Interpat

CRA Charles River Associates

Value of IP for health and growth

The economic benefits of strengthening the innovation environment in China

March 2024

CONTENTS

Executive summary

OBJECTIVES AND APPROACH

INTERPAT asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in China.

The objective of the study is to:

1. Set out the **policy framework** for supporting innovation in China and the current state of innovative activity

2. Undertake a **case study analysis** on countries with potential lessons from other countries which may represent an opportunity for China

3. Develop **scenarios** as to how innovative activity could change in China if policies adopted in other countries were pursued

The approach builds on a similar analysis applied to countries in Latin America (Argentina in 2018, Brazil in 2019, Mexico in 2020, Colombia in 2021)

The following approach was taken:

- Review the current intellectual property (IP) framework in China through **literature review** of academic publications, grey literature, and Chinese Official Statistics and International Databases

- Test key findings and hypotheses using an **iterative Delphi panel approach** with N=12 experts

- Establish **consensus** and **integrate** with findings from literature review

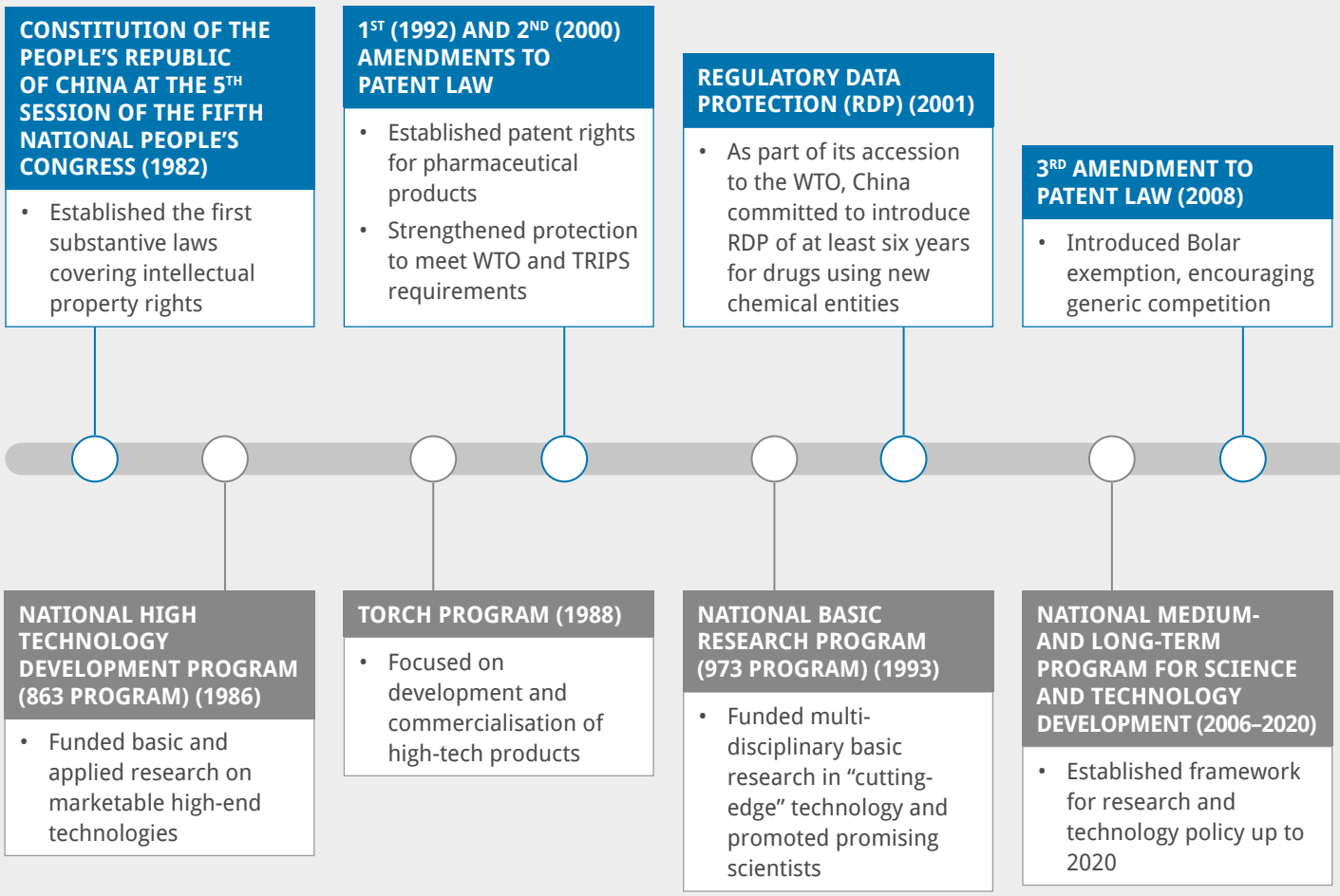
- Analyse **case studies** on other countries including Japan, Singapore, and South Korea selected based on criteria such as having observable outcomes from innovation and IP policy changes

- Develop **scenarios for growth** in research, R&D expenditure, employment, and patent granting

