharmaceutical companies, like Novo Nordisk, AstraZeneca, Servier, and GlaxoSmithKline, [33] set up research and development centres in Beijing, Shanghai, and Tianjin and applied for patent registration and marketing registration in parallel with the world. Second, the removal of all restrictions on foreign participation in commission, wholesale, and retail services promoted the full liberalisation of China's drug distribution market.[34] As a result, in 2005, the national pharmaceutical industry achieved sales revenue of 427.1 billion RMB, an increase of 251 billion RMB over 2000, and an annual increase of 19.4%.[35]

Alongside this, international exposure and involvement also started to become more important to China. However, barriers existed within and outside China.[36] First, the number of large pharmaceutical enterprises were small-scale, with low efficiency and capacity. Specifically, in 2004, there were 4738 pharmaceutical industry enterprises nationwide, of which small enterprises accounted for 83.4%. This made it challenging for Chinese pharmaceutical companies to compete with larger foreign firms. Second, there was low investment in scientific research and insufficient product innovation capacity. In 2005, China's overall pharmaceutical industry research and development investment accounted for only 1.02% of sales revenue.

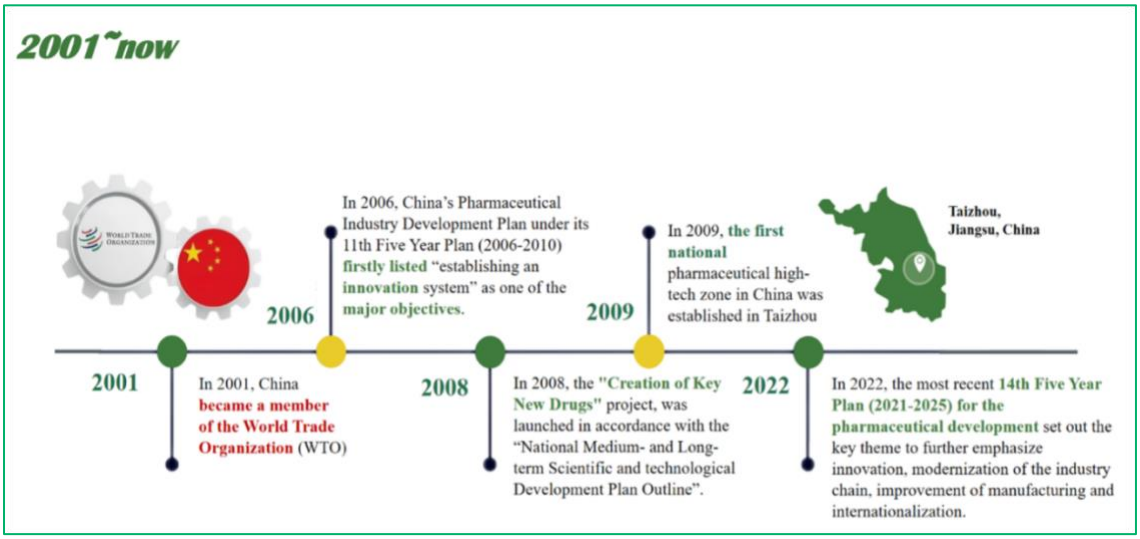
3.4 Stage 4: 2006 – 2010: Building innovation and optimizing the pharmaceutical industry

Under its 11th Five Year Plan (2006-2010), China's Pharmaceutical Industry Development Plan listed "establishing an innovation system" as one of the primary objectives for the first time.[37] It planned to effectively integrate research institutes, clinical medical institutions,

[33] Sohu News (2004). *多家跨国制药企业在中国设立其研发中心*. https://health.sohu.com/20040715/n221025455.shtml
[34] The Central Government of China.(2006) *医药行业"十一五"发展指导意见*. http://www.gov.cn/govweb/jrzg/2006-08/31/content_374829.htm
[35] The Central Government of China (2006). *发展改革委发布医药行业"十一五"发展指导意见*. http://www.gov.cn/gzdt/2006-09/05/content_378755.htm
[36] The Central Government of China. (2006) *医药行业"十一五"发展指导意见*. http://www.gov.cn/govweb/jrzg/2006-08/31/content_374829.htm
[37] Ibid

pharmaceutical enterprises, and other relevant stakeholders to improve the country's innovation capacity collectively.

Figure 8: Timeline of China's Pharmaceutical Industry Development 2001 – Present



In 2008, China launched the "Creation of Key New Drugs (重大新药创制)" project under the "National Medium- and Long-term Scientific and Technological Development Plan Outline". This project outlined five main objectives: development of medicine, construction of an innovation system, internationalisation of domestic drugs, modernisation of Chinese medicine, and development of the pharmaceutical industry. From 2006 – 2010, nearly 20 billion RMB was invested in this project, and more than 50 national technology centres were built.[38]

The Chinese government boosted market competitiveness for pharmaceutical companies through incentives for mergers and acquisitions (M&A) and restructuring to optimize and enhance the pharmaceutical industry. The number of industrial enterprises with sales revenue over 10 billion RMB increased from 1 in 2005 to 10 in 2010, and the number of enterprises with sales revenue over 5 billion RMB rose from 3 in 2005 to 17 in 2010.[39]

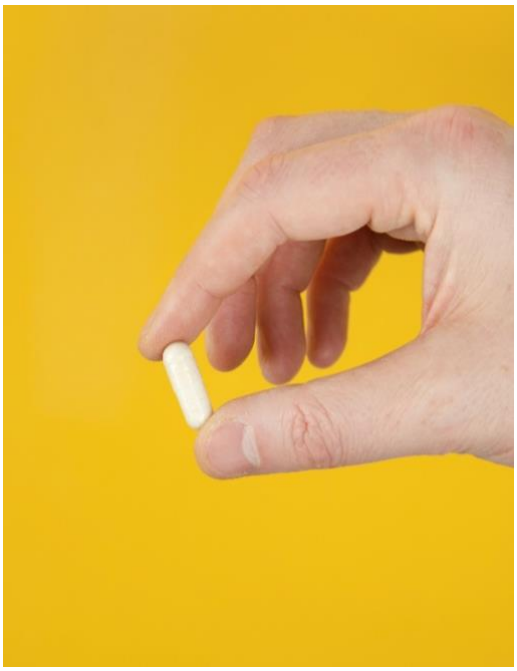
3.5 Stage 5: 2010 – date: Focusing on overseas sales, streamlining, and strengthening innovation

Since 2010, China has continued the rapid development of its pharmaceutical industry by tackling the existing challenges, such as low investment in R&D and poor industry concentration, then began to explore international markets in more earnest.

[38] State Council of China. The 12th Five Year Plan for Pharmaceutical Industry Development. http://www.gov.cn/gzdt/att/att/site1/20120119/782bcb8889ab1081f51901.pdf
[39] Ibid

Improving innovation capacity was a key theme. For example, Zhejiang Hisun Pharmaceutical Co., Ltd, founded in 1956, is now one of China's largest producers of antibiotics and anti-tumour drugs, with a total sales value of 10 billion RMB per year.[40] Hisun focuses on R&D in producing and selling innovative medicines, biological drugs, generic drugs, and high-end active pharmaceutical ingredients. The annual R&D investment accounts for more than 8% of the revenue. Specifically, Hisun has invested more than 500 million RMB in its Central R&D Institute, focusing on six areas: microbiology, synthesis, biotechnology, enzyme engineering, drug formulations, and natural compounds.[41] In 2019, the number of pharmaceutical companies with more than 10 billion in revenue increased from 2 to 17.[42] Moreover, R&D expenses of listed companies exceeded 6% of sales revenue in 2020.

Why was this important? Despite a large industry, China remains the world's second-largest importer of pharmaceutical products, with approximately US$80 billion in 2019,[43] increasing over the past ten years. Synthetic drugs, diagnostic and treating equipment, biotics, and biochemical drugs account for 90% of China's pharmaceutical imports. China still imports most of its pharmaceutical products from Germany, the USA, Japan, Ireland, and France.



New strategies proposed in the 12th and 13th Five-Year Plan aimed to help balance this by improving the export structure, such that synthetic chemicals and drugs and medical equipment increased by 260% and 170%, respectively.[44]

Furthermore, since the first WHO prequalification for a pharmaceutical product in 2005, China has continued to work closely with the WHO on drug accessibility, monitoring of adverse drug reactions, combating counterfeit and substandard drugs and medicines, and certification that has created an important new market.

According to the United Nations Global Market Place (UNGM), the UN's procurement from China in the pharmaceutical sector amounted to US$40.98 million in 2021.[45] Many Chinese pharmaceutical companies have become suppliers to international organizations, and some have built long-term partnerships, including Shanghai Fosun Pharmaceuticals

[40] Hisun Pharm. Hisun R&D Institute. https://www.hisunpharm.com/en/research.thtml?cId=11031
[41] Ibid
[42] Ministry of Science and Technology of China. *重大新药创制国家科技重大专项新闻发布会.* http://www.most.gov.cn/xwzx/twzb/fbh19073101/
[43] Ibid
[44] Ibid
[45] UNGM. Annual Statistical Report. https://www.ungm.org/Shared/KnowledgeCenter/Pages/asr_report

and ReYoung Pharmaceuticals. By February 2020, >50 APIs, >40 Finished Pharmaceutical Products (FPPs), eight diagnostic reagents, and vaccines had acquired WHO's prequalification. A summary of Chinese WHO prequalified medicines is listed in **Figure 21** in the Lessons section.

