Accelerating Innovation in Healthcare Transformation to Explore Healthy China Opportunities

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Abstract

Following a period of continuous social and economic development in China, the central government has elevated the people's health as a key priority in the country's ongoing strategic development. The government-proposed *Healthy China Initiative* promotes a shift in the current healthcare management framework from treatment-focused to prevention-focused. To support the *Healthy China Initiative* and also to contribute to high- quality economic development two opportunities will play critical roles:

(1) Advancing responsible healthcare data use

Strategic use of meaningful data at scale (MDAS) and advanced digital healthcare technologies can accelerate transformation in the approach toward (a) managing major, complex diseases, such as malignant tumors; (b) achieving early-screening, -diagnosis, and –treatment; and (c) encouraging a paradigm shift in utilization of health care resources. China's global leadership in digital transformation provides a unique and differentiated platform to model improvement in the quality and efficiency of healthcare service delivery through a deeper integration of healthcare and advanced digital technology, such as big data and artificial intelligence (AI).

Against the backdrop of fast-evolving, rapidly-developing digital technology, countries globally have begun to realise data's potential in addressing complex, intractable healthcare problems; hence also benefiting from responsible use of data as a production factor in healthcare industry growth. The COVID-19 pandemic further demonstrates the role of big data in the healthcare domain, such as its importance in proactively preventing and swiftly treating COVID-19 cases. On this front, the Chinese government has issued a series of regulations and policies to promote the application of healthcare data and unlocking its potential value, while still evaluating issues such as data ownership, quality, and safety. To further enhance these efforts and unlock full value for health system stakeholders, the following policies and actions may be considered:

- Establishing an integrated patient-centric healthcare database
- Building a dynamically-adjusted, classified data management mechanism to ensure legitimate use
- Fully maximizing the potential of digital technology and healthcare data through incentivizing development of innovative use case scenarios
- Improving healthcare stakeholder awareness of a "patient-centric, data-driven" healthcare system, while strengthening patient participation

(2) Encouraging biomedical innovation

Biomedical innovation is crucial to improving individuals' health, particularly in the treatment of complex diseases with high unmet need. In recent years, China has successfully promoted the development of the biomedical industry, and there is additional value creation opportunity through continuing to foster an environment that recognizes and encourages innovation as a strategic priority.

Specifically, China has made considerable progress in supporting clinical research, tightening supervision and approval, and improving healthcare security capabilities, ultimately promoting biomedical innovation. To continue on this positive trajectory and extract the full impact these efforts have had, ensuring sustainable financing and patient access to produced innovation will continue to encourage and incentivize both domestic and global ingenuity and investment. The required high investment and long investment cycles inherently come with significant risks of failure. Having the appropriate reward mechanisms and incentives in place is necessary to continue to encourage both longstanding and especially nascent players. The combination of empowered policies along with free market-driven dynamics will lead to more breakthrough therapies for Chinese patients and an environment that supports broad, affordable access. China is well-positioned to foster an environment of this nature with the broad reach of its long established universal health coverage for its population and the empowerment of government-issued policies. Key areas for potential consideration as part of the ongoing investment in biomedical innovation and to support sustainable healthcare financing for patients' needs may include:

- Continuing to foster a policy-empowered, market-driven environment with policies that highlight value recognition around innovation and reward innovative value creation – e.g. enhancing the review and listing mechanism in the national healthcare security system
- Enhancing medical insurance reimbursement policies and align total medicine innovation value with health system priorities through policies that actively explore and encourage innovative healthcare financing models – e.g. innovative risk-sharing payment models

As a leader in digital and personalized healthcare and a global healthcare company that operates in 100+ countries worldwide, Roche has accumulated rich industry experiences in the global healthcare market across the value chain. Roche is well-positioned to create new development opportunities brought to China by healthcare data and the innovation-driven biomedical industry and is eager to contribute its breadth of experiences, from R&D to market access innovation to insights capabilities. With a 90+ year history in China Roche continues its commitment to being a differentiated partner. This includes leveraging integrated, end-to-end capabilities across its full range of businesses and investments, as exemplified by recent commitments to build a next generation R&D engine in China to meet the needs of patients in China and worldwide.