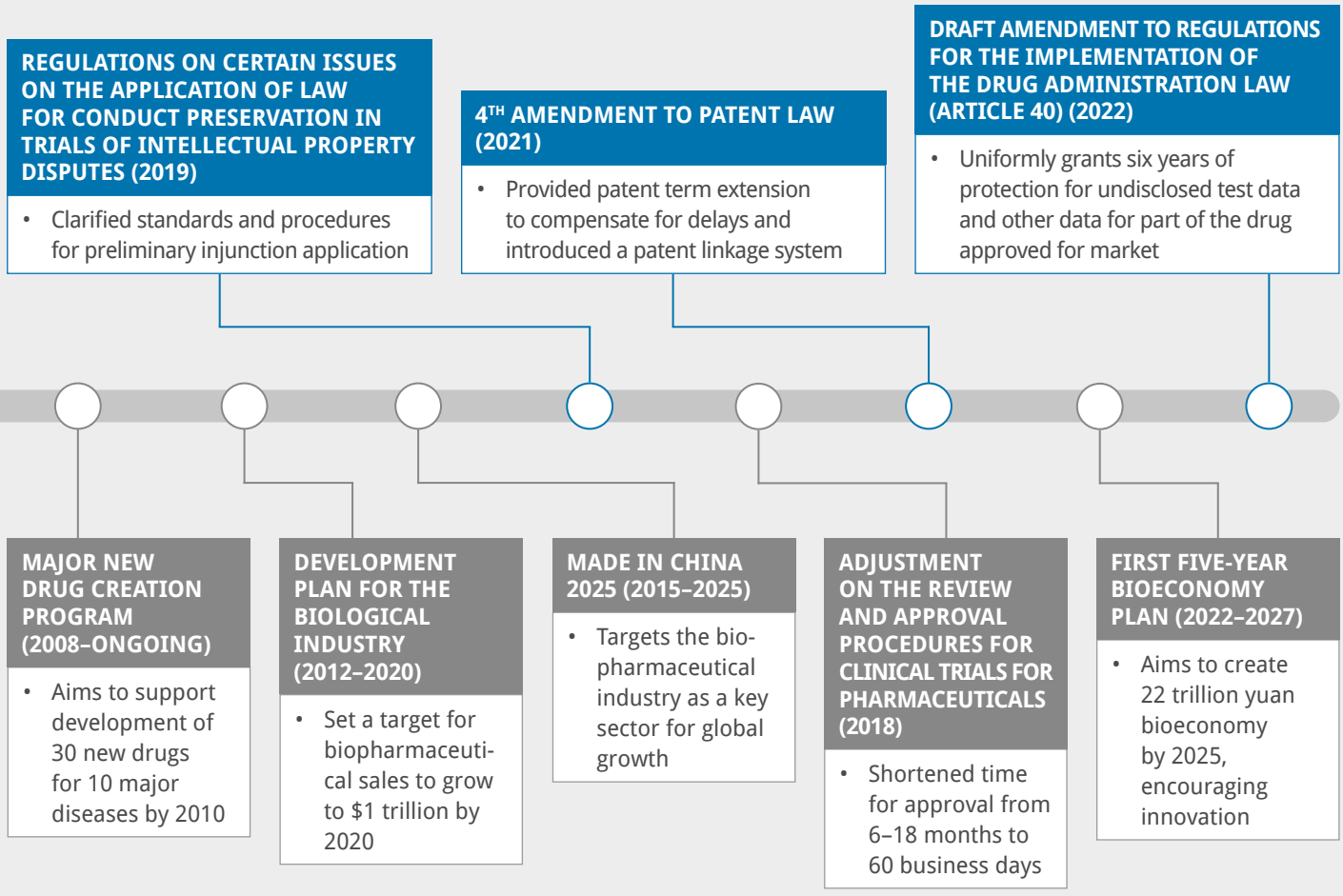
- **Refine and disseminate** findings

CHINA HAS BECOME A MUCH MORE FAVOURABLE ENVIRONMENT FOR SUPPORTING BIOPHARMACEUTICAL INNOVATION

CHANGES IN THE IP REGIME

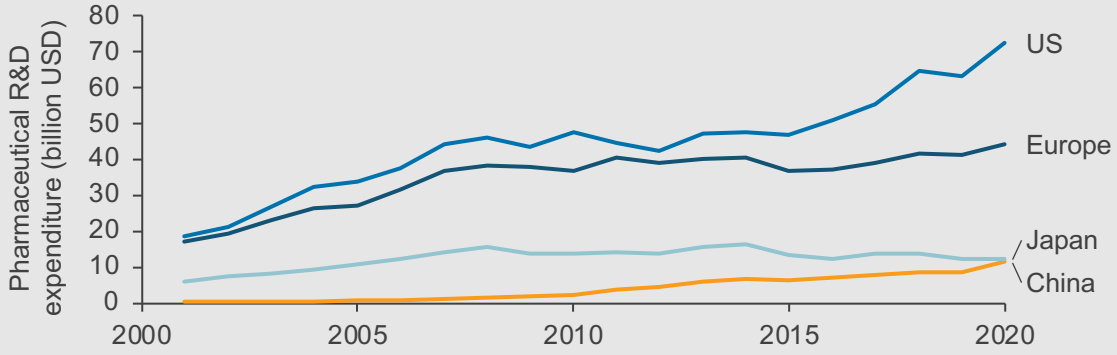


CHANGES IN INNOVATION POLICY

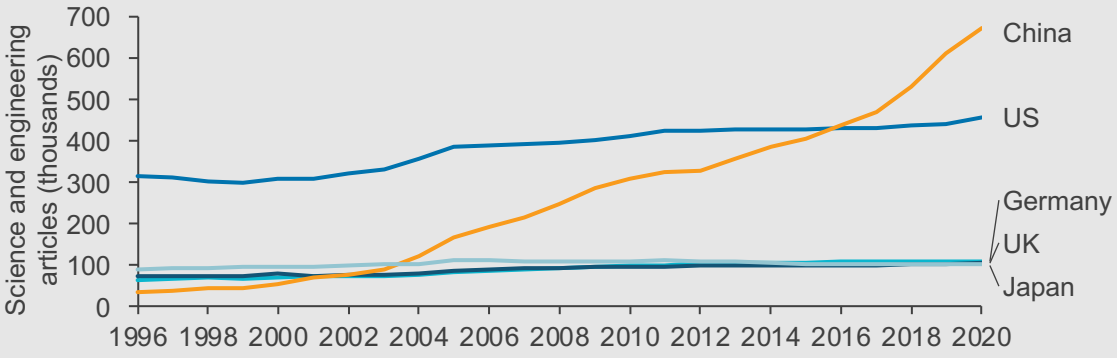

REGULATIONS ON CERTAIN ISSUES ON THE APPLICATION OF LAW FOR CONDUCT PRESERVATION IN TRIALS OF INTELLECTUAL PROPERTY DISPUTES (2019)
• Clarified standards and procedures for preliminary injunction application
4TH AMENDMENT TO PATENT LAW (2021)
• Provided patent term extension to compensate for delays and introduced a patent linkage system
DRAFT AMENDMENT TO REGULATIONS FOR THE IMPLEMENTATION OF THE DRUG ADMINISTRATION LAW (ARTICLE 40) (2022)
• Uniformly grants six years of protection for undisclosed test data and other data for part of the drug approved for market
MAJOR NEW DRUG CREATION PROGRAM (2008–ONGOING)
• Aims to support development of 30 new drugs for 10 major diseases by 2010
DEVELOPMENT PLAN FOR THE BIOLOGICAL INDUSTRY (2012–2020)
• Set a target for biopharmaceuti-cal sales to grow to $1 trillion by 2020
MADE IN CHINA 2025 (2015–2025)
• Targets the bio-pharmaceutical industry as a key sector for global growth
ADJUSTMENT ON THE REVIEW AND APPROVAL PROCEDURES FOR CLINICAL TRIALS FOR PHARMACEUTICALS (2018)
• Shortened time for approval from 6–18 months to 60 business days
FIRST FIVE-YEAR BIOECONOMY PLAN (2022–2027)
• Aims to create 22 trillion yuan bioeconomy by 2025, encouraging innovation

IMPROVEMENTS IN THE INNOVATION ENVIRONMENT HAVE LED TO SUBSTANTIAL AND RAPID GROWTH IN INNOVATIVE AND ECONOMIC ACTIVITIES

China has become a leading global hub of drug innovation; a rapid increase in pharmaceutical R&D expenditure has been observed

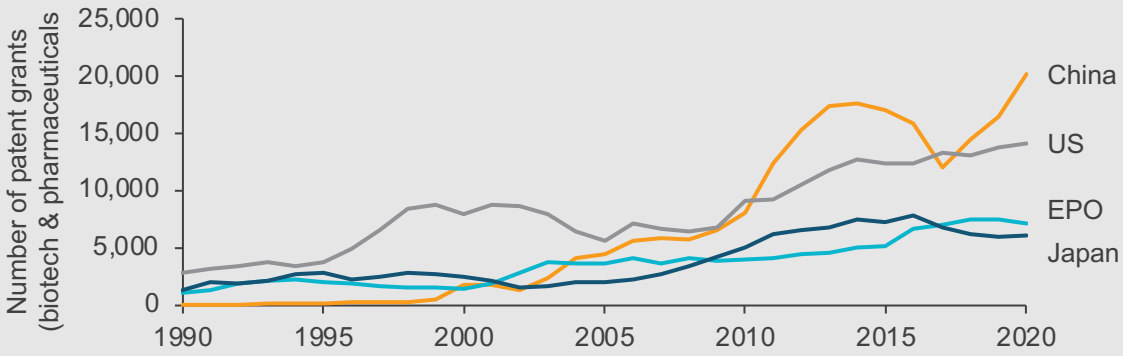


China has had strong academic R&D output in recent years and progress in facilitating collaboration between universities and industry

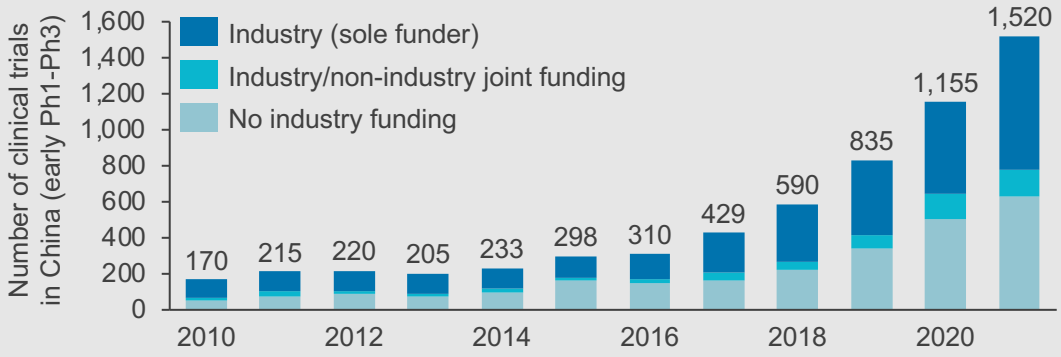


Abbreviations: EPO = European Patent Office

Following improvements to the IP framework, the rise of innovative activity in China can be observed through the number of patent grants

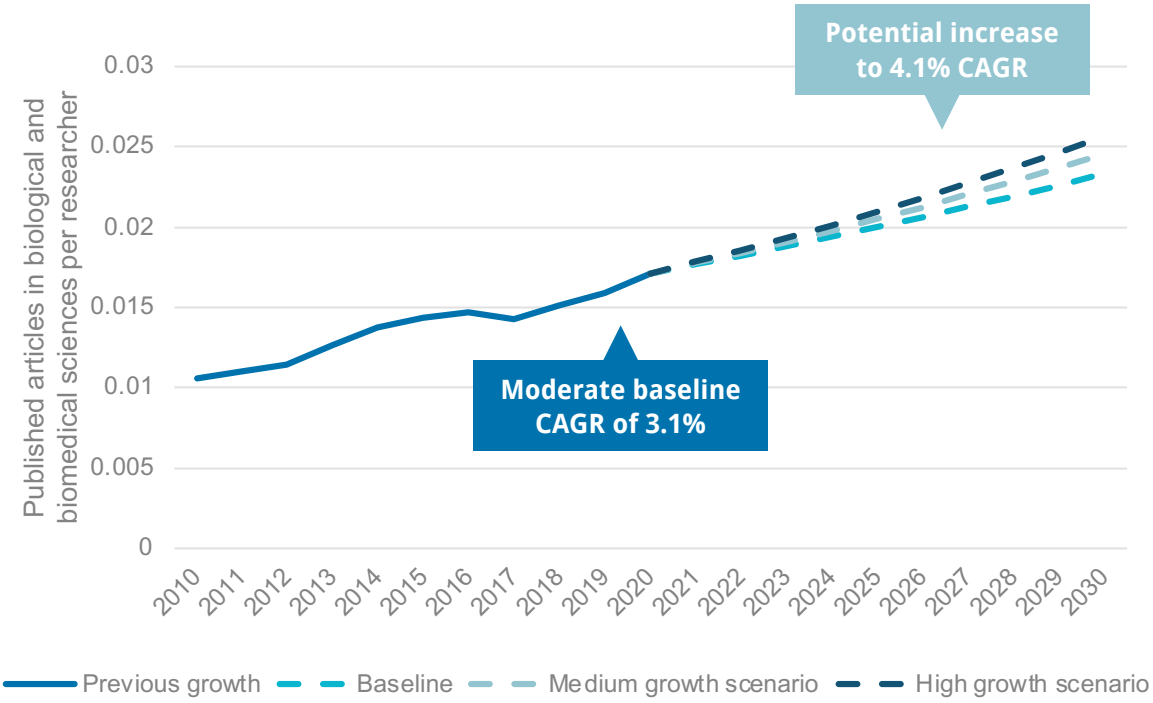


Clinical development of new drugs has experienced a significant boom since 2010, enabling patients in China to access innovative therapies



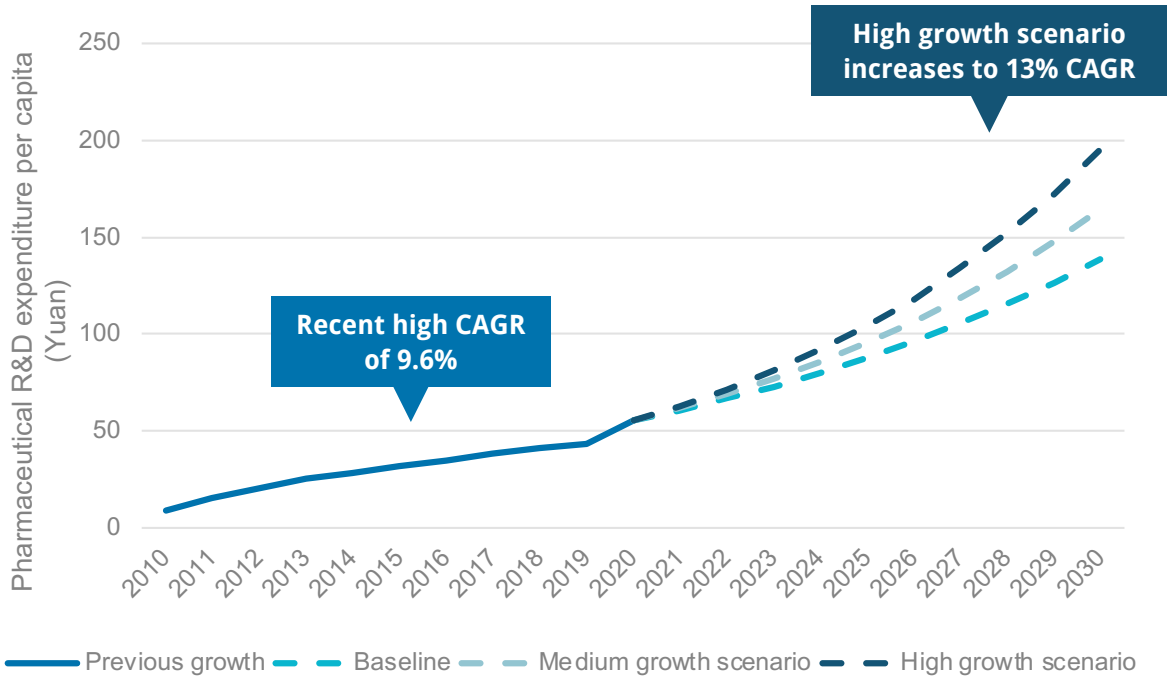
GROWTH SCENARIOS FOR INNOVATIVE ACTIVITIES IN CHINA WERE ANALYSED BASED ON CASE STUDY COUNTRIES SINGAPORE, SOUTH KOREA, AND JAPAN

BASIC RESEARCH GAINS



- Recent growth in biological and biomedical sciences publications has been relatively moderate in China.
- The medium and high growth scenarios suggest that there certainly could be improvements but these may be limited by relatively slow underlying growth.