While China managed to secure its first WHO prequalified pharmaceutical product / medicine – for malaria (Artesunate) in 2005[46] – it was not until 2011 that the WHO officially recognised China's vaccine control system, making it possible for China's vaccine products to apply for WHO prequalification. In 2013, the Japanese Encephalitis Vaccine produced by Chengdu Institute of Biological Products Co., Ltd became the first Chinese vaccine product to acquire WHO prequalification, marking a new milestone for the internationalisation of China's pharmaceutical development.

Further reform of the regulation system took place at this stage to strengthen drug regulation and support the innovation and development of new drugs. In 2018, the National Medical Products Administration (NMPA) was established under the State Administration for Market Regulation as the regulatory authority of China's pharmaceutical industry.

Figure 9: Key Responsibilities of the NMPA

China also enacted the Drug Register Regulation in 2020 to regulate drug registration and ensure drug safety, effectiveness, and quality control. The regulation is for the application of new, generic, and imported drugs and their supplemental and re-registration applications. In the same year, "Measures of the Supervision over and Administration of Pharmaceutical Production" came out to strengthen the administration and supervision of pharmaceutical production.

[46] WHO Prequalified Lists. https://extranet.who.int/pqweb/medicines/prequalified-lists

Figure 10: NMPA in International Cooperation

China joined the International Conference for Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) in 2017 as a full regulatory member. In 2018, China's health authority (NMPA) was elected as a member of the ICH Management Committee in 2018 and 2021 to further participate in international drug development and registration. To date, NMPA has established working communication and liaison mechanisms with regulatory authorities in nearly 70 countries and regions and signed cooperation documents with 26 of them. NMPA is strengthening its partnership with regulatory agencies of developed countries including the EU, US, and Japan through annual work plan discussions, regular updates of the latest regulations and policies, as well as in-depth technical exchanges in the review, inspection, testing of products.

Lastly, implementing the revised Patent Law in 2020 became a (second) key milestone for China to establish its entire legal framework of pharmaceutical intellectual property. In principle, from the 1992 laws and WTO accession, and before the amendments, drug patents were protected for twenty years in China.

However, pharmaceutical companies usually apply for patent protection after completing the screening of a new drug, then undergo clinical trials and the drug administration's approval. This process often took ten years from patent application to market entry, meaning new drugs would only be protected for ten years after entering the market. As a result, pharmaceutical companies were under tremendous pressure to recover their costs, as new drug development is often expensive and time-consuming. To cope with the issue, the Patent Law amended in 2020 compensated patent drugs for up to five years for audit and approval, improving the market's attractiveness thereafter.

The most recent **14th Five Year Plan (2021 – 2025) for pharmaceutical development** set out the key theme to further emphasise innovation, modernisation of the industry chain, improvement of manufacturing, and internationalisation.[47]

By the end of 2018, more than 280 Chinese generic drugs had been registered in Europe and the U.S. 29 specially supported varieties had been approved for marketing in developed countries in Europe and the US. Twenty-three formulation varieties and four vaccine products have passed WHO prequalification, and more than 100 innovative drugs are conducting clinical trials in Europe and the US.

[47] State Council of China. The 14th Five Year Plan for Pharmaceutical Industry Development. http://www.gov.cn/zhengce/zhengceku/2022-01/31/5671480/files/b2cafa62d001408e8e20acf71ab4bf26.pdf

3.6 Future trends

Bringing us to the present, we believe two key global trends will affect the development of China's pharmaceutical industry in its next stages.

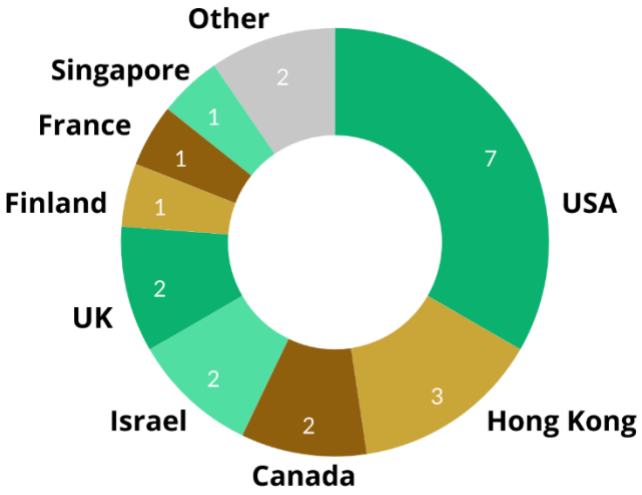
- First, COVID-19 has obviously created significant challenges for the Chinese pharmaceutical industry but has also provided an opportunity to accelerate mRNA technology development and commercialisation. Current mRNA technology focuses primarily on the COVID-19 vaccine and secondly on oncology. Although China has not yet been able to manufacture an mRNA vaccine, nine Chinese companies are currently exploring the development of mRNA, [48] and the pandemic indicates the significant potential and value of mRNA technology. It has thus attracted more investment into the field in China.

- Second, the Belt and Road Initiative creates potential opportunities for China's pharmaceutical industry. China's export of pharmaceuticals to BRI countries increased from US$16.4 billion in 2015 to US$22.4 billion in 2019. The export of synthetic drugs, medical equipment, and traditional medicine is US$14.9 billion (66.89%), US$6.32 billion, and US$1.8 billion, respectively. The export market shows India, Vietnam, Indonesia, Thailand, and Russia are the top five export destinations of China's pharmaceutical products amongst BRI countries. According to CCCMHPIE, 70% of India's APIs are from China, making India China's largest importer of APIs. In the meantime, traditional medicine products are prevalently recognised in Southeast Asia, and the region has a large demand for drugs, medical supplies, and equipment.

However, China's overseas investment in the pharmaceutical sector is minimal, with only 21 projects from 2010 to 2019, as shown in **Figure 11** below. Eight of these projects are biotechnology enterprises, while five are in pharmaceutical manufacturing. [49]

[48] 药融云. (2021). *国内 mRNA 疫苗现状：首个进入 III 期临床，相关企业仅 9 家。*https://www.cn-healthcare.com/articlewm/20210726/content-1245653.html
[49] Ibid

Figure 11: China's Overseas Pharmaceutical Investment Projects (2010–2019)



Will these projects increase and expand beyond mostly "developed" markets?

With more calls for local manufacturing in Africa and partnerships announced in recent years, such as Sansheng Pharmacetuticals establishing local manufacturing in Ethiopia in 2018[50], and the Sinovac vaccine manufacturing deal agreed upon between China and Egypt in 2021[51]; there is space and demand for further cooperation and investment in this area.

However, a constraint might be posed concerning IP waivers, as China has not been granted a TRIPS waiver for its own domestically generated drugs. However, it supported India and South Africa's proposal to WTO for a temporary TRIPS waiver for COVID-19 vaccines in October 2021, to provide equal access to life-saving vaccines and therapeutics for people in low- and middle-income countries. In addition to the establishment of local manufacturing in Africa, the TRIPS waiver backing displays China's cooperative stance on pharmaceutical manufacturing and medicines sector development in developing regions.

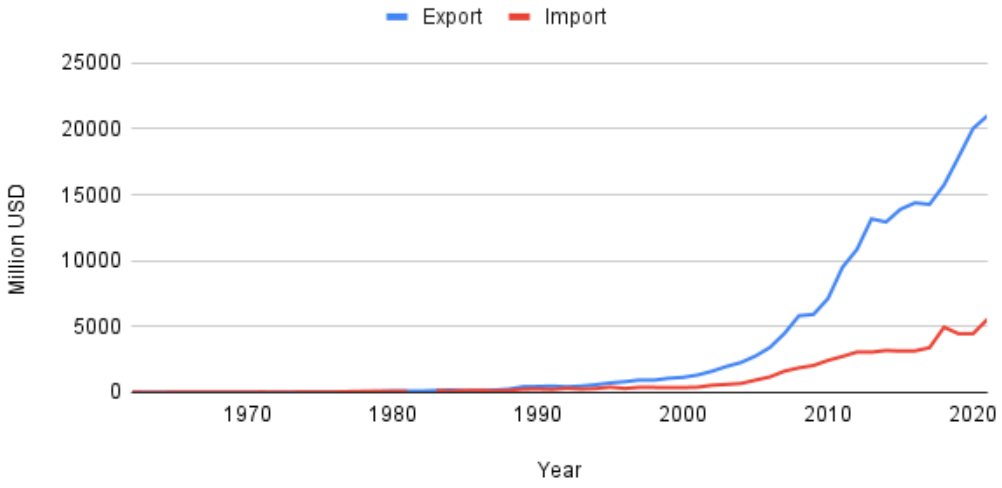
[50]Chinese pharmaceutical giant starts production in Ethiopia (2018). http://www.chinadaily.com.cn/a/201806/11/WS5b1dec5ba31001b82571f4e8.html
[51] Egypt signs agreement with China to manufacture Sinovac vaccine locally (2021). http://www.xinhuanet.com/english/2021-04/23/c_139899433.htm

4. PART 2: LESSONS FROM INDIA

The Indian pharmaceutical industry is growing at a compounded annual rate of 13.7%. India has grown into the 3rd largest pharmaceutical industry globally and the 13th largest in terms of value.[52] With the second-largest global population[53] and one of the fastest-growing economies,[54] the country has the advantage of a vast and appealing market. India has a well-established domestic pharmaceutical sector with a robust network of 3,000 pharmaceutical businesses and over 10,500 production facilities. As shown in Figure 12 (and unlike China and the African continent), its exports exceed its imports (it has an overall pharmaceutical trade surplus). India's pharmaceutical trade expanded from less than US$2 billion to over US$27 billion during the last 20 years.[55]

However, this is not just about growth, it is also about health. One of the crucial factors in India's decreasing illness burden has been improved access to inexpensive medications – mostly provided domestically.