Chapter 1, Introduction: Strategically focusing on the application of healthcare data and biomedical innovation as opportunities to build a Healthy China together

China's economy and society have realised leapfrog development and made remarkable achievements in the past 40+ years of reform. Over this period, China has hit key economic and social milestones, including laudable accomplishments in eliminating absolute poverty and operating as the world's sole major economic growth engine. China's position of having the world's second-highest total investment in research and development (R&D) not only demonstrates the coordination and sustainability of its economic development as a country but also is a key indicator of the country's transformation into an innovation-driven economy.

China's prioritisation of the people's health for strategic development in the Fifth Plenary Session of the 18th Communist Party of China (CPC) Central Committee and the October 2016 issuance of the *Healthy China 2030 Planning Outline* demonstrate China's commitment to the construction of "Healthy China" and clearly highlight the importance of health as a prerequisite for the country's all-around development. Additionally, *The Outline*, stresses enhancing disease prevention efforts and a desire to accelerate the transformation of healthcare management increasingly from "treatment-centric" to "health-centric."

Healthcare data application and biomedical innovation are two critical areas that will bring new opportunities for the development of China's rapidly growing healthcare industry. The continuous advancement of digital technology will accelerate the rapid development of the healthcare industry and further propel China towards its vision as a powerhouse biomedical innovator. Focusing on the intersection of healthcare data applications and biomedical innovation will bring a unique competitive advantage to China and accelerate its entry into the first echelon of global biomedical industry innovation. Digitization will help China meet the multi-faceted, diversified, and personalised health needs of individuals more accurately, while comprehensively promoting and advancing *Healthy China 2030*.

Roche welcomes the opportunity to support China in achieving strategic goals set forth in Healthy China 2030 through relevant experiences and technologies in the field of healthcare. Since its establishment in Switzerland in 1896, Roche has been a pioneer in healthcare disruption and breakthroughs. Roche Group biopharmaceuticals and diagnostics protect patients' health in several key areas, including oncology, infectious diseases, antivirals, transplants, and rheumatism. In 2020, Roche Group ranked the largest biotech company in the world, investing over USD 13 billion into R&D, more than any other healthcare company in the world. With the unique advantages stemming from industry-leading pharmaceutical/biotechnology and

diagnostic businesses coupled with key acquisitions of next-generation genomic sequencing and insights businesses, Roche Group has also become a leader in personalised healthcare.

Roche has had a front seat in witnessing China's impressive development over the decades and as an early partner was the first to develop a full pharmaceutical value chain in China and, going forward, Roche remains to partnering to support China in its drive toward its next chapter of innovation-led development. Following the vision outlined in the *Healthy China Initiative,* Roche has actively participated in advocacy and the practice of disease prevention and treatment. Recently, under the guidance of the Healthy China Action Promotion Committee's Office, People's Daily hosted a "Healthy Chinese People" round-table forum during the Two Sessions in 2021. Roche advocated that all societal sectors should work together to pay attention to cancer prevention and treatment, and build a closed-loop ecosystem of tumor screening, diagnosis, and treatment.

Chapter 2: Healthcare data applications will uncover new opportunities for establishing a *Healthy China*

With the rapid development of information technology, countries globally have realised the strategic role of data as a production factor in the growth of the healthcare industry. ***The organic integration of the deepening digitalisation and healthcare will promote the rapid development of digital healthcare.*** A *McKinsey r*eport *(Big Data Revolution in US Health Care)* predicted that digitalisation in healthcare will lead to a 12 to 17 per cent reduction in health expenditure. With big data deeply integrated into all facets of the healthcare system, its scaled-up system-wide impact will be reflected across all aspects of healthcare, from pharmaceutical R&D to clinical treatment and health management, and will significantly improve the efficiency of the healthcare system.

In the post-epidemic era, accelerating the release of data elements' value has become a global development trend. In 2020, COVID-19 exposed a series of shortfalls in many countries' and cities' social governance capabilities and public health systems. Big data has played a crucial role in the healthcare industry as a counteragent. Roche has been a pioneer of harnessing digital solutions and insights in improving the efficiency and delivery of healthcare across the value chain and has launched cooperative applications in many countries. For example, during the pandemic, Roche collaborated with companies in Canada and other countries to launch a data science coalition and establish a publicly available population database. This partnership leveraged Roche Group's advanced diagnostic data solutions to contribute to epidemic prevention efforts***.*** This experience has continued to build on Roche's industry-leading platform around meaningful data at scale (MDAS), digitization, and appropriate use cases for value creation in the healthcare industry. In full cooperation with and following the lead of China's government, Roche is fully committed to proactively exploring additional opportunities that data applications and technologies can bring to support the realisation of a *Healthy China*.