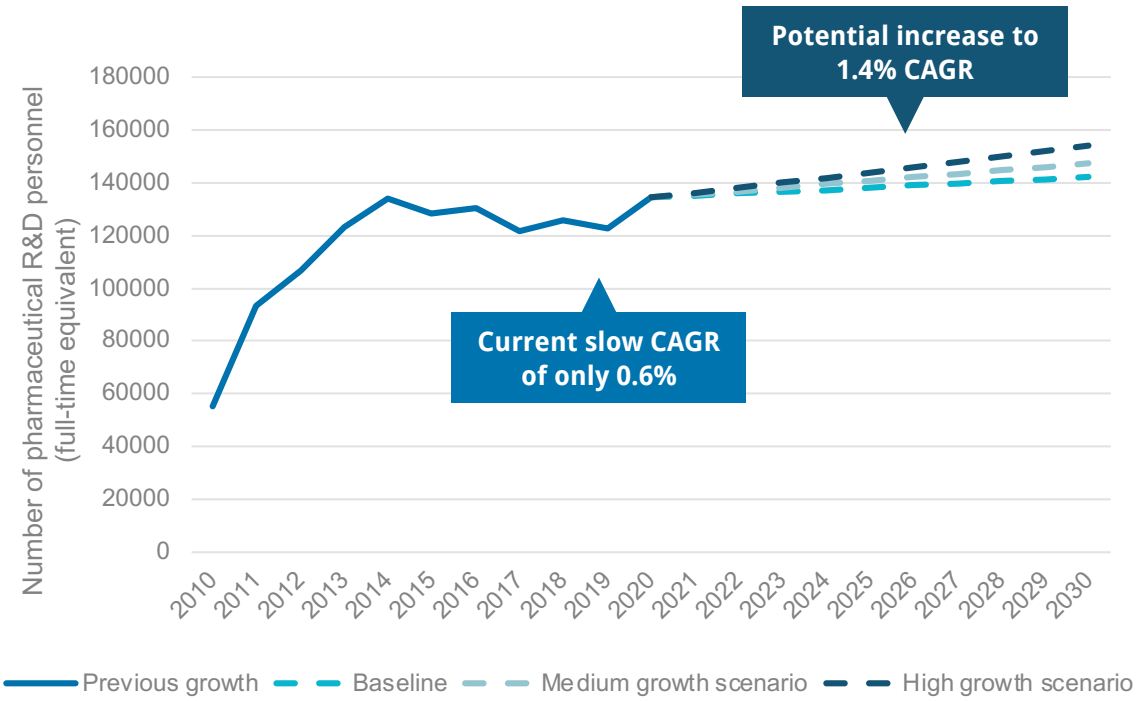
PHARMACEUTICAL R&D EXPENDITURE GAINS



- Pharmaceutical R&D expenditure in China is already rapidly growing, so further changes based on alternative markets make it appear that growth in China would increase much faster.

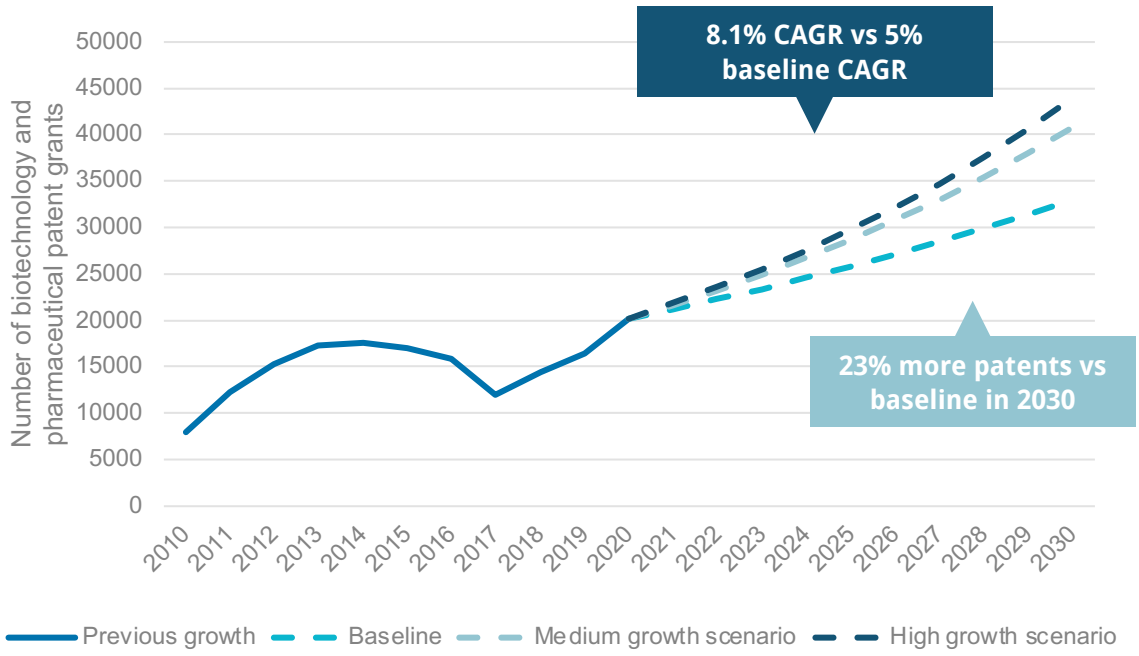
BASED ON THE GROWTH SCENARIOS, POTENTIAL GAINS FROM IMPROVEMENT IN THE INNOVATION ENVIRONMENT COULD BE SIGNIFICANT FOR METRICS SUCH AS INVENTION PATENT GRANTS

PHARMACEUTICAL EMPLOYMENT GAINS



- In recent years there has been limited growth in Chinese pharmaceutical employment, so even with a high growth scenario the gains for China appear modest.
- However, this is more reflective of the low baseline growth, and demonstrates the need for improvements to the innovation environment if growth in pharmaceutical employment is to return to pre-2014 levels.

PATENT GRANT GAINS



- In all case study countries, improvements in the innovation environment led to a significant increase in patent grants, so the possible magnitude of gains for China is substantial even in a medium growth scenario.

CONCLUSIONS

1. THE SCALE OF CHINA'S PROGRESS TO DATE

China has become a much more favourable environment for supporting biopharmaceutical innovation

- China's biopharmaceutical sector is in a sustained period of rapid growth and has been supported by ongoing progress in innovation and IP policy since the 1980s.

- Several national innovation plans and amendments to the IP regime – including but not limited to the successive Amendments to Patent Law, the Major New Drug Creation Program (2008–ongoing) and the Development Plan for the Biological Industry (2012–2020) – have been a major contributor to these improvements.

Improvements in the innovation environment have led to substantial and rapid growth in innovative and economic activities

- Across key metrics in innovative and economic activity, China has demonstrated extensive growth in the previous 20 years or so. It has narrowed the gap to the global leaders – particularly the US – in terms of investment in R&D, educational attainment, and clinical trials.

2. REMAINING GAPS IN THE INNOVATION ENVIRONMENT

There remain some notable shortcomings to the innovation environment in China

- Although China has made substantial progress in terms of the innovation environment and resulting innovative and economic activities, there are still some significant areas for further improvement.

- This is especially the case with regards to the IP regime, and innovative activity could be further stimulated if the Chinese IP regime were improved in line with the US, EU, and Japan.

The most significant gaps include provisions around regulatory data protection and patent term extensions

- A key barrier to investment in China has been the lack of transparency, and ambiguities in RDP-related policy. Fully implemented and enforced RDP with clarification on scope and wording would be a significant enabler of further innovative activities in China.

- There is also a need to strengthen the patent system to better align with international best practices. While this includes several issues (including patent linkage procedural issues and the protection of valid patents), there is a particular gap around patent term extensions

CONCLUSIONS

3. THE BENEFITS OF FURTHER IMPROVEMENTS

Addressing the remaining gaps in the innovation environment would lead to substantial benefits for China

- If the innovation policy environment were improved in a way that addresses the remaining barriers, the impact would be to encourage innovation from domestic and international pharmaceutical companies.

- This would deliver benefits across the innovation pathway, from early innovative activity around scientific publications and basic research, through to investment in R&D and employment of researchers, and ultimately leading to more clinical trials, patent applications, and new innovative therapies for patients.

Based on the experience of other countries, our conclusion is that further improvements in China could lead to an acceleration in innovative and economic activity

- In order to assess potential gains from an improvement in the enablers of innovation, we applied the change in growth rates from case study countries where positive changes in the IP and innovation regime were introduced, to China's current baseline growth rate.

- While there are some significant challenges with this methodology, it nevertheless illustrated that the potential gains in China could be substantial for key metrics including pharmaceutical R&D expenditure and biopharma patent grants.

4. KEY POLICY IMPLICATIONS

Strengthening the IP regime could lead to further progress in China

- China already has a significantly improved policy environment for biopharmaceutical innovation. It is crucial that China remains on this positive trajectory and that the risk of regressing towards a less favourable environment is minimised.

- To ensure this, there are a number of specific policy implications for how further progress in China could be brought about:

A patent regime to match China's aspirations for world-leading innovation

- China has already become close to – or in some cases is – the global leader in terms of key metrics of economic and innovative activity. A patent regime that is as supportive of innovation as those in the EU, US, and Japan will likely be necessary if China is to attain consistently world-leading levels of innovative activity.

- This should include addressing ambiguity in terminology and scope and lack of effective implementation of patent term extensions, and the high patent invalidation rate and restrictive criteria.

Implemented RDP as a prerequisite for further international investment

- The lack of strong RDP in China has discouraged some biopharmaceutical companies from investing more there. Fully implemented and enforced RDP is needed for China to become more attractive to international investment.

Innovation policy that enables accelerated future growth

- Although gaps in innovation policy are less significant than in the past, the speed of future growth could be supported by targeted policy attention regarding the Negative List for Foreign Investment, prolonged innovative drug approval times, and comparatively low R&D tax incentives.