Figure 12: India's Export-Import of Pharmaceuticals (1962 – 2021)



So how did India get here? What are the differences with China's story?

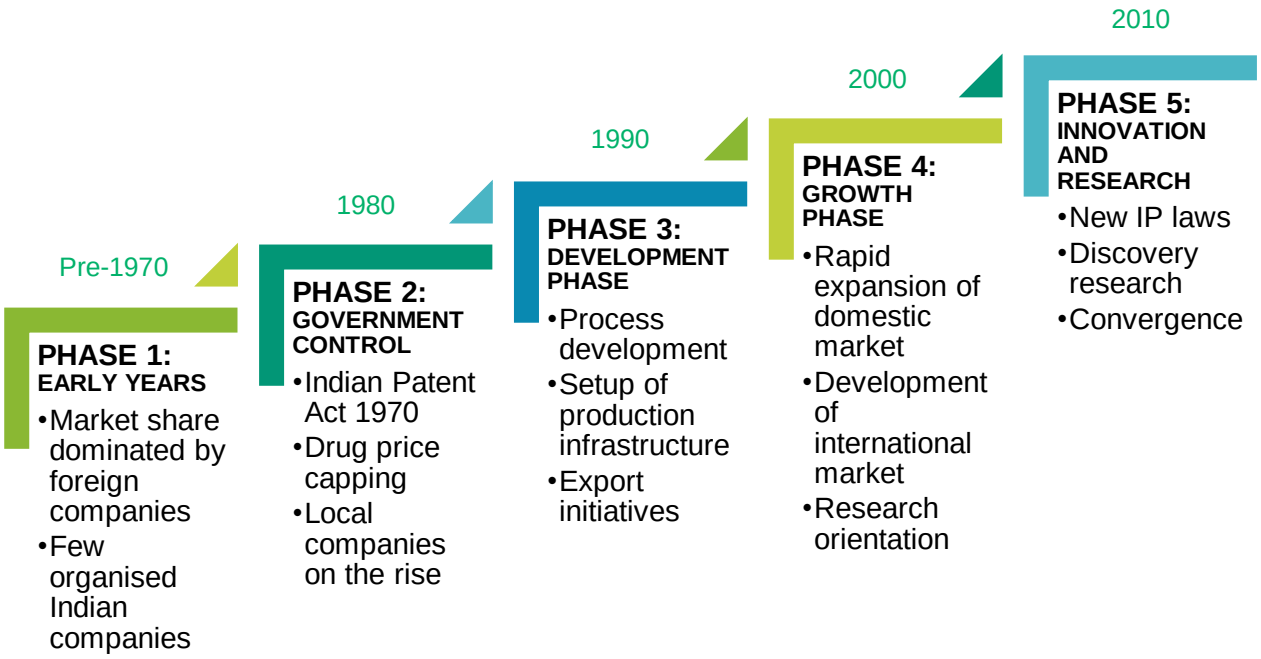
Indeed, although both markets have large populations and large numbers of pharma companies, India's pharmaceutical business has several distinct features. First, between 70% and 80% of the retail market comprises what is known as "generics" – i.e., reverse engineered or replicated branded medicines (often covered by patents abroad). Second, the domestic market is dominated by local firms in a commanding position. Third, prices are generally low. Nevertheless, the industry's turnover has grown from US$0.3 billion in

[52] Ministry of Chemicals and Fertilizers Department of Pharmaceuticals (2021)
[53] Registrar General and Census Commissioner of India (2011)
[54] International Monetary Fund (2022)
[55] Dhar, B., & Joseph, R. K. (2019). The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS. Innovation, Economic Development, and Intellectual Property in India and China, 299–323. https://doi.org/10.1007/978-981-13-8102-7_13

1980 to about US$13.73 billion in 2009-2010. According to the Department of Pharmaceuticals, the Indian pharmaceutical industry employs about 340,000 people, an estimated 400,000 doctors, and 300,000 chemists.[56]

Despite these different results, however, like China, India also got here in stages - precisely four distinct periods, primarily driven by regulatory changes made by the Indian government – and shown in **Figure 13** below as between 1911–1970, 1970–1995, 1995–2005, and 2005–2018. We review these stages below and reflect on potential future trends.

Figure 13: Phases of India's Pharmaceutical Sector Growth (1970 – 2010)



4.1 Stage 1: 1911 – 1970: The slow rise of domestic producers and fall of foreign companies

The establishment of the "Bengal Chemical and Pharmaceutical Works" in 1901 in Calcutta marked the beginning of the formal Indian pharmaceutical sector. Subsequently, institutes like the Kings Institute of Preventive Medicine in Chennai, Pasteur Institute in Connor, and the Central Drug Research Institute in Kasauli, were set up.

The pharmaceutical industry primarily used traditional Ayurvedic treatments and medications in these early years. However, the allopathic medical industry was brought to India during the British era. As at India's independence in 1947, Western multinational companies (MNCs) dominated India's pharmaceutical market and controlled the larger

[56] SWOT analysis of Indian Pharmaceutical Industry. (n.d.) http://indianresearchjournals.com/pdf/IJMFSMR/2013/May/4.pdf

market share primarily through imports. At that time, eight of the top 10 pharmaceutical firms in India (in terms of sales) were subsidiaries of MNCs. These MNCs dictated the terms of the distribution and manufacturing of medicines, with a high import dependency. India's R&D activities were practically non-existent.

At the time, the intellectual property regime was based on the Indian Patents and Design Act, enacted in 1911[57], which was mainly based on the principles laid down in the Statute of Monopolies, Patents, Design and Trademarks Act of 1883, and the Patents and Designs Act of 1907. The Act recognised product and process patents of foods, pharmaceuticals, chemicals and more for 16 years. Hence, western MNCs held about 90% of India's market shares of all pharmaceutical products protected by patents. Furthermore, the domestic drug prices in India were among the highest in the world. The MNCs were permitted to export medications, primarily low-cost generics, and a few expensive specialised goods.[58]

However, following India's independence in 1947 and towards the early 1960s, the government began to intervene and promote the domestic production of bulk pharmaceuticals.[59] Five public sector ("state-owned") pharmaceutical companies, such as Hindustan Antibiotics Ltd., and Indian Drugs and Pharmaceuticals Ltd., were set up to reduce the import of essential antibiotics and meet the country's demand for indigenous production. This pressure promoted MNCs to establish formulation facilities in India and only import bulk (finished) medications into India.

4.2 Stage 2: 1970 – 1995: Government action to create a low-price generics market

Not satisfied with the results of initial actions to manage the local pharmaceutical market, the Indian government took two significant steps during this period. Firstly, the introduction of the Indian Patents Act of 1970[60] on April 20, 1972, and secondly, the establishment of the Drug Price Control Order (DPCO) in 1979 to protect consumers against high prices.

The Patents Act was largely based on the advice of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. The Act introduced new recommendations and adjustments to the 1911 Act and replaced the 'product patent', inherited from the British colonial Patent Rule of 1856. Chaudhuri, Goldberg, and Jia (2006) note, "*The two stated objectives of the 1970 act were: the development of an indigenous pharmaceuticals industry; and the provision of low-cost access to medicines for Indian consumers*".

[57] History of Indian Patent System. https://ipindia.gov.in/history-of-indian-patent-system.htm#:~:text=The%20Indian%20Patents%20and%20Designs,Patents%20for%20the%20first%20time.
[58] The emergence of India's pharmaceutical industry... - USITC. (n.d.). Retrieved July 12, 2022, from https://www.usitc.gov/publications/332/EC200705A.pdf
[59] Joshi, H. (1970, January 1). Analysis of the Indian pharmaceutical industry with emphasis on opportunities in 2005: Semantic scholar. undefined. Retrieved July 12, 2022, from https://www.semanticscholar.org/paper/Analysis-of-the-Indian-Pharmaceutical-Industry-with-Joshi/98c63432ec3687e757bcc89385607ffe49a26f14
[60] Racherla, U. S. (1970, January 1). Historical evolution of India's patent regime and its impact on innovation in the Indian Pharmaceutical Industry. SpringerLink. Retrieved July 12, 2022, from https://link.springer.com/chapter/10.1007/978-981-13-8102-7_12

The Act's impact was to remove India's acceptance of Western style "product patent" protection for pharmaceuticals, agricultural products, and atomic energy. This meant that a slight modification in the synthesis of a molecule was patentable and allowed several firms to produce the same product.[61] Instead of the typical 20-year patent term in Western nations, only "process patents" for pharmaceutical compounds and novel chemical entities (NCEs) were permitted for five to seven years. In other words, the Act allowed Indian businesses to reverse engineer or replicate foreign-patented medicines without paying a license fee to the patent owners who held the original patents. This soon became the primary driver of the industry's rapid and ongoing growth in India, albeit benefiting Indian firms at the expense of MNCs, causing some MNCs to opt for minimal presence in India. As long as they employed a production process different from the patented process in India, this allowed the Indian sector to sell a wide variety of cheaper generic equivalents legally.[62]This policy made the Indian pharmaceutical sector one of the major competitors both at home and abroad.