2.1 Internationally, countries have begun to actively explore initiatives in the area of digital medicine

Denmark and its Ministry of Science, Innovation and Higher Education have jointly established a national biobank, collecting more than 10 million bio-samples across various diagnostic categories. In addition, the ***national biobank is connected to a significant number of civil registries that contain the population's electronic medical records (EMRs***), assisting researchers in accessing comprehensive healthcare data, such as patient prognoses, rehabilitation and health management data. The biobank not only facilitates innovation of the country's healthcare industry, but also supports disease prevention, treatment, and progression-tracking during clinical practice.

In England, the Ministry of Health initiated the ***'100,000 Genomes Project' to collect and sequence 100,000 genomes from cancer and rare disease patients, while also collecting clinical and childhood illness data from patients' medical records.*** Since 2017, the project has gradually optimised the research environment, through enrichment and improvement in accuracy of genomics data, yielding a year over year increase in the number of academic papers published in the fields of cancer and rare diseases. In addition, the research

results of the project have also been applied to the training of local healthcare staff to help them better understand the needs of patients and improve the quality of healthcare services.[1]

2.2 In recent years, China has made progress in the application of healthcare data

The central government has issued a series of regulations and policies to encourage the application of data. In 2016, the State Council issued *Opinions on Promoting and Standardizing Big Data Application in the Healthcare Industry*, integrating big data and healthcare development and raising the concept to become a national strategy. Following this, the National Health Commission released the *National Population Health Informatization Development Plan of the 13th Five-Year Plan (FYP)* and other policies to vigorously promote the exploration and construction of healthcare informatization and healthcare big-data service system by consolidating infrastructure, deepening data application and developing innovative models, etc. In April 2020, the central government's *Opinions on Accelerating the Building of a Better Institutional Mechanism for the Market Allocation of Production Elements* clearly defined the strategic position of data by designating it as a new type of production factor for the first time. In addition, the government aimed to "promote the improvement of data classifications and hierarchical security systems within the big data ecosystem." Later in May, the State Council proposed to "establish a management mechanism of data resource list, and improve standards and measures for data ownership, data sharing, and data transactions."

At present, China has established several digital platforms with grading, classification, and different applications to provide preliminary healthcare information and data-sharing for businesses, scientific research, and other services, which played an active role during the epidemic. In June 2019, *China established the National Genomics Science Data Center (NGSDC), creating a shared management platform dedicated to the R&D of biodiversity and health big data.* During the epidemic, the data centre's COVID-19 information database collected and released 56,036 pieces information of COVID-19 viral sequences and 208 pieces of relevant clinical information.

2.3 There is an opportunity to further improve and develop the application of healthcare data.

Although China has made many achievements in healthcare digitalisation, its continuing development still faces many challenges. To share and use meaningful data at scale (MDAS), which contains medical value, it needs to address questions related to data ownership, quality, security, as well as means to harness its potential healthcare value (see 2.3.1-2.3.3) . These problems are worth joint exploration and resolution through government and industry partnership.

2.3.1 Data ownership

As a new type of production factor, data—like land, capital, labour, and other production factors—involves ownership issues. In theory, there is no uniform, complete and general definition of data ownership, nor is it entirely recognised and clearly defined in law. Establishing an integrated healthcare database and clarifying data ownership is a fundamental task. Only when the rights and interests of data owners and relevant stakeholders are fully protected can efficient data circulation occur and increased data accessibility be fully achieved.