1. Project objectives and methodology

BACKGROUND AND OBJECTIVES

INTERPAT asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in China

The objective of the study is to:

1. Set out the **policy framework** for supporting innovation in China and the current state of innovative activity
2. Undertake a **case study analysis** on countries with potential lessons from other countries which may represent an opportunity for China
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The approach builds on a similar analysis applied to countries in Latin America (Argentina in 2018, Brazil in 2019, Mexico in 2020, Colombia in 2021)

THE PROJECT HAD FOUR STEPS

1 → REVIEW OF THE INNOVATION ENVIRONMENT

Activities

- Review the current IP framework in China
  - The current rules and regulations
  - Recent changes in the regime and changes to enforcement
  - Academic, grey literature on how it works in practice
  - The existing policy debate

Deliverables

- A description of the current regime, including challenges and opportunities

2 → GATHERING OF STAKEHOLDER PERSPECTIVES

Activities

- Agree on N=12 experts to validate findings
- Develop materials for testing: key findings and straw men hypothesis
- Conduct iterative testing using Delphi-panel approach with external experts (two rounds)

Deliverables

- A set of validated statements regarding the innovation environment

3 → DEVELOPMENT OF CONSENSUS FINDINGS AND APPLICATION OF BEST PRACTICES

Activities

- Conduct roundtable with policy and industry experts
- Combine findings from literature review, statistical analysis
- Develop scenarios

Deliverables

- Consensus statements
- Case studies on the potential speed of improvement
- Scenarios

4 → DEVELOPMENT OF PAPER AND DISSEMINATION

Activities

- Refine and finalise report
- Additional review from co-authors of publication
- Develop dissemination plan
  - Identify relevant platforms and events
- Translate report into Chinese and prepare for external publication

Deliverables

- Final report with policy implications (English and Chinese)

RESEARCH ON THE INNOVATION AND IP ENVIRONMENT WAS CONDUCTED THROUGH A REVIEW OF INTERNATIONAL AND LOCAL SOURCES IN CHINA

- We used more than 45 international and local publications and databases in both English and Chinese language on the current innovation environment as well as the challenges in the IP regime in the Chinese pharmaceutical industry:

ACADEMIC PUBLICATIONS AND GREY LITERATURE

- International and local academic literature including RDPAC reports, Yu (2020), Wexler et al. (2021), and Campbell (2013)
- Literature found through targeted Google searches, including online media articles, reviews and op-eds, from local and international sources

CHINESE OFFICIAL STATISTICS AND INTERNATIONAL DATABASES

- Data analysis and comparisons were drawn from sources including Chinese Statistical Yearbook, CNIPA Annual Reports, and World Bank

Abbreviations: RDPAC = R&D-based Pharmaceutical Association Committee; CNIPA = China National Intellectual Property Administration

AFTER A THOROUGH LITERATURE REVIEW, A DELPHI APPROACH WAS USED TO REACH CONSENSUS AROUND THE INNOVATION AND POLICY ENVIRONMENT

PHASE 1

SURVEY 1

Nov. 28 2022 – Dec. 20 2022

- Review list of key historical policy developments and rate their impact
- Validate list of policy gaps and concerns
- Review list of expected future policy trends and estimate potential impact

SURVEY 2

Dec. 23 2022 – Jan. 27 2023

- Review revised list of key policy developments and gaps (using aggregate anonymised feedback from survey #1) and refine ratings
- Evaluate list of most significant policy barriers as well as the impact if said barriers were addressed

OUTPUT: PRIORITISED LIST OF POLICY AREAS WHERE THE INNOVATION ENVIRONMENT COULD BE STRENGTHENED

Survey Details:

Panellists were asked to provide insights and rationale through open questions

Panellists were asked to rate their agreement with closed statements on the Likert scale ranging from strongly disagree (1) to strongly agree (9):

80% of respondents to reach consensus

PHASE 2

VIRTUAL MEETING

Feb. 6 2023 – Feb. 8 2023

- Discuss rationale for ratings given in surveys
- Finalise list of expected future policy changes and their anticipated impact
- Determine appropriate scenarios for modelling future growth of innovative activity in China

THE DELPHI PANEL COMPOSED OF A BALANCED REPRESENTATION OF CHINA EXPERTS

THE DELPHI TECHNIQUE IS A VALIDATED, STRUCTURED PROCESS INVOLVING MULTIPLE ROUNDS OF ANONYMOUS SURVEYS AND/OR DISCUSSIONS TO COLLECT GROUP OPINION AND DEVELOP CONSENSUS

DELPHI PANEL PARTICIPANTS

- **8 IP professionals:** Practicing lawyers in the Chinese pharmaceutical industry
  - Provided perspectives on the current regulatory environment and IP legislations
  - Validated the impact and gaps in current IP legislation

- **4 industry experts:** Patent attorneys and legal counsel at major global pharmaceutical companies (e.g. Johnson & Johnson and Takeda)
  - Contributed perspectives on industry impact of IP regulations and legislation
  - Validated key areas of concern and gaps in the innovation and IP environment

Amy Feng, Juhua Luo, Tina Tai, Jie Wei, Shudan Zhu, Jing He, Li Wu, additional anonymous participants

Xin Liu, Changgang Lou, additional anonymous participants

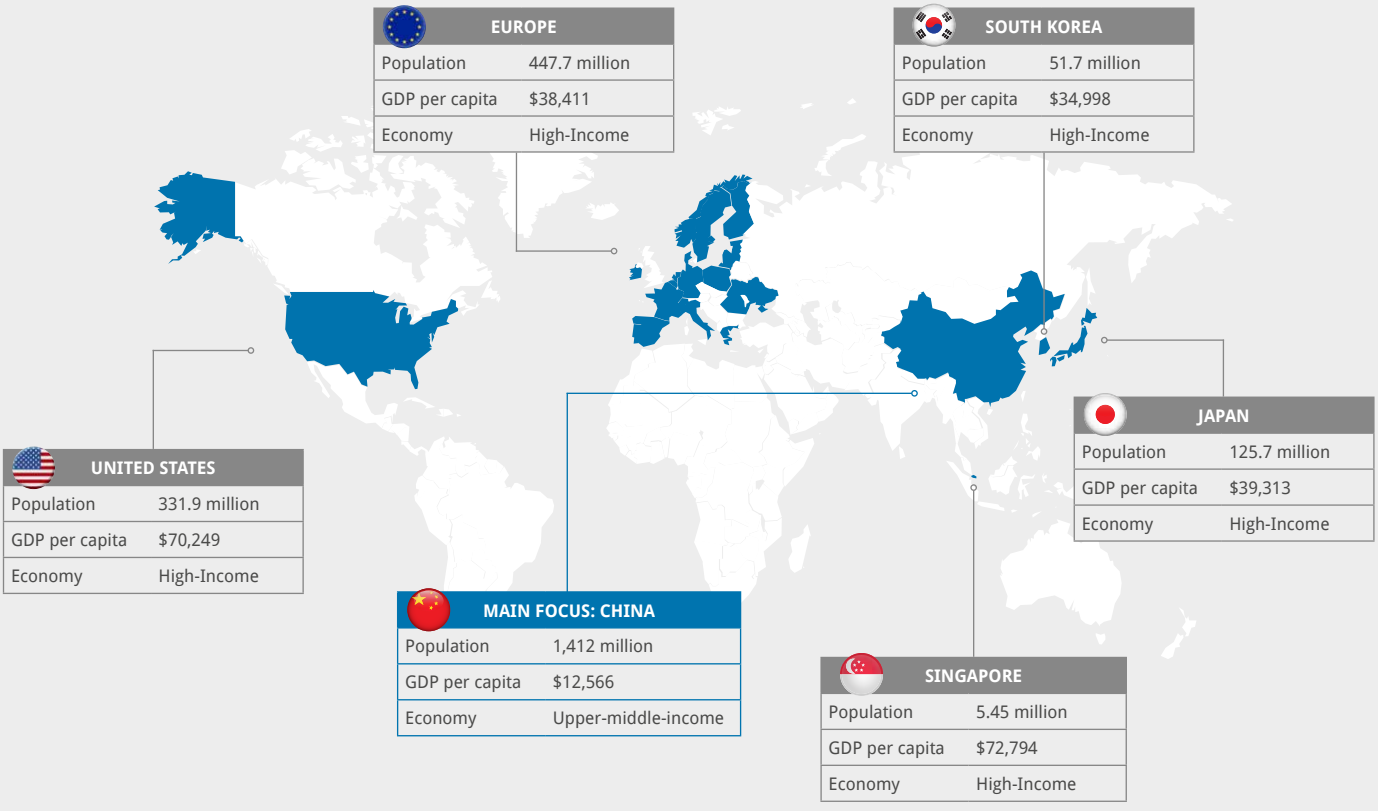
CASE STUDIES TO ILLUSTRATE BENEFITS

THE OBJECTIVES OF A CASE STUDY APPROACH ARE TO:

- **Quantify the impact of policies** to strengthen innovation environment
- Develop **understanding of the context,** to better understand the success of innovation policy change
- Understand the **possible scenarios for how biopharma patent grants could evolve** in China

THE SELECTION CRITERIA FOR OUR CASE STUDY MARKETS AND EXPERT ADVICE SUGGEST SEVERAL MARKETS TO INVESTIGATE:

1. Have shown a **focus on strengthening innovative environment,** particularly the IP protection
2. Placed **broadly in the same income, size and development category as China** when started focusing on innovation
3. Show an observable impact on **innovative activity**



2.

The benefits of changes to the life sciences innovation environment in China

THE FOLLOWING FRAMEWORK WAS USED TO UNDERSTAND THE OVERALL INNOVATIVE ENVIRONMENT THROUGH EVIDENCE COLLECTION AND THE DELPHI METHOD

We used a framework that links the policy environment to innovative and economic activities and finally patient access

In the following pages we:

- **First,** set out the evidence
- **Second,** test statements through the Delphi panel

POLICY ENVIRONMENT → RESOURCES FOR INNOVATION

OVERALL INNOVATION SUPPORT

- National innovation plans
- Targeted initiatives

RULES FOR INNOVATION PROTECTION

- IP rules and patentability criteria
- Patent filing and granting process
- Regulatory data protection
- Preliminary injunction process
- Free Trade Agreements

INCENTIVES FOR INNOVATION

- R&D tax credits

FUNDING FOR INNOVATION

- Public and private funding for research
- Foreign Direct Investment

EXPERTISE AND INFRASTRUCTURE

- University quality and education attainment
- Care: Hospital infrastructure and physician availability
- Collaboration and clusters

HEALTH SYSTEM STRENGTH

- Care provision indicators

INNOVATIVE ACTIVITIES → ECONOMIC ACTIVITIES → PATIENT IMPACT

EARLY AND BASIC RESEARCH

- Publications
- Public private collaborations

PRODUCT DEVELOPMENT

- Clinical trials by phase, type and funder

OUTPUTS OF INNOVATION

- Number of patents filed, granted both domestic and international

EMPLOYMENT

- Researchers employed in pharma
- Types (roles) of employees in pharma in the country.
- Compensation levels