As a result, between 1970-1971 and 1980-1981, the number of patents granted decreased by 75%.

Consistent with the recommendations of the Ayyangar Committee Report, the Drug Price Control Order (DPCO) was established in 1979 – the intent was to meet national policy goals to prioritise the availability of essential medicines, as well as stop what was felt to be excessive profiteering from necessary medications. This kept pharmaceutical prices low and increased demand locally but also put an effective cap on the overall revenues of pharmaceutical corporations.[63]

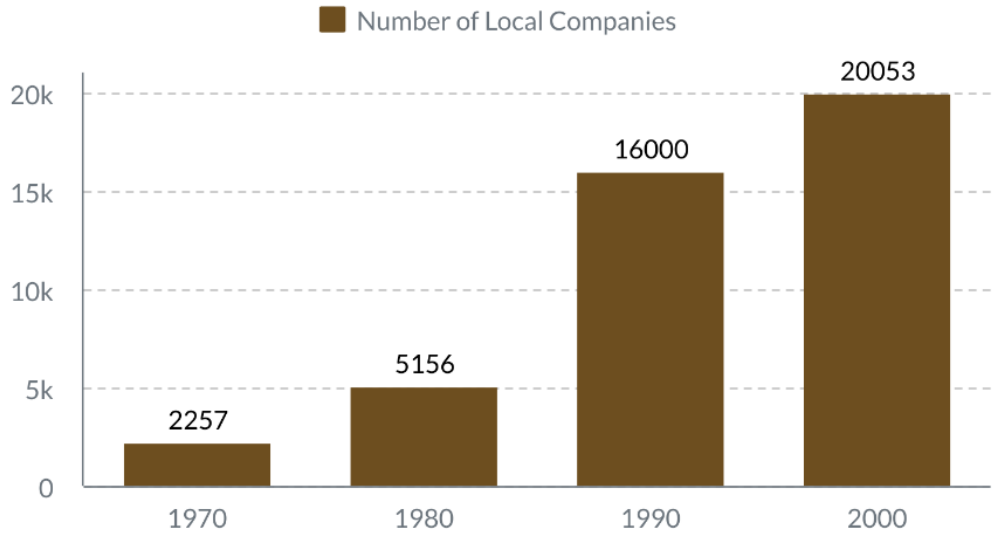
Several other complementary measures were introduced - restrictions on capacity expansion and limits on multinational equity shares (MNCs were required to cut their stakes in their Indian businesses to 40%).

As a result of these shifts, foreign ownership in the Indian drug industry decreased to 39% in 1993 compared to 80% in 1970, before the introduction of the Act and the DPCO.

On the other hand, domestic pharmaceutical companies prospered throughout the 1980s and 1990s,[64] increasing in number dramatically from 2,000 in 1970 to around 20,000 in 1995, resulting in a flourishing generic pharmaceutical market,[65] as shown in **Figure 14** below.

[61] Duggan, Mark & Goyal, Aparajita. (2012). Pharmaceutical patents and prices: a preliminary empirical assessment using data from India.
[62] Progress of the Indian Pharmaceutical Industry: A shifting perspective... (n.d.). Retrieved July 12, 2022, from https://www.researchgate.net/publication/274473518_Progress_of_the_Indian_pharmaceutical_industry_a_shifting_perspective
[63] The Indian pharmaceutical industry: The 'pharmacy of the world'? - Thoughts from the Centre. (n.d.). The Indian Pharmaceutical Industry: The 'Pharmacy of the World'? - Thoughts from the Centre | Deloitte UKhttps://blogs.deloitte.co.uk/health/2020/03/the-indian-pharmaceutical-industry-the-pharmacy-of-the-world.html
[64] ibid
[65] ibid

Figure 14: India's Pharmaceutical Industry Growth (Number of Manufacturers, 1970 – 2000)



This also shifted the characteristics of patenting. Based on statistics from the European patent office, the number of pharmaceutical applications increased steadily, and approximately 6,000 were published each year, of which 10% were from India.

The 1970 Act remained mostly unchanged until 2005, providing 35 years within which the Indian pharmaceutical industry could perfect its scientific and manufacturing capabilities, allowing many of its leading companies to move up the value-added chain.

From 1980-1981 to 1994-1995, the growth rates in the value of production of bulk drugs and formulations in India were 6.1% and 6.6% per annum, respectively.[66]

4.3 Stage 3: 1995 – 2005: Growth through competitive exports and gradual opening to foreign investment

By 1995, the Indian pharmaceutical industry was one of the world's most price-competitive industries, meeting around 90% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals, and injectables. It had approximately 300 big and medium-scale companies and about 8,000 small-scale units that formed the core of the industry in India. That meant it was also an extremely fragmented market with severe price competition within the government price controls.

[66] J. Ravinder. (2007). Options for Indian Pharmaceutical Industry in the Changed Environment. Economic and Political Weekly. 42(39) 3958-3967. http://dx.doi.org/10.2307/40276473

However, as more Indian pharmaceutical businesses entered the market, the experience acquired by concentrating manufacturing on generic medications allowed them to increase their capabilities and gain a global presence. The share of pharmaceuticals in national exports increased from 0.55% in 1970-1971 to over 4% by 1999-2000. India's share in world exports of pharmaceuticals rose by 2.5 times over the 1970 to 1998 period - making India the second largest middle-income country exporter of pharmaceuticals after China (among 17 low- and middle-income countries) by exporting products to countries like Russia, Africa, China, and South America.

During this period, India's pharmaceutical exports climbed from a little over US$1 billion in 1996 to US$1.9 million in 1999 to US$5.2 billion in 2005, as seen in **Figure 12**. India began exporting a wide range of pharmaceutical products globally – APIs, drug intermediates, finished dosage formulations, biopharmaceuticals, and clinical services. The growth of Indian exports was around 16.5% - a total of US$451.4 billion - over the period of 10 years from 2002 to 2012.[67]

[67] R. Diksha. (2020). An Analysis Of The Trends In Indian Pharmaceutical Trade. JAC: A Journal of Composition Theory. XIII. 724.

How did this export growth occur? A major reason was the 1991 economic liberalisation of India, which allowed for the economy's opening to privatisation and globalisation[68].

While the country's expanding middle class, rising demand for greater healthcare access, growing use of health insurance, and upgrading medical facilities all pointed to profitable investment potential in the country's pharmaceutical industry, the industry itself had a strong reputation – a proven track record in bulk drug and formulation patents, alongside low costs of innovation and capital expenditure - which provided leverage in terms of pricing.

These strengths were bolstered by three regulatory changes the Indian government also made in this period, in line with the 1991 economic liberalisation policy.

First, the government introduced a new Exclusive Marketing Rights (EMR) provision in 1995. Still, India's Patent Act amendments did not come into force until 1999[69], effectively tightening the domestic intellectual property regime. EMRs were valid for five years or till the date of grant of the patent or date of rejection of the application for the grant of a patent - whichever is earlier. This made investing in generics for domestic use or export more attractive to foreign investors – even if their shares still had to be limited.

Second, in 1995, India became a founding member of the WTO (like many African countries, unlike China) – see **Figure 7**. The WTO obligated India to set up a "mailbox" where patent applications could be submitted between January 1995 and 2005, even if India was not expected to change its IP regime until 2005 (see next stage). Thus, the act of joining the WTO attracted a sizable number of foreign pharmaceutical firms to enter the Indian market. By 2005, foreign drug producers had filed about 8,926 patent applications to protect their patented medicines offered as generics in the Indian market. Some Indian businesses also developed new compounds, while others went into R&D joint ventures with foreign pharmaceutical corporations.[70]

Under India's new product patent system, Roche (Switzerland) was the first foreign business to secure a patent. The patent, issued in March 2006 for the hepatitis C medicine (*Pegasys*), would be in effect for 20 years as of May 15, 1997. By 1996, Pfizer (US) had submitted the most patent applications (373), followed by Johnson & Johnson (262) and Procter & Gamble (261) & (187).[71] The applications issued by companies from various countries are shown below in **Figure 15.**

https://www.researchgate.net/publication/340224643_AN_ANALYSIS_OF_THE_TRENDS_IN_INDIAN_PHARMACEUTICAL_TRADE

[68] The Indian pharmaceutical industry: The 'pharmacy of the world'? - Thoughts from the Centre. (n.d.). The Indian Pharmaceutical Industry: The 'Pharmacy of the World'? - Thoughts from the Centre | Deloitte UK. https://blogs.deloitte.co.uk/health/2020/03/the-indian-pharmaceutical-industry-the-pharmacy-of-the-world.html

[69] Acharya R. The Global Significance of India's Pharmaceutical Patent Laws (n.d.). https://www.aipla.org/list/innovate-articles/the-global-significance-of-india-s-pharmaceutical-patent-laws

[70] The Indian pharmaceutical industry: The 'pharmacy of the world'? - Thoughts from the Centre. (n.d.). The Indian Pharmaceutical Industry: The 'Pharmacy of the World'? - Thoughts from the Centre | Deloitte UK. https://blogs.deloitte.co.uk/health/2020/03/the-indian-pharmaceutical-industry-the-pharmacy-of-the-world.html

[71] Narendranath KA (2005). Patent mailbox opens, Pfizer is top applicant. The Financial Express.