Some places in China have begun to test different approaches to managing meaningful data at scale (MDAS) and data ownership. In 2019, Shanghai pioneered the release of *Shanghai's Interim Measures on Open Public Data,* which defines the scope of public data as data collected and generated by public management and service agencies in the process of performing their duties. Simultaneously, individuals *(i.e. natural persons, legal persons, and unincorporated organizations)* are allowed to submit evidence and suspend the opening of public data that may infringe on individual privacy. Shenzhen recently released a public data policy—*Shenzhen Special Economic Zone Data Regulations (Draft for Comment)*—clearly defining public data as state-owned assets and indicating that healthcare data collected by public healthcare institutions will be

[1] Genomics England. (2020). Delivering the Project. [2021-03-02] https://www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/

established as state-owned assets. Nevertheless, under this policy, individuals still have the right to understand what data is being collected and to provide consent during data collection. Additionally, the Shenzhen Municipal Health Commission is setting up a healthcare big data scientific research and sharing platform, whose data access and usage rights may be open to institutions and individuals in the future.[2]

2.3.2 Data quality

While healthcare data is abundant and complex, only when it reaches a high level of quality, matched with rigorous data analysis methodologies, can it support medicine development, standardized supervision, and clinical treatment.

Currently within the healthcare industry, data quality is a major concern. Different analytical purposes and data users—e.g. researcher and supervisors—have diverse demands of data quality (e.g., clinical relevance, accuracy, completeness, transparency, and scalability). In general, the quality of most real-world data (RWD) currently cannot meet the requirements of data users. Among them, the problem of insufficient longitudinal RWD is particularly prominent. In traditional databases, health data usually exists in the form of scattered, fragmented or incoherent data points. Longitudinal data is of high value and can provide insights on evaluating clinical pathway designs, supporting medicine optimizations, and disease management, as well as providing strong support to analyze the impact of clinical decisions on efficacy.

2.3.3 Data security and unlocking the potential value of data

Under the trend of digitalisation, privacy issues have increasingly become a social focus, with many countries introducing policies and measures to try and meet this challenge. For example, the EU issued the *General Data Protection Regulation (GDPR)* in 2018, emphasising the principle of informed consent to protect personal information. The freedom to operate with respect to storage, processing, or release of personal data must be obtained through the data subject's informed consent. If the subject submits a legal informed consent withdrawal application, the data user must process it promptly. Similarly, the Australian government has issued the *Guiding Framework for the Secondary Use of My Health Record (MHR) System Data*, requiring the establishment of a Data Governance Board to review data applicants, ultimately helping to protect patient data privacy.

At present, China has also begun to gradually improve the management regulations concerning healthcare data security. In 2019, the State Council issued the *Data Security Management Approach (Draft for Comment),* formulating a framework of regulations that guide the collection, storage, transmission, processing, and use of data, as well as measures around data security protection, supervision, and management. In addition, the *Guidelines for Information Security Technology, Health and Medical Information Security* ("*Guidelines*"), which specifically encompasses healthcare data, was also being formulated. The *Guidelines* put forward detailed recommendations on security measures for typical healthcare data use scenarios and corresponding management processes to providing detailed guidance for actual operations. Building on the existing foundation and principles in China, the Chinese government can also refer to relevant international experiences to further explore formulation of a comprehensive and complete healthcare data management system.

2.4 Policy Recommendations

2.4.1 Optimize top-level design while establishing an integrated patient-centric healthcare database

Breaking through database barriers from different fields, integrating multiple resources, and improving the operational efficiency of the entire healthcare system with high-quality data is the key to further unlocking the potential value of meaningful data at scale (MDAS). The central government can encourage local areas to

[2] China Government Procurement Platform. (2019). *Shenzhen Medical Information Center's Announcement on Shenzhen Healthcare Big Data Research and Sharing Platform (Phase I) Bidding Result.* [2021-03-04]. http://www.ccgp.gov.cn/cggg/dfgg/zbgg/201909/t20190911_12880660.htm

conduct pilot projects, explore the opening-up of various healthcare data resources, link electronic medical records, genomic data, biological samples, health management files, as well as introduce innovative data sources, such as wearable devices into the database. All these facets can help to establish an integrated patient-centric healthcare database that leverages high-quality data to improve the operational efficiency of the whole healthcare system and save social costs.

2.4.2 Establish a dynamically-adjusted, differentiated data management mechanism

Considering the sensitivity of health data, the centralised storage and management of enormous amounts of data pose significant challenges to data management capabilities. Therefore, in order to protect and ensure legitimate use, after the establishment of an integrated healthcare database, pilot areas can consider exploring a management mechanism for differentiated data classifications. By adopting a data management mechanism, local and central governments can more effectively control and supervise different subjects' rights to access data, reducing the risk of illegal access or data misuse. Based on this, the differentiated data management mechanism can also be integrated into emergency public health responses, releasing relevant epidemic-related medical data promptly to aid in vaccine and medicine R&D, conducting epidemiological investigations, and implementing relevant quarantine solutions.