TRADE

- Imports vs exports in pharma and biotech

ACCESS TO MEDICINES

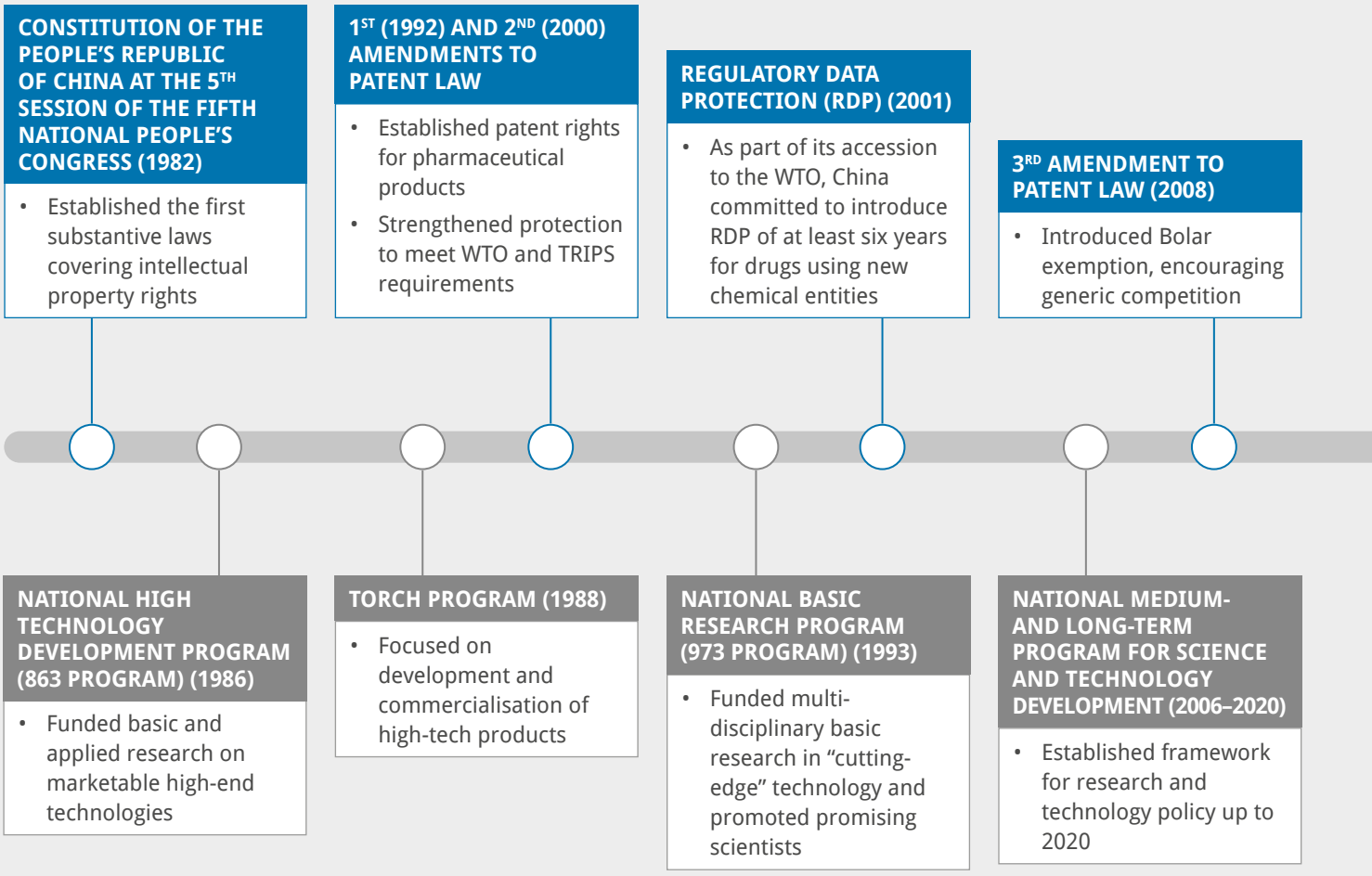
- Approval of innovative drugs
- Access to clinical trials

PATIENT HEALTH OUTCOMES

- Life expectancy and mortality

SUMMARY:
LEGISLATION TIMELINE

CHANGES IN THE IP REGIME



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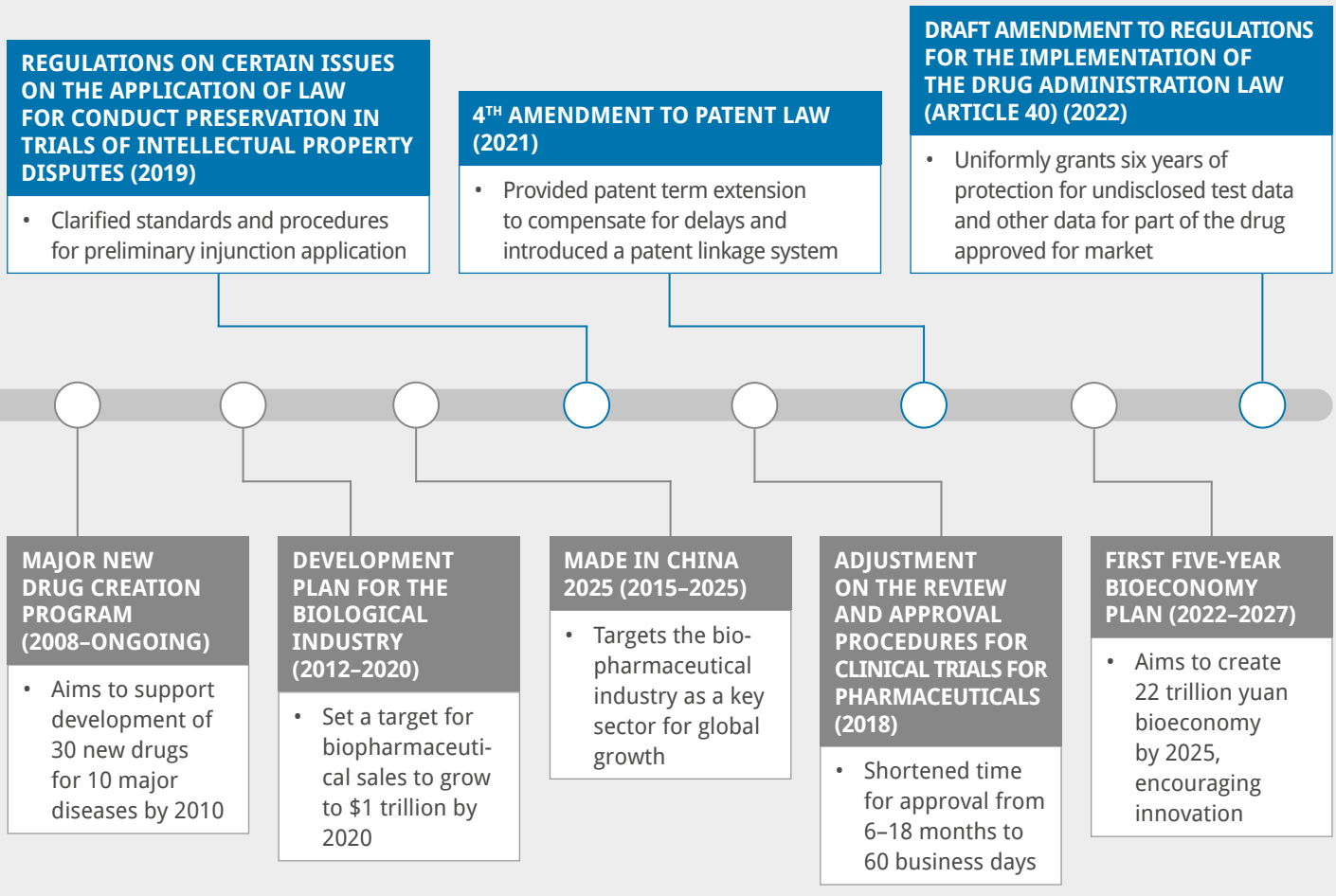
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DELPHI PANEL OUTPUT: ALL PANELLISTS AGREED THAT SUPPORT FOR INNOVATION THROUGH NATIONAL POLICY HAS RAPIDLY IMPROVED THE PHARMACEUTICAL INNOVATION ENVIRONMENT

DELPHI STATEMENT
A
The interaction between innovation policy and industrial policy since the 1980s has resulted in China significantly and rapidly improving in terms of scientific innovation in the biopharmaceutical industry.
CONSENSUS LEVEL:
100%

SUMMARY OF DELPHI PANEL RESPONSES:

- As one of the largest pharmaceutical markets in the world coupled with China's rapidly aging population and growing affluent middle-class, China's biopharmaceutical sector is in a period of growth and transformation.
- In addition to progress in innovation policy and industrial policy since the 1980s, the underlying economic development and the resulting investment into the biopharmaceutical industry were also key drivers of scientific innovation.
- While not yet a global leader in drug development technology, China has become a source of global drug innovation, partly due to these changes in the policy environment.

THE FOLLOWING PAGES COVER KEY PLANS AND POLICY REFORMS THAT HAVE SHAPED THE POLICY ENVIRONMENT AND SUPPORTED INNOVATION

POLICY ENVIRONMENT

OVERALL INNOVATION SUPPORT

- National innovation plans
- Targeted initiatives

RULES FOR INNOVATION PROTECTION

- IP rules and patentability criteria
- Patent filing and granting process
- Regulatory data protection
- Preliminary injunction process
- Free Trade Agreements

INCENTIVES FOR INNOVATION

- R&D tax credits

OVERVIEW

OVERALL INNOVATION SUPPORT

- National innovation plans and programs from 1984 to the present provided funding for R&D, encouraged development of high-tech capabilities, and drove growth in the biopharmaceutical industry.
- These initiatives set up an environment foundational to biopharmaceutical innovation, driving use of more advanced technology and development of new innovative medicines.

RULES FOR INNOVATION PROTECTION

- Amendments to guidelines and patent law from 2000 to 2021 strengthened IP protection while balancing patient access.
- These amendments further provided support for biopharmaceutical innovation and implemented various international IP best practices in the Chinese patent regime.