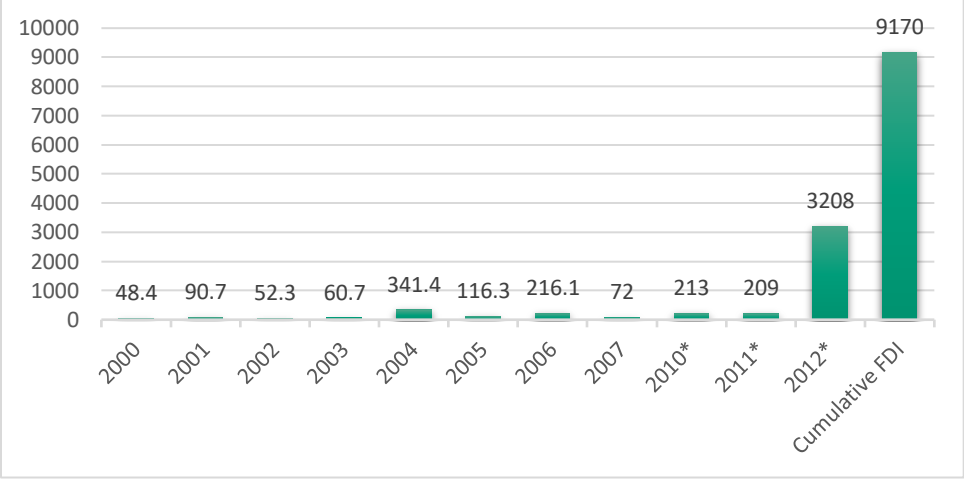
Figure 15: Number of Patent Applications (1978 – 1996)

Country	No. of patent applications
US	2111
Switzerland	1312
Denmark	261
India	538
Japan	434
Belgium	170
Germany	1090
Sweden	351
UK	573
France	280

Third, from January 2000, the Indian government changed the rules governing Foreign Direct Investment (FDI) in the pharmaceutical industry to automatically permit Indian companies to receive up to 100% foreign (non-resident) investment to produce medical equipment, subject to specific regulations. Before this, foreign investment into hospitals (and therefore medical equipment) had been allowed only on an *ad hoc* and limited basis, subject to internal approval by the Foreign Investment Promotion Board (FIPB).

As is visible from **Figure 16**, the industry saw a jump of around 418% in FDI from 2003 to 2004 and maintained the levels until 2012, when there was a further jump (see next stage).

Figure 16: FDI Inflows in the Indian Drugs and Pharmaceutical Industry (2000 – 2012, USD millions)[72]



[72] Kumar K. and Kulshreshtha. (2013). SWOT ANALYSIS OF INDIAN PHARMACEUTICAL INDUSTRY. *International Journal of Marketing, Financial Services & Management Research*, *2*(5). http://indianresearchjournals.com/pdf/IJMFSMR/2013/May/4.pdf

Hence, and perhaps contrary to some economic theories, despite a stricter IP regime, the growth rate of the Indian pharmaceuticals industry was able to be maintained in the post–1995 period. However, given the new incentives, the composition of growth shifted. The growth rate of bulk drugs increased to 10.2% per annum, while that for formulations fell marginally to 5.6% per annum from 1995-1996 to 2004-2005.

4.4 2.4 Stage 4: 2005 – 2018: The impetus for research & development, clustering, and innovation

As explained in **Part 1,** the WTO's Agreement on TRIPS made it mandatory for all countries to establish standards for intellectual property (IP) protection. However, while developed countries were to implement protection requirements by 1996, India needed to fulfil the above requirements by 2000, and the least developed countries by 2005.

Specifically, TRIPS made it mandatory for India to add patent protection for pharmaceutical products from January 1, 2005, creating a new setting for India's pharmaceutical market development.

TRIPS compliance made a 20-year term available in India for any pharmaceutical product or process invention. Additionally, compulsory license provisions were also now TRIPS-compliant, and the government could grant such licenses, only on the merit of each case, after allowing the patent holder to state their position. In addition, no discrimination was permitted between imported and domestic products in the case of patent infringement. In the case of process patents, the burden of proof rested on the party that allegedly infringed.

This had **four major effects**, which will be explored below.

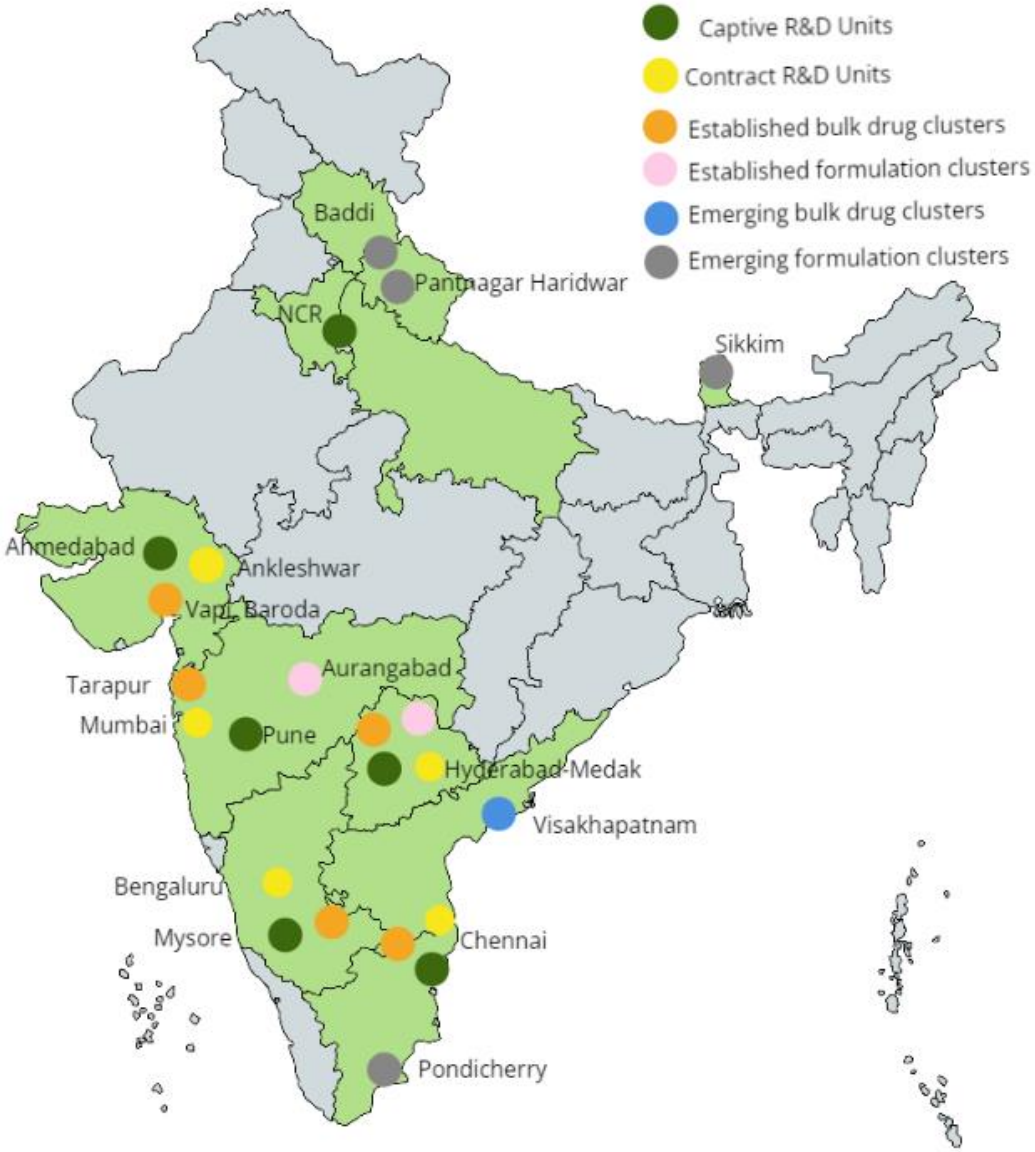
- **First**, at that point, around 97% of all medicines produced in India were unpatented, so this Act did not impact them. However, the new potential for monopoly profits led Indian pharmaceutical firms to invest more in the Research & Development (R&D) of new chemical entities (NCEs) and novel drug delivery products – both for sales domestically as well as internationally.

While many of India's pharmaceutical firms had already been clustering in certain regions of India (see **Figures 17 and 18** below), the Indian government at this point decided that the requirement for R&D growth necessitated the formal establishment of special economic zones (SEZs).