Relying on a hierarchical differentiated data management mechanism, local and central governments can explore relaxing access to various data types for different industries. This mechanism could encourage related industries, such as the biomedical industry, to leverage their advantages to ensuring legitimate use of data, and to further explore new areas for integrating industries.

2.4.3 Encourage partnerships and cooperative efforts to fully maximise the potential of information technology, medical data, and innovative data scenarios

To achieve goals pertaining to high-quality data collection and management, it is also necessary for multiple parties to collaborate and make full use of information technology to achieve in-depth data analysis.

To better meet the personalised health needs of patients, Roche recommends leveraging new technologies and meaningful data at scale (MDAS) to carry out precise oncology medicine research and development. The development of modern biomedical technology—especially in the field of complex diseases such as tumours and rare diseases—is rarely achieved independently by one institution. Different research fields, companies, and industries should collaborate and innovate together to promote the improvement of technology. The Chinese government could consider actively encouraging organizations from diverse industries to explore innovative partnerships for data-sharing, to work collaboratively, and develop advanced treatment solutions that can meet patients' needs.

Medical institutions can be encouraged to apply advanced information analysis technology, promote the development of clinical decision support systems (CDSSs), improve the level and quality of diagnosis and treatment, and optimize patient experiences. Through innovative information technology, massive amounts of clinical data can be transformed into information that guides actual operations and provides clinical decision support for medical staff. CDSS can support doctors in transcending the limitations of their own experience and knowledge, and to utilize a large number of research results and past practical experience to design the best diagnosis and treatment plan for patients.

2.4.4 Improve medical staff's awareness of a "patient-centric, data-driven" healthcare system, while strengthening patient participation

Medical staff are the main force behind medical services, and patients are at the center of the healthcare system. It is very important to encourage both parties to actively participate in building a "patient-centric" ecosystem. The Chinese government can test a variety of measures to promote collaboration between doctors and patients and jointly promote the advancement of the healthcare system. For example, efforts could be taken to deepen medical staff's understanding of "patient-centric," promoting and popularizing this concept.

Similarly, patients could be encouraged to participate in all aspects of digital healthcare, helping patients to realize patient empowerment, and enabling them to truly benefit from digital medicine.

2.5 Roche's Contribution

Roche has global, industry-leading experience in the management, integration and analysis of large volumes of medical data, which can help China further realize its healthy China strategy

Roche has created the world's first clinical genome database of cancer patients. Roche's subsidiaries Foundation Medicine Inc. (FMI) and Flatiron Health jointly created the world's first database that integrates oncology patients' genomic data and clinical data. The database contains not only clinical data—such as demographic data, medication, diagnosis, tumor metastasis date, medication history, medical examination results—but also genomic data, such as tumor genomic analyses, genomic changes, samples, and biomarkers. The database has large volumes of high-quality data, which has the potential to assist in more efficient clinical decision-making and to accelerate the realization of personalized healthcare.

Roche is actively involved in personalized cancer care in China. In April 2018, Roche's FMI subsidiary signed a cooperative agreement with China's DIAN Diagnostics, and subsequently launched FoundationOneCDx (F1CDx), the first comprehensive genomic-sequencing analysis service on the market for solid tumor patients. The genomic analysis presented by the F1CDx test can provide doctors with comprehensive molecular information, helping to guide doctors in formulating targeted cancer treatment and prevention plans. F1CDx for solid tumors will break the traditional tumor diagnosis and treatment model and establish a new standard for personalized patient care in China. Furthermore, following the wide-spread use and application of this technology, it is expected that more tumor data in China will provide even more effective support for future cancer prevention, diagnoses, and treatments.

Continuing on its legacy of commitment in China, Roche has had the privilege of participating in the *Healthy China Initiative*, to transparently share Roche's global experience and leading biotechnology solutions in promoting early cancer screening, diagnosis, and treatment, and to support China in achieving its *Healthy China* ambitions.