OVERALL INNOVATION SUPPORT:
NATIONAL INNOVATION PLANS 1986–2004

NATIONAL INNOVATION PLANS

- Prior to 1985, nearly all R&D was government-led [2]

NATIONAL HIGH TECHNOLOGY DEVELOPMENT PROGRAM (863 PROGRAM) (1986) [1,2]

- Funded both basic and applied research on pharmaceutical technologies; companies encouraged to participate in projects (following the US's NIH model)
- Acquisition of IP protection adopted as an indicator to encourage innovation
- Implemented through multiple successive Five-Year Plans; funding greatly expanded from 2014 onwards

KEY IMPACT

- Funded pharmaceutical research and encouraged local companies to participate

TORCH PROGRAM (1988) [2]

- Focused on development and commercialisation of products in new high-tech fields (including biotech)
- Helps local governments set up innovation zones for start-ups; supports training of high-tech personnel, supports cooperation between domestic and international firms
- Receives lower magnitude of funding than other major R&D programs (RMB 0.2 billion in 2009 vs 5.0 billion for 863 Program)

KEY IMPACT

- Facilitated development of innovation zones and personnel to support the commercialisation of high-tech products

NATIONAL BASIC RESEARCH PROGRAM (973 PROGRAM) (1993) [2,3]

- "People-orientated", aiming to promote promising young to middle-aged scientists to cultivate future generations of talent
- Also focused on supporting innovative environment, encouraging scientists to explore new fields of research at frontier of science

KEY IMPACT

- Supported the innovative environment and encouraged scientists to explore "cutting-edge" technology

- From 1999 to 2004, nearly all government-run research institutes were merged or sold off to companies [2]

Abbreviations: NIH = National Institutes of Health

[1] https://www.fmprc.gov.cn/ce/ceno/eng/kj/program/t715317.htm

[2] Campbell, J. R. (2013)

[3] https://www.mfa.gov.cn/ce/ceno//eng/kj/program/t715316.htm

OVERALL INNOVATION SUPPORT:
NATIONAL INNOVATION PLANS 2005 TO PRESENT

NATIONAL INNOVATION PLANS

NATIONAL MEDIUM- AND LONG-TERM PROGRAM FOR SCIENCE AND TECHNOLOGY DEVELOPMENT (2006–2020) [1]

- Established the framework for Chinese research and technology policy up to 2020
- Targets involved an increase in R&D expenditure to at least 2.5% of GDP and the R&D contribution to economic growth to 60% of GDP

MAJOR NEW DRUG CREATION PROGRAM (2008–ONGOING) [2]

- Aimed to support the clinical development of 30 new drugs for 10 major diseases by 2010; focused on supporting domestic companies
- Initial budget of 1.67 billion yuan, half of which was used in the form of subsidies to help companies develop new drug platforms
- Other channels for the funding included clinical trials, R&D for existing products, and safety and efficacy appraisals of Class-1 new drugs*

DEVELOPMENT PLAN FOR THE BIOLOGICAL INDUSTRY (2012–2020) [4]

- Set a target for biopharmaceutical sales to grow to $1 trillion by 2020 at an annual growth rate of 20%
- Focused on collaboration on R&D projects, commercialisation of new drugs, advances in medical devices and traditional Chinese medicine

MADE IN CHINA 2025 (2015–2025)

- Targets the biopharmaceutical industry as a key sector for global growth

OUTLINE FOR BUILDING A POWERFUL INTELLECTUAL PROPERTY COUNTRY (2021–2035)

- Improves the level of creation, utilisation, protection, management and service of intellectual property
- Plays an important role in the intellectual property system to promote the construction of a powerful IP country

FIRST FIVE-YEAR BIOECONOMY PLAN (2022–2027) [3]

- In line with requirements of 14th Five-Year Plan, which pledged to accelerate drug development and promote digital integration
- Aims to create 22 trillion yuan bioeconomy by 2025, encouraging innovation in R&D and financing support for biotech companies

Abbreviations: GDP = gross domestic product

[1] https://www.itu.int/en/ITU-D/Cybersecurity/Documents/National_Strategies_Repository/China_2006.pdf

[2] https://ihsmarkit.com/country-industry-forecasting.html?id=106596437

[3] https://english.www.gov.cn/policies/policywatch/202205/11/content_WS627b169ec6d02e533532a879.html

[4] http://www.gov.cn/zhengce/content/2013-01/06/content_2754.htm

*Class-1 new drugs refer to drugs that have never been marketed in China or overseas.

RULES FOR INNOVATION PROTECTION: IP RULES AND PATENTABILITY CRITERIA – AMENDMENTS SINCE 2000'S

NATIONAL INNOVATION PLANS

2ND AMENDMENT TO PATENT LAW (AUG. 2000)

- Prohibited the "offers for sale" of infringing products
- Required innocent infringers to prove the legitimate source of the patented product
- Allowed for damage calculations based on appropriate royalties when it was difficult to determine

KEY IMPACT

- Strengthened IP protection and punitive action against infringement

3RD AMENDMENT TO PATENT LAW (DEC. 2008)

- Established rules around the role of compulsory licensing and parallel importation
- Introduced a Chinese equivalent of a Bolar exception which allows generic pharmaceutical producers to import, manufacture or test a patented product prior to patent expiration

KEY IMPACT

- Focus switched to balancing innovation with patient access by encouraging generics

AMENDMENT TO THE GUIDELINES FOR PATENT EXAMINATION (JAN. 2021) [3]

- Provisions on post-filing data were further clarified and relaxed, permitting post-filing data in pharmaceutical patent applications in two circumstances even if there is no data or little data in the patent application as filed
- Standard for inventive step of antibodies has been relaxed by shifting the focus on unexpected technical effects to non-obviousness of the difference in key sequences

KEY IMPACT

- Post-filing data will be taken into consideration during patent examination process

4TH AMENDMENT TO PATENT LAW (JUN. 2021) [4,5]

- Increased the amount of statutory damages that can be awarded to a patentee and introduced punitive damages
- Empowered the CNIPA to handle patent infringement disputes that have "significant impact nationally"
- Provided a patent term extension granted by CNIPA to compensate for delays caused by regulatory review and approval of a new drug
- Introduced a patent linkage system for early resolution of patent disputes, before the marketing and sale of the generic drug

KEY IMPACT

- Increased patent protection through patent term extension to compensate for delays and facilitation of early resolution of disputes

Abbreviations: WTO = World Trade Organization; TRIPS = Trade-related Aspects of Intellectual Property Rights; CNIPA = China National Intellectual Property Administration

[1] Yu, P (2020) China's Innovative Turn and the Changing Pharmaceutical Landscape. https://scholarship.law.tamu.edu/facscholar/1441/

[2] Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

[3] Che, J. et al. (2021) China's Newest Examination Guidelines: Post-Filing Supplemental Data for Compounds (Part I). https://chinapatentstrategy.com/chinas-newest-examination-guidelines-post-filing-supplemental-data-for-compounds-part-i/

[4] Huang, H. et al. (2020) China Promulgates Fourth Amendment Patent Law. https://www.jonesday.com/en/insights/2020/11/china-promulgates-fourth-amendment-to-patent law#:~:text=The%20amendment%20will%20come%20into,to%20align%20with%20international%20practices

[5] Wexler, B. et al. (2021) Takeaways from Recent Implementation of China's Patent Linkage System. https://www.paulhastings.com/insights/client-alerts/takeaways-from-recent-implementation-of-chinas-patent-linkage-system

SUPPORT FOR INNOVATION: ACADEMIC RESEARCH SUGGESTS THE FOUR MAIN PHASES OF R&D POLICY HAVE EVOLVED ALONGSIDE THE ENACTION OF CHINESE PATENT LAWS

NATIONAL INNOVATION PLANS

1949–1984 ★	1985–1992 ★	1993–2008 ★	2008 ONWARDS
"PURE IMITATION"	**"INNOVATIVE IMITATION"**	**"IMITATIVE INNOVATION"**	**"INDEPENDENT INNOVATION"**
Focus on **copying synthetic methods** and preparation technologies of drugs from foreign companies	Focus on **modifying delivery methods** and preparation formulations of existing drugs without changing molecular structure	Focus on chemical modifications of the structure of existing drugs to develop **"me-too" drugs**	Focus on discovery of **new chemical entities** using advanced technologies

ONLY 5 DOMESTICALLY DEVELOPED DRUGS APPROVED FROM 1949 TO 2008

40 APPROVED FROM 2008 TO 2018

KEY POLICY DEVELOPMENTS:

- **1949:** (CAS) Chinese Academy of Sciences established
- **1983:** Project 211 initiated to develop institutions of higher education
- **1986:** National High Technology Development Program established
- **1988:** Torch Program established
- **1993:** National Basic Research Program established
- **1998:** Ministry of Science and Technology (MOST) established
- **1998:** Project 985 initiated to continue development and founding of world-class universities
- **2008:** National Intellectual Property Strategy Compendium issued

Key: ★ = Major change in patent law

Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

Zhihua, L. 2019 Pharma companies move up the value chain. http://www.chinadaily.com.cn/global/2019-07/26/content_37495602.htm

DELPHI PANEL OUTPUT: PANELLISTS AGREED THESE IMPROVEMENTS HAVE BEEN SIGNIFICANT IN SHAPING THE INNOVATION ENVIRONMENT AND IN DRIVING GROWTH

DELPHI STATEMENT
B
The most significant improvements in the innovation environment have been: • The strengthening of patent protections, such as through the 1st (1992), 2nd (2000), 3rd (2008), and 4th (2021) Amendments to Patent Law, and the Outline for Building a Powerful Intellectual Property Country (2021–2035) • Policies encouraging the development of innovative biopharmaceutical companies, including support for biopharmaceutical clusters and technology parks and a series of national innovation plans supporting biopharmaceutical R&D such as the Major New Drug Creation Program (2008–ongoing) and the Development Plan for the Biological Industry (2012–2020) • Government support for biopharmaceutical research and scientific capabilities, such as Projects 211 (1995) and 985 (1999) targeting university development and subsequent continued investment into strengthening universities and STEM education • Streamlined clinical trial and regulatory approval processes, such as the NMPA's Adjustment on the Review and Approval Procedures for Clinical Trials for Pharmaceuticals (2018)
CONSENSUS LEVEL:
100%

Abbreviations: STEM = Science, technology, engineering and mathematics ; NMPA = National Medical Products Administration;

SUMMARY OF DELPHI PANEL RESPONSES:

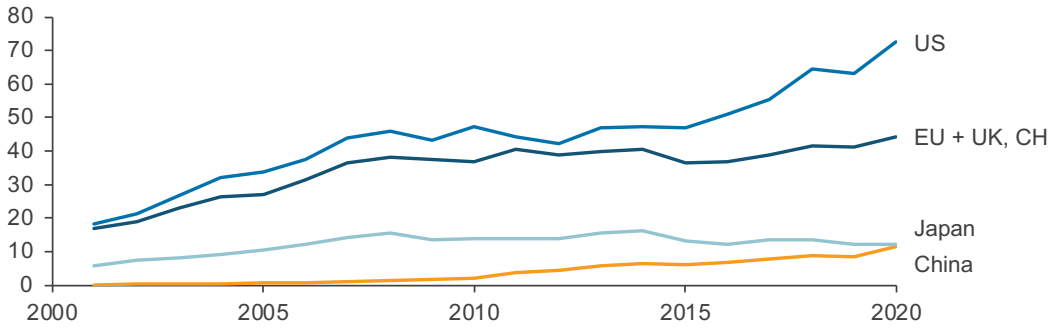
- All panellists agreed that the Amendment to the Guidelines for Patent Examination according to the CNIPA Announcement No. 391 (2021) is a significant amendment not noted in the above statement, impacting consideration of post-filing data and likely leading to more antibody patents being filed and granted in China as the standard for the inventive step of antibodies has been relaxed by shifting focus on the unexpected technical effects to non-obviousness of the difference in key sequences.
- The return of Chinese talents from overseas in the past two decades due to these policies has also contributed greatly to the growth of the Chinese biopharmaceutical industry.