Notably, the Indian state of Telangana is particularly renowned as a hub for the country's pharmaceutical industry, accounting for 35–40% of national pharmaceutical production. Telangana and Andhra Pradesh, both central-south states, have the most pharmaceutical manufacturing companies out of all Indian states. Major pharmaceutical hubs are in Ahmedabad (in Gujarat state), Bangalore (Karnataka), Hyderabad (Telangana), and

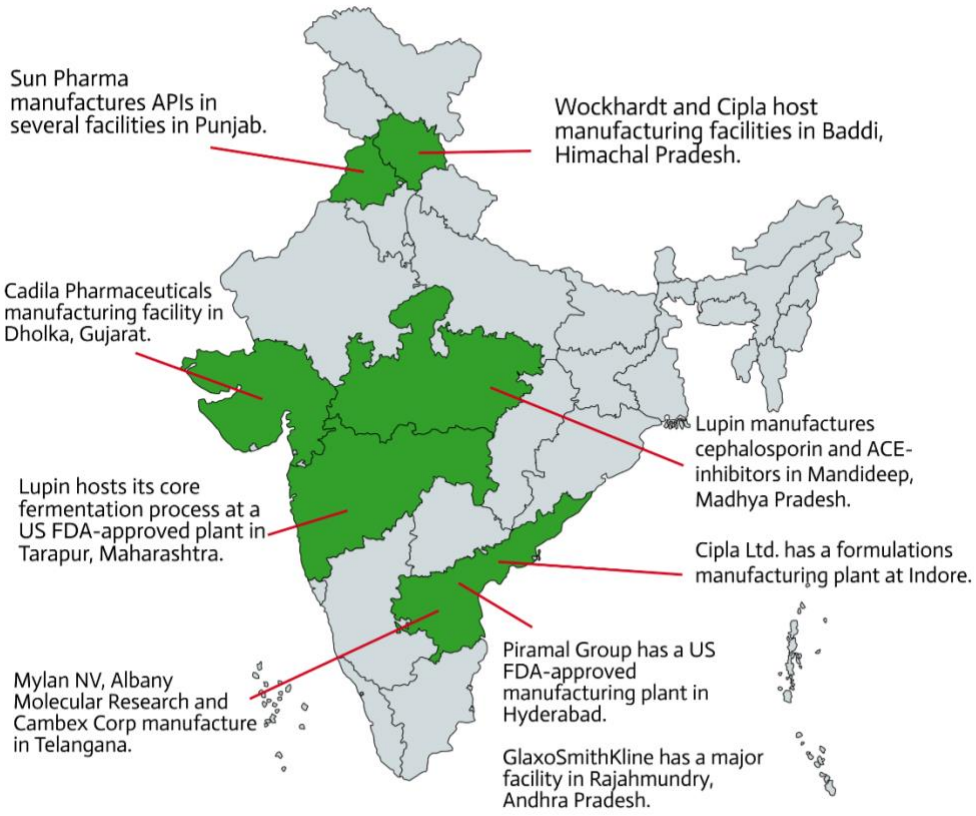
Mumbai (Maharashtra). Recently, there has been more development in the northern states, but they still lag other regions.[73]

Figure 17: Pharmaceutical Clusters in India



[73] Andhra Pradesh and Telangana: Indian contract manufacturing powerhouses for US API supply (2019). https://www.pharmaceutical-technology.com/comment/andhra-pradesh-and-telangana-indian-contract-manufacturing-powerhouses-for-us-api-supply/

Figure 18: Key Pharmaceutical Ventures In India by State



The establishment of special economic zones (SEZs) in India – like their application in China – allowed for tailoring of the industry in different states, easing logistics and promoting production clusters, which brought greater economies of scale for local generation of pharmaceuticals. as of July 2019, out of 232 Special Economic Zones (SEZs) assigned by the Indian Ministry of Commerce and Industry, 11 were reserved to the pharmaceutical industry[74].

The focus of the Indian pharmaceutical industry thus began to shift from mainly generic products to more innovation-based patentable R&D, generating huge investments by the Indian pharmaceutical industry in innovation-based research and patenting.

Case Study 1 illustrates the location and scale of this R&D effort and concentration.

[74] Press Information Bureau. Selected areas for SEZs (2019). https://pib.gov.in/Pressreleaseshare.aspx?PRID=1579192

Case Study 1: Bangalore, Karnataka – Home to biologics innovation

A large proportion of biotech and international pharma companies in India are in or around the high-tech city of Bangalore in Karnataka, which is regarded as the "Silicon Valley of India." Several R&D centers, pharmaceutical industrial zones, and exclusive pharmaceutical Special Economic Zones (SEZ) support the developing pharmaceutical industry and incentivise international investment.

Karnataka houses the largest number of FDA- and/or European Medicines Agency (EMA)-approved manufacturing facilities. However, even together, the four states of Karnataka, Tamil Nadu, Goa, and Kerala have far fewer facilities than the other southern states of Andhra Pradesh and Telangana, which have a combined 248 FDA- and/or EMA-approved sites.[75] Karnataka has one of the fastest-growing pharmaceutical sectors in India: approximately 40% of the state's pharmaceutical production is exported overseas. The state is an emerging pharmaceutical powerhouse, particularly its city of Bangalore, and its success is largely driven by its biologics production. The emerging pharma powerhouse of Karnataka has international pharmaceutical companies such as Mylan NV (Hertfordshire, UK) and Adcock Ingram Holdings Ltd (Gauteng, South Africa) operating excess capacity contract sites.[76]

- **Second**, India's escalating presence on the market for formulations confirmed India's position as the world's leading provider of low-cost generic medications. The new globally applicable TRIPS regime suggested more markets could open up globally for nations like India, South Africa, Brazil, and China, who already had domestic manufacturing capacity in pharmaceuticals.

Hence, formulation exports began to climb while API exports stalled consistently. India's export value rose further from US$5.2 billion in 2005 to over US$20 billion in 2016, as seen in **Figure 12**.

As a result, India established its top five pharmaceutical export destinations - the US, Germany, Russia, the UK, and China. The US market for Indian pharmaceuticals grew from less than US$300 million in 2005 to more than US$5.2 billion in 2016. As a result, the European Union's relative importance as a market for Indian generics decreased over the same period. Today, one in three medications used in the US is estimated to be made

[75] Andhra Pradesh and Telangana: Indian contract manufacturing powerhouses for US API supply (2019). https://www.pharmaceutical-technology.com/comment/andhra-pradesh-and-telangana-indian-contract-manufacturing-powerhouses-for-us-api-supply/

[76] Karnataka, Goa, Tamil Nadu, and Kerala: Mixed success for southern India's pharma manufacturing industry (2020). https://www.pharmaceutical-technology.com/comment/southern-india-pharma-manufacturing/

by an Indian generic manufacturer.[77] About 25% of the medicines used in the UK are produced in India.

The penetration of India's generic businesses in Africa also strengthened during this period. India's formulation exports to Africa rose from US$270 million in 2003 to approximately US$3 billion by 2016. **Case Study 2** below illustrates the degree of this penetration not only in export terms, but also in terms of overseas manufacturing capacity through the case of South Africa.

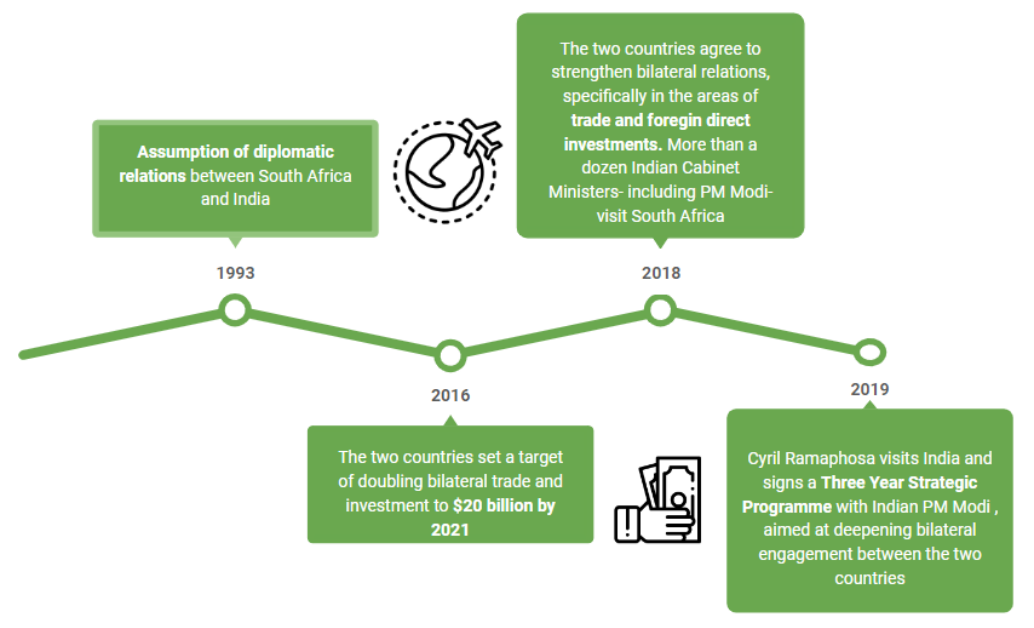
Case Study 2: India and South Africa's Relationship

The acronym BRICS (Brazil, Russia, India, China, and South Africa) stands for five of the most rapidly middle-income economies in the world today. India was South Africa's eighth-largest import source when it joined the group in 2010. The South African pharmaceutical industry holds Africa's largest medication market and the fifth highest per-capita pharmaceutical spending. According to estimates, the market had a total value of R44.0 billion (US$2.52 billion) in 2015, of which R34.2 billion (US$1.96 billion),

[77] The Indian Pharmaceutical Industry – the way forward. (n.d.) https://www.ipa-india.org/wp-content/uploads/2020/10/indian-pharmaceutical-industry-way-forward.pdf

86.7% was due to the private healthcare market, and R6.8 billion (US$390 million), 13.3% to the public sector.[78]