Chapter 3: Innovative biomedical industry development will generate new opportunities for establishing a *Healthy China*

At the Fifth Plenary Session of the 18th CPC Central Committee, President Xi Jinping prioritised 'Innovation' at the top of five new development concepts.[3] As the *13th Five-Year Plan for National Economic and Social Development* clearly stated "innovation is the first driving force for development," China is currently actively optimising the macro-environment for innovation and gradually transforming into an innovation-driven economic development model, creating a path for sustainable development. China has entered the steepest section of the curve of "imitative innovation, business innovation, and technological innovation". Overcoming difficulties with regards to technological innovation will bring significant possibilities for China's next stage of economic development.

3.1 Biomedical innovation is essential to improving people's health

During the past ten years, with the continuous advancement of China's healthcare system reform, China has made remarkable achievements in four aspects: healthcare security,public health services, healthcare services, and medicine supply reliability. In fact, China has become the world's second-largest consumer market for medicines. However, despite rapid growth, traditional pharmaceutical industry faces limitations in fully meeting the population's increasing healthcare demands. For example, major diseases such as malignant tumours seriously threaten the Chinese people's health. Studies have shown that in the face of currently incurable diseases, breakthrough innovations are essential to reducing disease burden significantly. Also,

[3] Five new development concepts: Innovation, Harmony, Green, Open, Sharing.

during the COVID-19 pandemic, the importance of health-related technological innovation has become even more prominent in epidemic prevention and control efforts, as well as the economy's recovery. In other words, the strategic significance of an innovative biomedical industry to accomplishing a *Healthy China* has become increasingly evident. It plays a critical role through the development of new technologies, programs, and products.

China has included the biomedical industry in its top-level development strategy. The *13th Five-Year Plan for the Development of Biological Industry* clarified that the bio-industry is a core part of China's strategic, emerging industries. In May 2015, the State Council issued *Made in China 2025*, identifying biomedicine as a key area for breakthrough development. In October 2016, the CPC Central Committee and the State Council jointly issued the *Outline of the Healthy China 2030 Plan*, encouraging improvement of the "industry-university-research-application" collaborative innovation system, biomedical innovation, as well as the industry's transformation and upgrade.

Innovative biotechnology companies are currently collaborating with domestic partners to leverage big data, artificial intelligence, 5G, and other technological advancements to promote the innovative development of the biomedical industry. Biotechnology companies also play a crucial role in promoting healthcare transformation from "treatment-centric" to "health-centric" models.

3.2 There is an opportunity to evolve China's policy environment to promote innovation and sustainable development of the biomedical industry

In recent years, China has made considerable progress in supporting clinical research, tightening supervision and approval, and improving healthcare security capabilities—with the policy environment significantly improving and health technology innovation being promoted. China has implemented a record system to manage the accreditation of clinical trial institutions. The number of clinical trial centres has increased from 375 in 2015 to 1,072 in 2019.[4] In 2018, the 60-day approval system for clinical trials was announced, significantly improving clinical trial efficiency. The newly revised *Medicine Registration Regulations* was issued in 2020, introducing several expedited review processes, such as priority review and approval, review and approval of breakthrough medicines, and conditional and special medicine approval. Four COVID-19 vaccines have been approved through conditional approval procedures. The priority review and approval policy introduced in 2016 increased the number of fast-approved medicines from 7 in 2016 to 82 varieties in 2019.[5] Additionally, the frequency of updating the *National Reimbursement Drug List (NRDL)* has continually increased, with an annual dynamic adjustment mechanism being established in 2020. The duration in years for innovative medicine inclusion on the NRDL through negotiation has been greatly reduced to 3.7 years, from an average of 7.8 years in 2017. Fourteen medicines entered the NRDL in the same year they were approved. These collective policies, among others, have driven important reform in medicine approval procedure and broader medicine access, greatly accelerating market access reimbursement and significantly improving patient medicine accessibility.