Abbreviations: CNIPA = China National Intellectual Property Administration

FUNDING FOR INNOVATION:
PUBLIC AND PRIVATE FUNDING FOR RESEARCH

THERE IS SIGNIFICANT GOVERNMENT R&D FUNDING; THIS IS SEEN AS SUPPORTING PRIVATE FUNDING INCLUDING FROM VENTURE CAPITAL

Total pharmaceutical R&D expenditure (billion USD)[4]



FUNDING FOR RESEARCH

- In 2008, China's drug R&D expenditure was only 1.3% of drug sales revenues in China (versus over 13% in the US, EU and Japan).[1] Since then this has increased, and in 2020 pharmaceutical R&D was 3.1% as a percentage of revenue.[3] There has been a significant increase in the absolute value of private R&D investment, which has increased every year since 2001.[2]
- Although it has closed the gap to Japan in R&D investment, China still remains far behind the US and EU.[4]

Abbreviations: R&D = research and development; CH = Switzerland

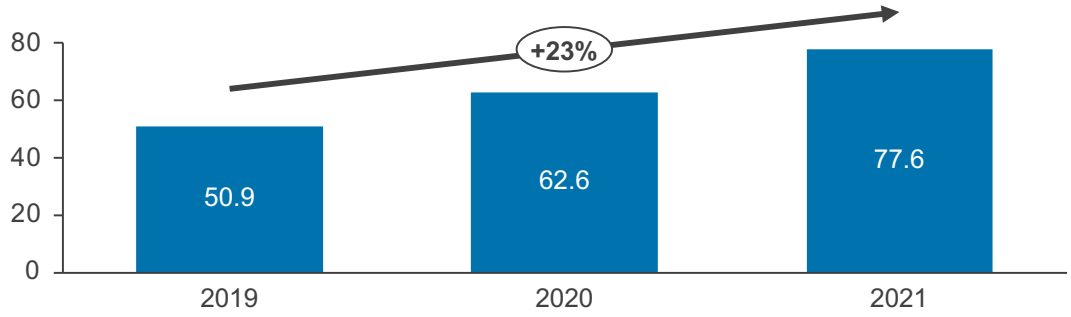
[1] Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

[2] Chinese Statistical Yearbook

[3] Mills, M., Zhang, A. and Kanavos, P. (2019)

[4] Various

Average venture capital funding raised per round (million USD)[6]



FUNDING SOURCE

- In 2002, total R&D funding by businesses was less than double that provided by the government. By 2019, business funding was nearly four times the value of government funding. Over this period, business R&D grew by 21% on average each year, and government funding grew by 16%.[2]
- Although the absolute difference between government and business R&D funding has significantly increased, the ratio between the two has remained relatively stable: between 2011 and 2019, business funding was 3.4 to 3.8 times the value of government funding.[5]

Abbreviations: R&D = research and development

[2] Chinese Statistical Yearbook

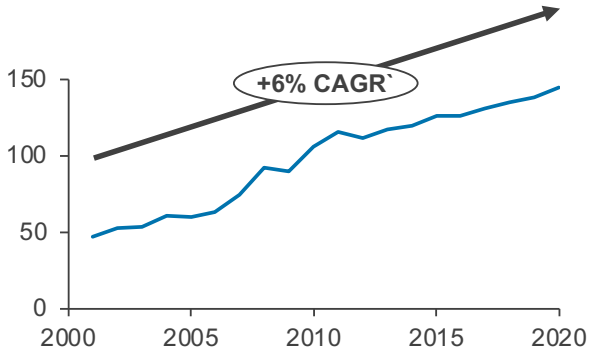
[5] Ministry of Science and Technology, China Science & Technology Statistics Data Book 2021. https://www.lse.ac.uk/business/consulting/assets/documents/Gilead-Pharmaceutical-Policy-in-China-Final.pdf

[6] BCIQ (April 2022) from McKinsey Report. Unchartered Waters – Can European Biotech Navigate Through Current Headwinds? https://go.biocentury.com/rs/731-BYF-828/images/BioEquity%20McKinsey%20Report%202022.pdf

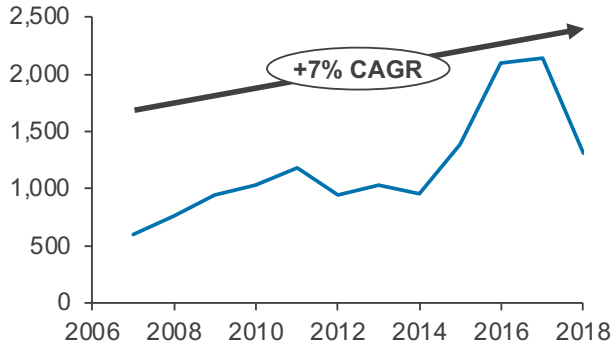
FUNDING FOR INNOVATION:
FOREIGN DIRECT INVESTMENT

THERE HAS ALSO BEEN GROWTH IN FOREIGN DIRECT INVESTMENT IN THE PHARMACEUTICAL INDUSTRY, WITH AN OVERALL COMPOUND ANNUAL GROWTH RATE OF 7% SINCE 2006

Total FDI to China (realised FDI value, billion USD)[1]



FDI – Medicinal and pharmaceutical products (million USD)[3]



FOREIGN FUNDING

- The total value of foreign direct investment (FDI) in the pharmaceutical industry increased from US$0.5 billion in 2006 to US$2.1 billion in 2016, at a compound annual growth rate of 15% (vs 7% for all FDI). However, from 2017 to 2018 FDI fell from $2.1 billion to $1.3 billion.[2]
- The stagnation and decline in FDI in 2017 may be partially attributed to the global political and economic environment at the time (e.g. Brexit, uncertain US-China relations), leading investors to take a more cautious approach.[7]

Abbreviations: CAGR = Compound annual growth rate; MNC = multinational companies

Notes: Innovative molecules defined as new molecular entities (both chemical and biological) in China

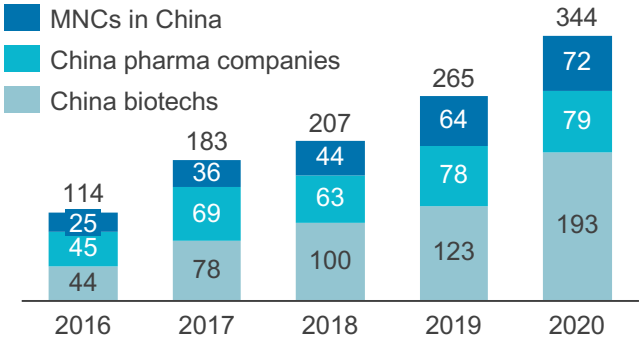
[1] National Bureau of Statistics of China, Chinese Statistical Yearbook

[2] Li, S., Angelino, A., Yin, H. & Spigarelli, F. (2017). Determinants of FDI localization in China: A county-level analysis for the pharmaceutical industry. International journal of environmental research and public health, 14(9): 985.

[3] CEIC

[7] Hu, W (2017) FDI in China during 2017 Shows More Cautious Approach. https://www.china-briefing.com/news/fdi-trends-show-cautious-foreign-investment-china/

Number of innovative molecules for clinical trial applications in China by company type[6]



FOREIGN R&D RESOURCES

- Multinational pharmaceutical companies are bringing significant R&D resources into China by setting up research centres.
- The first global pharmaceutical company to establish a research facility in China was Novo Nordisk in 1997, and now 7 of the top 10 global pharmaceutical companies have research centres in China (this excludes GlaxoSmithKline's Shanghai site, which was closed in 2020).[4]
- Alongside local companies, multinational pharmaceutical companies have been establishing research and development hubs in China.
- Favourable regulatory reforms alongside the growing market size have made China a more attractive environment for multinational companies to establish R&D bases.[8]

[4] Company websites;

[5] Clinical Trials Arena. 2022. The great wall: why overseas sponsors are yet to fully tap into China's clinical trial resources. https://www.clinicaltrialsarena.com/analysis/china-clinical-trial-challenges-cta-exclusive/

[6] GBI, McKinsey analysis;

[8] Lo, C. (2018) Is China the next great hope for the pharma industry? https://www.pharmaceutical-technology.com/features/foreign-pharma-companies-china/

EXPERTISE AND INFRASTRUCTURE: CLUSTERS

THE DEVELOPMENT OF CLUSTERS AND BIOPHARMACEUTICAL TECHNOLOGY PARKS WHERE COMPANIES WORK TOGETHER SYNERGISTICALLY HAS BEEN A KEY DRIVER OF INNOVATION

Biomedical clusters established by the government[8]

In 2019, the government established 17 biomedical clusters to foster biological research.[8] The objective is to promote the development of emerging clusters in key industries to improve overall competitiveness.[9]

[8] Puglisi and Chou. 2022. China's Industrial Clusters: Building AI-Driven Bio-Discovery Capacity. Centre for Security and Emerging Technology. https://cset.georgetown.edu/wp-content/uploads/Chinas-Industrial-Clusters.pdf

[9] China Association for Science and Technology. 2021. Judgment of strategic emerging industries and development proposals for the 14th Five-Year Plan (Part 2). https://www.scimall.org.cn/article/detail?id=5072584

CLUSTERS

- The pharmaceutical industry in China was previously characterised by small companies scattered in many regions, leading to poor resource-sharing and cooperation. The Chinese government established policies to support cooperation, including financial support and tax incentives for projects within industry clusters.[1]
- In 2007 the State Development and Reform Commission issued proposals to guide the development of industrial clusters, resulting in the development of many clusters and biopharmaceutical technology parks.[1]
- Science and technology industrial parks (STIPs) have been promoted as areas to create research synergies and stimulate innovation by different research centres – including both public and private research sites – working in close proximity. In 2013 there were over 50 STIPs.[4]
- A large number of domestic and multinational companies have chosen biotech parks to set up their research facilities. For example, Shanghai Zhangjiang Hi-Tech Park was selected as the location for R&D centres by Roche, Novartis, AstraZeneca, GSK, Eli Lilly, Johnson & Johnson, and Pfizer, as well as domestic and international contract research organisations (CROs) such as Shanghai ChemPartner, HD BioSciences, Medicilon, and Charles River Laboratories.[5]
- CROs are concentrated in the main life sciences clusters: according to a 2015 study 61% are located in the Yangtze River delta cluster and a further 20% in the Beijing cluster.[6]