Over 150 Indian businesses operate in South Africa, and the Confederation of Indian Industry (CII) claims they have had an immeasurably good influence on the nation. Indian businesses have invested more than 50 billion rupees, and more than 18,000 South Africans work in the Indian economy.[79]



Indeed, being a WTO founder, India managed to negotiate new markets through "global health" organizations over this period. India now produces 60% of the world's vaccinations, providing 40% to 70% of the WHO's requirements for the Diphtheria, Tetanus, and Pertussis (DPT) and Bacillus Calmette-Guérin (BCG) vaccines, and 90% of those for the measles vaccine.[80] The affordability of Indian medicines is said to have made AIDS therapy more widely accessible in the African region.[81]

This is also why many major Indian generic businesses devote a sizable portion of their sales to R&D, as seen by their patenting practices. They were substantially less active in domestic patenting but more active in submitting patent applications in international

[78] PHARMACEUTICAL INDUSTRY SOUTH AFRICA INDIA BILATERAL. (n.d.). https://www.cgijoburg.gov.in/pdf/Pharmaceutical%20Report%20Approved.pdf
[79] PHARMACEUTICAL INDUSTRY SOUTH AFRICA INDIA BILATERAL. (n.d.). https://www.cgijoburg.gov.in/pdf/Pharmaceutical%20Report%20Approved.pdf
[80] Ministry of Chemicals and Fertilizers Department of Pharmaceuticals, 2021
[81] Waning, B., Diedrichsen, E., & Moon, S. (2010). A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. Journal of the International AIDS Society, 13, 35. https://doi.org/10.1186/1758-2652-13-35

countries.[82] It is worthwhile. India's exports made up about 30% of its profits and around 40% of the industry's total production during the past five years, which have more than doubled. Similarly, the pharmaceutical industry has been the only manufacturing sector in India to have achieved continuous export growth during the COVID-19 pandemic, a period in which India's exports were generally plagued by uncertainty. The industry's annual sales in 2021 roughly amounted to US$ 41 billion.[83]

- **Third**, by shifting the patent regime from "process" to "product" protection and elongating IP protection, the 2005 patent regime effectively deregulated the Indian pharmaceutical market – opening it to foreign competition and motivating foreign trade through IP incentives (i.e., the incentive to have a 20-year monopoly in this large domestic market). This is reflected in **Figure 12**, where there are sudden rises in imports after the 2005 patent regime change; prior to 2005, the growth rate had stagnated.

Overall, the import of drugs by India increased by a compound annual growth rate of 17.6% (compared to 16.5% in exports between 2002 and 2012), although imports have never exceeded exports. Today, India remains a net exporter despite import restrictions on drugs with narcotic substances.[84] This is because the Indian pharmaceutical industry was already mostly self-reliant in the production of formulations - so imports mostly concentrated on bulk drugs and intermediaries. However, the fact that India is now a significant importer of APIs has slightly weakened its position as a provider of generic medications on the international market. With over two-thirds of all API imports from its neighbor, China has emerged as India's top supplier.[85] That said, while India's imports of API more than tripled between 2005 and 2016, India's API exports still almost tripled over the same period.

- **Fourth** and finally, the IP protection and new global market penetration potential from TRIPs application elsewhere prompted FDI into India to rise further over this period. According to government statistics, the Indian drugs and pharmaceuticals sector received cumulative FDI inflows worth US$17.75 billion between April 2000 and December 2020.[86] [87] India saw 46 Mergers and Acquisitions (M&As) in the pharmaceutical sector in 2017, totaling US$1.47 billion.[88] And just in the second

[82] Chen, X., Xue, S., Lv, M., & Wang, R. (2019). Pharmaceutical Industry in China: Policy, Market and IP. Innovation, Economic Development, and Intellectual Property in India and China, 215–250. https://doi.org/10.1007/978-981-13-8102-7_10
[83] Ministry of Chemicals and Fertilizers Department of Pharmaceuticals, 2021
[84] Government of India, 2012
[85] Dhar, B., & Joseph, R. K. (2019). The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS. Innovation, Economic Development, and Intellectual Property in India and China, 299–323. https://doi.org/10.1007/978-981-13-8102-7_13
[86] Annual Report (2012). Department of Industrial Policy & Promotion, Ministry of Commerce and Industry, Government of India.
[87] BMI, Business Standard, DPIIT
[88] Agarwal A. & Ahuja P. (2016). Intellectual Property and the Indian Pharmaceutical Industry - Drug Discovery and Development. Drug Discovery and Development; www.rdmag.com. https://www.rdmag.com/article/2016/02/intellectual-property-and-indian-pharmaceutical-industry

quarter of 2018, the Indian pharmaceutical industry reported US$396 million in private equity and venture capital investments.

4.5 Future trends

Mueller claims that during this "globalization" phase, India's eventual admission to the World Trade Organization (WTO), along with its ratification of the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty (1999 – see **Stage 3**), has been crucial to strengthening India's innovation capacity.[89] Mueller suggests that the effects of such modifications, which are still being implemented, have not yet been completely realized.

The Government of India plans to embark on an ambitious plan to cut dependence on China for key raw materials as it seeks to become self-sufficient. Under the Production-Linked Incentive scheme (PLI), a government program launched in mid-2020, when military tensions with China were high, 35 APIs began to be produced at 32 plants across India in March 2022. This is expected to reduce dependence on China by up to 35% before the decade's end. It aims to incentivise companies across all sectors to boost domestic manufacturing by US$520 billion by 2025. For the pharmaceutical sector, the government has earmarked over US$2 billion worth of incentives for private Indian companies and foreign firms to start producing 53 APIs that India currently relies heavily on China for.

[89] Mueller, JM. (2007). The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation. University of Pittsburgh Law Review, 68(3). https://doi.org/10.5195/lawreview.2007.79

5. CONCLUSIONS – OPPORTUNITIES AND LIMITATIONS

This report was intended to offer insights into – and provide actionable recommendations for – the decolonization and sustainable improvement of Africa's pharmaceutical sectors by learning lessons from the development of China's and India's pharmaceutical industries – which represented the world's 18th and 10th largest by export volume in 2021 respectively.

The first observation from this effort is that the development of the two pharmaceutical heavyweights has differed widely, with significantly different outcomes.

China has developed as both a major exporter and importer of pharmaceutical products, with a huge uptick in exports in 2020, with just over twice the value of Indian exports. On the other hand, India has steadily increased its trade surplus in pharmaceuticals since the early 1990s.

However, both have developed in stages – we describe five stages for China and four stages for India, mostly determined domestically, but also to some degree determined internationally.

To describe these stages, we begin around the end of World War II for China, and half a century earlier for India, but really kicking off significantly in terms of a "modern" pharmaceutical industry from India's independence in 1947 and the establishment of the PRC in 1949.

For China – the five stages begin with an industry dominated by imports, to an industry protected from foreign ownership and organised into special zones to gradually meet domestic needs, to an industry protected in terms of IP even in the early 1980s, but still very domestically-oriented and dominated by small firms, to an industry given incentives to merge for efficiency, move up the value chain and invest in innovation. And from the 2010s onwards, we document a country still importing significantly (in a deficit), but eventually starting to increase exports as certification through the UN and global health bodies improves its reputation and global awareness.

For India – the four stages also see a pre- and post-independence industry initially dominated by imports, which transitioned to exportation and IP protection for its own goods, and finally into an industry protected from foreign ownership. Although India – like China – introduces industrial policies, the mainly small-firm-dominated Indian industry primarily thrives because of domestic competition, combined with price controls and an open IP environment. India moved to access global export markets around a decade earlier than China. This prominence in international export markets, as well as its maintenance of foreign ownership controls, provides a cushion for India as it changes its own IP laws while inviting FDI.

The final twist in the history of the two countries gives an indication of their respective future challenges - both economies are trying to shift up the value chain, increase

innovation and R&D. Yet India now imports much of its APIs from China, and China registers more product patents than India.

These histories of the two countries both reinforce and shatter stereotypes. The histories chart some aspects of the two countries' differing development pathways that seem familiar. For instance, China's use of special economic zones as an industrial and innovation strategy is well documented. India's reputation for generics production is well known.

On the other hand, we see India – often perceived as the more economically liberally-oriented country – move to protect IP much later than China, while we see China – often perceived to be the global manufacturer and exporter – much more dependent and in a trade deficit versus India – consistently in a trade surplus over the period we document and to today.

This shattering of stereotypes illustrates exactly why it is important for African governments, businesses, and citizens to understand these histories in a clear and factual manner. As consumers of both Indian and Chinese pharmaceutical products, and potential attractors of FDI from India and China in future (for example, under China's BRI), understanding the previous actions and plans of the businesses and governments for their industries also matters.

6. EIGHT KEY LESSONS FOR AFRICA FROM INDIA AND CHINA

So what lessons can be drawn from these two pharmaceutical giants for the African pharmaceutical industry? We identify eight as follows.

Lesson 1: Self-sufficiency is possible

The first lesson is that it is possible to move from a highly import-based to a more balanced, self-sufficient, and even export-dominated pharmaceutical market. Both China and India provide this inspiration – India is more so to date.

Lesson 2: Government planning and direction matter.