Nevertheless, there are still key aspects that may be reviewed. These include two considerations: ***(1) Supporting overall access through financing of innovative, life-saving and life-enhancing medicines to meet patients' growing and unmet needs.*** While China has made significant strides in the last decade in improving the five-year cancer survival rate from 30.9 per cent to 40.5 per cent, this survival rate still lags that of developed countries. [6] One key reason is that despite innovative medicines with better clinical efficacy having approvals for the Chinese market, they may only benefit a limited number of patients due to factors such as lack of national reimbursement and public hospital formulary listing. In fact, half of the innovative

[4] China Pharmaceutical Innovation and Research Development Association & R&D-based Pharmaceutical Association Committee of China Association of Enterprises with Foreign Investment. (2021). *the first part of the series of reports on the construction of China's pharmaceutical innovation ecosystem: 2015-2020 development review and future prospects*. [2021-03-02] http://cnadmin.rdpac.org/upload/upload_file/1614646546.pdf
[5] Center for Medicine Evaluation. (2020). *2019 Medicine Evaluation Report*. [2021-03-03] http://www.cde.org.cn/news.do?method=largeInfo&id=68f4ec5a567a9c9a
[6] State Council. (2020). *Report on Nutrition and Chronic Disease Status of Chinese Residents (2020)*. [2021-03-03] http://www.gov.cn/xinwen/2020-12/24/content_5572983.htm

medicines approved during 2016 to 2020 have not yet entered the NRDL. ***(2) Strenghtening* access mechanism to *China's national healthcare security by accounting more for diversity of innovation.*** Considering the long R&D cycle, large investments, and high risks associated with developing innovative medicines, it is suggested that apart from reducing medicine prices and increasing accessibility, national medical insurance negotiations could explore approaches that comprehensively consider protecting biotechnology companies' enthusiasm for innovation. This may include policies that support sustainable health system medicine financing, while ensuring reasonable returns to the innovative biomedical industry. One example may be to encourage and reward creative reimbursement models, such as risk-sharing agreements..

3.3 Policy Recommendations

First, innovative biomedical industry development requires a policy environment that protects innovation. R&D for innovative medicines, medical devices, and other products requires time, knowledge, and the accumulation of technology. Strengthening intellectual property rights protection, improving the legal system, encouraging the protection of innovative achievements, and creating a social atmosphere that advocates for innovation can all contribute to the biomedical industry's innovative vitality and promote the industry's development. Additionally, establishing a long-term, stable policy system, continuous improvement of the review system of health technologies, and gradual integration of the regulatory system with international standards are also keys to promoting the biomedical industry's sustainable development.

***Second*, *a sound healthcare financing policy that rewards innovation is required*.** For example, regarding national basic medical insurance (BMI) coverage, the establishment of a value-based, scientific and comprehensive health technology assessment, evaluation, and appraisal system and inclusion of more innovative medicines onto the NRDL can enhance the sustainability of the biomedical industry's development. Additionally, China could refer to international examples and establish innovative risk-sharing payment mechanisms in order to deal with potential uncertainties including budgetary concerns with respect to the increased availability of newly approved innovative medicines in the NRDL. A sound and appropriate healthcare financing policy will support biotechnology companies in their enthusiasm in building towards a biomedical industry that is led by science and driven by unmet patient-needs.

3.4 Roche's Contribution

Since entering China's market 90+ years ago, Roche has supported China's biotechnology industry's overall development. As a signal of its continued commitment to the biomedical industry's next stage of development, in September 2019, the Roche Innovation Center was established in Shanghai (RICS). The centre aims to promote the overall development of China's innovative biotechnology industry's R&D capabilities through in-depth cooperation and talent exchange with local institutions, companies, and research hospitals. Roche is committed to working with the Chinese government to promote innovation and development of the country's biotechnology industry, continuing to introduce cutting-edge technologies into China, further building out China's R&D capabilities, and supporting China in becoming a top-tier global leader of biomedical innovation.

Chapter 4, Conclusion: Forward-looking application of healthcare data and biomedical innovation to enable achievement of *Healthy China* and propel China to global innovation leadership

In support of the *Healthy China* goals, Roche is privileged to build on its position in China via its existing suite of solutions across diagnostics, biopharmaceuticals, and insights capabilities. In going forward, Roche aspires to differentiate itself in the eyes of China's health system and leaders as a partner that has a deep commitment to practicing patient-centric values, fulfilling diverse Chinese patient needs, and providing China with high-quality products and breakthrough solutions. In its approach, Roche will continue as a partner to focus on the overall healthcare ecosystem and explore holistic, shared value opportunities in reducing disease burden.


Roche