The second lesson is that government planning and direction matter. In both the cases of China and India, government-determined stages, focus, and policies have driven change in the industry structure and results. African governments must realise their role. Specific successful policies from both India and China could be used in African contexts – for instance:

- limiting of foreign ownership (and gradual opening)
- use of process patents rather than product patents
- price controls to ensure basic access to medicines
- planning of pharmaceutical hubs or special economic zones
- raw material requirements on finished goods (i.e., local content requirements)
- Funding for drug innovation
- Funding for the development of human resources

While these policies may have their drawbacks, these types of successful policies are hardly, if at all, mentioned in UN documents or global health analysis. In some cases, policies such as import limits or restrictions are mentioned and dismissed. This is partly due to the colonial nature of the institutions and global health practice. However, such policies are important to consider, especially as they are based on actual experience.

Lesson 3: Transparency matters

Third, transparency matters. India's pharmaceutical sector remains one of the most strictly regulated in the world, yet foreign firms are often more ready to invest than in China. Part of this is because India's policy tends to be very transparent and clear, and China's less so - although partly this is also due to translation – India's policies tend to be translated into English more readily. Similarly, African governments are more aligned to India's government structures due to colonialism and similar engagement levels with international organisations (e.g., early WTO accession), so they have the potential to meet India's standards.

Lesson 4: Use the domestic market to build a base

The fourth lesson is that the domestic market is the primary market to focus on and use to build experience, scale, and efficiency. Both China and India's pharmaceutical markets "took off" based on their large domestic markets, which they largely protected from international sales (albeit in different ways). The African region can do the same, especially given its similar market size to China and India.

Lesson 5: Engage strategically with international organisations

The fourth lesson is to use the UN and other international organisations established for "development" strategically. For example, achieving prequalification status - a service offered by the WHO, which assesses the continued international quality, safety, and efficacy standards in medicine manufacturing – for some APIs or other generics fairly early on will be useful, including to establish a global reputation at a later stage. **Figure 19** shows the vast difference between prequalified medicines approval for India (ahead) versus China (behind), and Africa further behind.

Figure 19: WHO prequalified medicines and vaccines summary

AFRICA	CHINA	INDIA
• Prequalified Medicines: 10 • Prequal. vaccines: 1 • Manufacturers of prequal. vaccines: 1 • Prequal. APIs: - • Prequal. Quality Control Labs: 9	• Prequalified Medicines: 48 • Prequal. vaccines: 8 • Manufacturers of prequal. vaccines: 5 • Prequal. APIs: 55 • Prequal. Quality Control Labs: 2	• Prequalified Medicines: 415 • Prequal. vaccines: 54 • Manufacturers of prequal. vaccines: 8 • Prequal. APIs: 94 • Prequal. Quality Control Labs: 5

Lesson 6: move up the value chain in stages

The sixth lesson is to move up the value chain in stages. The development of innovative chemical drugs requires high investment with high risk, and the clinical development times for a new drug can take up to 20 years.[90] The vast majority of domestically owned African pharmaceutical players cannot manage this. Similarly, arrangements to comprehensively strengthen drug regulatory capacity are not needed immediately. It is best to start where India and China began – APIs, simple formulations, and so on, and build from there.

[90] Brown DG, Wobst HJ, Kapoor A, Kenna LA, Southall N. (2021) Clinical development times for innovative drugs. Nat Rev Drug Discov. doi: 10.1038/d41573-021-00190-9. Epub ahead of print. PMID: 34759309.

Lesson 7: Support small-scale producers at the early stages

The seventh lesson is that domination by small-scale producers is not an impediment to industrial growth. While the pharmaceutical industry requires considerable capital, this is less necessary in the earlier stages of development. In fact, domination by large, often MNCs, may be a hindrance to development. For example, in the case of India, high prices by large oligopolistic MNCs after independence led to inaccessible health products for the general population and, therefore, worse health outcomes. On the other hand, learning from both China and India, if reliant on small-scale producers, African governments must be ready to deal with frequent incidents caused by low-quality drugs and/or poor implementation of standards set at a central level. This can be dealt with gradually as the industry strengthens and firms merge e.g., the process China is trying to go through now; but can be difficult to manage in the face of worried and connected citizens.

Lesson 8: Use IP protection strategically

The eighth and final lesson is that stringent IP protection is not a key driver of success, at least in the early stages. In later stages, India was able to use IP protection to its advantage. African countries could seek to do the same, especially given their existing accession to TRIPS and other WTO protocols.

6.1 Four Caveats to Lessons Learning

Despite these eight key lessons, there are also four key caveats to lessons learning from both India and China.

Caveat 1: Centralised planning across the African region could be challenging

First, China and India are large countries divided into several sub-regions. China is made up of 23 provinces, five autonomous regions, four municipalities, and two special administrative regions, while India is made up of 28 states and eight "union territories". Africa is a region – made up of 55 countries. Africa has the African Union, but no central planning agency with decision-making power on a similar scale to the Chinese or the Indian government. This makes it significantly more difficult to, for instance, introduce similar policies that India and China did in a blanket way. The risk of one large country reneging on, say, an agreement to restrict foreign ownership of pharmaceuticals on the continent for a period of even 10 years, let alone 35 (as per India's case) is high. Price controls would likely need to differ across countries. And who could tell Ghana or Nigeria to agree that the other should become the regional pharmaceutical hubs, or Kenya and Ethiopia the same? All will likely want to vie for these positions.

Caveat 2: Difficulties in managing international stakeholders and organisations

Second, China and India had to be incredibly brave to institute some of their policies. Limiting foreign ownership came with a great deal of negative publicity and today would likely attract potentially costly legal action. In addition, for instance, we are unsure if there is precedent for WTO members shifting from product to process patents (the type of

patents that India kicked off its generic journey with) – which again may be met with negative publicity and risk potential legal action due to TRIPS.

Caveat 3: Need for global health to prioritise local production in procurement

Third, and relatedly, the UN and other global health institutions may pose a significant barrier. Many of these organizations distribute pharmaceuticals procured from the US, Europe, India, and now China for free or cheaply to African consumers. While the aims of this are laudable, this also undercuts local production, which at this point is inefficient in comparison. To support any domestic industrial policy changes of the nature India and China introduced, African governments would need to ensure their efforts are not undermined by well-meaning international organisations, or the original sourcing countries and companies, even if it means health outcomes in Africa might temporarily regress. Part of this will almost certainly involve encouraging and engaging directly with sourcing companies to relocate to African countries to deliver their pharmaceutical production, rather than export.

Caveat 4: Need for global health to prioritise localisation in procurement

Fourth and finally, and in relation to caveat 3, China and India themselves pose competition now that did not exist. India is ahead of China to some degree - for example, the average revenue of India's top 10 pharmaceutical companies was US$2.18 billion in 2020. India's Sun Pharma, the largest pharmaceutical company, generated US$4.576 billion in revenue, with 70% coming from overseas markets.[91] In contrast, China's leading generic pharmaceutical company, Huahai Pharmaceutical, generated US$1.018 billion in revenue, 59% from overseas, while innovative pharmaceutical leader Hengrui Pharmaceuticals reported only 3% overseas revenue. That said, India and China are now working to grow and compete for global market shares and transitioning to an R&D focus. They may well seek the kinds of protections in African countries that American and European firms sought in their countries since the 1960s and 1970s. African firms will need to be ready to compete in such an environment, and African governments effectively stand up to even more players now than India and China did back then.

6.2 The Way Forward and Further Analytic Gaps to Fill

While we have attempted to make this research as comprehensive as possible regarding India and China, no research is complete. There are likely areas we have missed out on and other analysts may have other interpretations of the policy directions and trajectories. However, we have done our best to seek out the right information, and welcome feedback on how our analysis of the Chinese and Indian markets can be refined.

Moreover, there will be more lessons to learn from specific policy analysis in the two countries, including lessons learned beyond pharmaceutical manufacturing, for example, on the development of traditional medicine in both countries, which could be of great

[91] Brown DG, Wobst HJ, Kapoor A, Kenna LA, Southall N. (2021) Clinical development times for innovative drugs. Nat Rev Drug Discov. 2021 Nov 10. doi: 10.1038/d41573-021-00190-9. Epub ahead of print. PMID: 34759309.

interest to African countries. There is even scope for Africa's potential to locally manufacture traditional medicine products to be realised through cooperation with China and India.

In addition, our analysis must not be interpreted as suggesting that China and India are the best models or have all the answers. Far from it. We have tried to avoid that suggestion explicitly by comparing the approaches, as well as explaining the aspirations that the respective governments continue to have for their pharmaceutical sectors, as they are a work in progress and have significant limitations. That said, other pharmaceutical manufacturers also have their limitations – and thus, the intention of our work is simply to enable a better understanding of different models so that Africans can move ahead in an informed manner rather than be confined by traditional analysis.

Linked to this, the experience of other non-African low- and middle-income countries – beyond China and India - in growing their pharmaceutical sectors may also be very relevant to explore.

Finally, transforming some of the lessons learning recommendations into actual policy implementation –for example, applying certain adaptations to specific existing legislation in African countries – will also require significant work.

However, despite the caveats and the limitations above, we are optimistic that this report will enable African governments to better learn from other low- and middle-income nations' growth paths to expedite Africa's pharmaceutical development. Adapting tested methods while avoiding noted pitfalls will be key to Africa harnessing its full potential and taking its place in the global market for pharmaceuticals and in self-sufficiency for medicines – a goal that has become more pressing in the wake of the COVID-19 pandemic and the undeniable inequity experienced by the continent in accessing much needed pharmaceutical products. There is no time like the present to really explore a new path.