[1] Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

[2] https://ncses.nsf.gov/pubs/nsb20206/international-collaboration

[3] EvaluatePharma

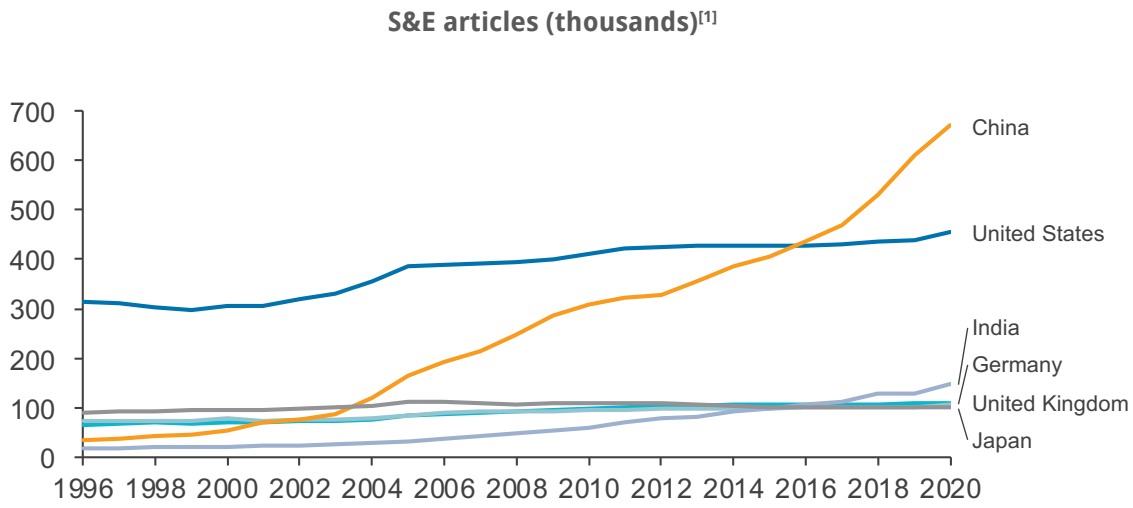
[4] Campbell, J. R. (2013) Becoming a Techno-Industrial Power: Chinese Science and Technology Policy. Issues in Technology Innovation No. 23

[5] PWC. Investing in China's Pharmaceutical Industry – 2nd Edition https://www.pwc.com/gx/en/pharma-life-sciences/assets/en-pharma_03-26-small.pdf

[6] Xia and Gautam. 2015. Biopharma CRO industry in China: landscape and opportunities. Drug Discovery Today. https://www.sciencedirect.com/science/article/pii/S1359644615000768#sec0070

OUTPUTS OF INNOVATION: ACADEMIC ACTIVITY AND ACADEMIA-INDUSTRY COLLABORATION

CHINA HAS HAD STRONG ACADEMIC R&D OUTPUT IN RECENT YEARS, WITH INCREASES IN PUBLICATIONS AND GRANTED INVENTION AND CREATION PATENTS COMING FROM HIGHER EDUCATION INSTITUTIONS



PUBLICATIONS

- Since 2016, China has been the global leader in terms of publications output for science and engineering articles, accounting for 23% of the world total in 2020 (the next highest was the US, with 16%).[1]
- The types of institutions producing science and technology papers has remained relatively stable, with higher education institutions consistently accounting for around two-thirds of papers between 2014 and 2020. There has been a small increase in the share of papers produced by businesses, rising to 7% in 2020.[2]

Abbreviations: S&E = Science and engineering

[1] National Center for Science and Engineering Statistics

[2] Ministry of Science and Technology, China Science & Technology Statistics Data Book 2021

INDUSTRY COLLABORATION[5]

- There have been strong increases in granted invention and creation patents from Chinese universities from ~10000 in 2009 to ~35000 in 2013.[4]
- However, commercialisation of academic research has not been proportional to these large quantities of patents.
- As academia is largely government-funded, academic IP is generally considered state-owned property, making both academics and industry more cautious when considering collaboration.
- China has been making progress on facilitating collaboration between universities and industry through a series of policy reforms starting in 2015, demonstrating an increasingly positive position on academic and industry collaboration.
- This includes the revised Law on Promoting the Transformation of Scientific and Technological Achievement (PTSTA) that gave universities the power to decide how to transfer knowledge without government approval.
- An opinion issued by the Ministry of Human Resources and Social Securities in 2017 also encouraged universities to collaborate with industry players.

[3] Chemical Abstracts Service. 2022. Global Science & Technology Trends Report: Gene and Cell Therapy R&D

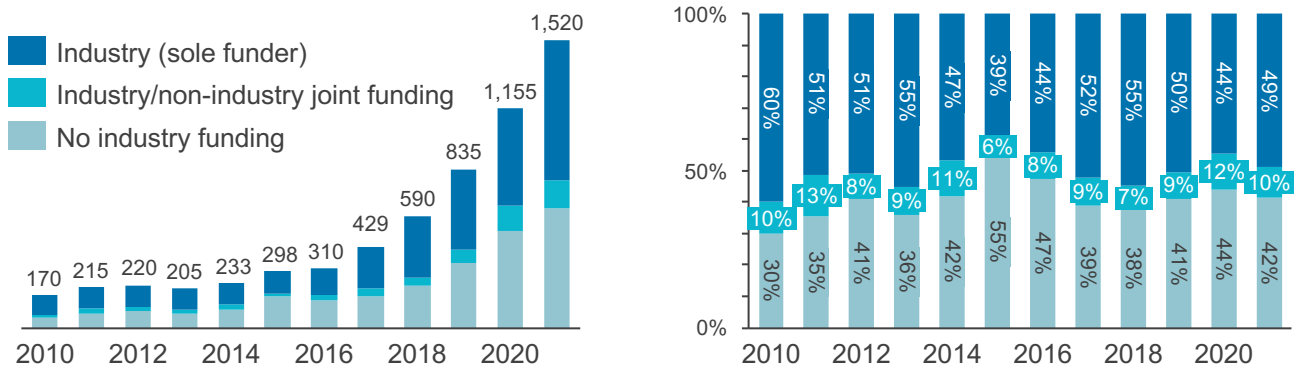
[4] Ni, J. et al. 2017. Obstacles and opportunities in Chinese pharmaceutical innovation. Globalization and Health. https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-017-0244-6#Fig2

[5] Zhang, Y. et al. 2022. From academy to industry: China's new trend and policies on academic technology transfer. IAM Media. https://www.iam-media.com/global-guide/global-life-sciences/2022/article/academy-industry-chinas-new-trend-and-policies-academic-technology-transfer

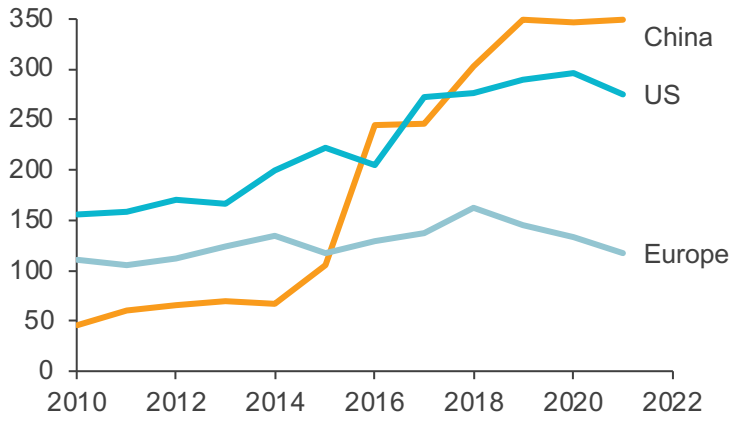
OUTPUTS OF INNOVATION: CLINICAL TRIALS

CLINICAL DEVELOPMENT OF NEW DRUGS HAS EXPERIENCED A SIGNIFICANT BOOM SINCE 2010; INNOVATIVE TRIALS ON CELL AND GENE THERAPY HAVE SURPASSED THE US AND EUROPE IN THE LAST SIX YEARS

Clinical trials (early Ph1-Ph3) by funder type[5]



Cell and gene therapy clinical trials by start year[4]



China has demonstrated rapid growth in clinical trials in several areas, such as immuno-oncology and CAR-T cell therapies,[3] overtaking the US and Europe to become the country with the highest number of cell and gene therapy clinical trials.[4]

[3] Atkinson. 2020. The Impact of China's Policies on Global Biopharmaceutical Industry Innovation. Information Technology & Innovation Foundation. https://itif.org/publications/2020/09/08/impact-chinas-policies-global-biopharmaceutical-industry-innovation/

[4] Analysis of GlobalData Clinical trials database

[5] Clinical Trials Arena. 2022. The great wall: why overseas sponsors are yet to fully tap into China's clinical trial resources. https://www.clinicaltrialsarena.com/

CLINICAL TRIALS

- Since 2010, the number of clinical trials conducted in China has increased nearly tenfold. The sources of funding for trials have remained relatively consistent, with about 40% of Phase 1 to Phase 3 trials involving industry funding.[5]
- Since 2015, the NMPA has proposed reforms to improve and streamline drug development, including clinical trials, and many of these have been implemented.[2]
    - Under the NMPA's Adjustment on the Review and Approval Procedures for Clinical Trials for Pharmaceuticals (2018), the NMPA adopts a negative notification system for trial approval, rather than requiring positive approval, shortening the time for approval from 6–18 months to 60 business days.[6]
    - From the early 1990s to early 2000s, the average time required for clinical trials declined from 79.5 to 63.2 months.[1]
    - Since 2017, foreign companies have been able to conduct Phase 1 trials in China. Previously, the amount of capable early-stage researchers in the country had been limited by a requirement that companies had to complete Phase 1 overseas before being able to conduct studies in China.[7]

Abbreviations: NMPA = National Medical Products Administration

[1] Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

[2] ThePharmaLetter. 2017. China loosens grip on clinical trials, improves IP protection to boost innovation. https://www.thepharmaletter.com/article/china-loosens-grip-on-clinical-trials-improves-ip-protection-to-boost-innovation

[5] Clinical Trials Arena. 2022. The great wall: why overseas sponsors are yet to fully tap into China's clinical trial resources. https://www.clinicaltrialsarena.com/analysis/china-clinical-trial-challenges-cta-exclusive/

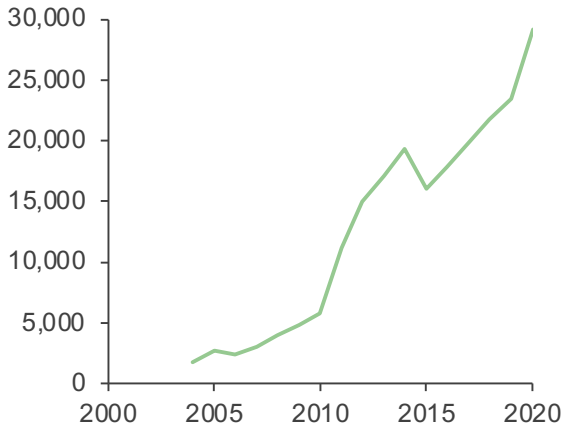
[6] Baker McKenzie. 2019. Clinical Trials Handbook Asia Pacific: China. https://www.bakermckenzie.com/-/media/files/insight/publications/2019/healthcare/ap/dsc125067_clinical-trials-handbook--china.pdf?la=en

[7] Cairns. 2017. China's new clinical trial regulations a win-win for all. Pharmaceutical Technology. https://www.pharmaceutical-technology.com/pricing-and-market-access/chinas-new-clinical-trial-regulations-a-win-win-for-all-html/

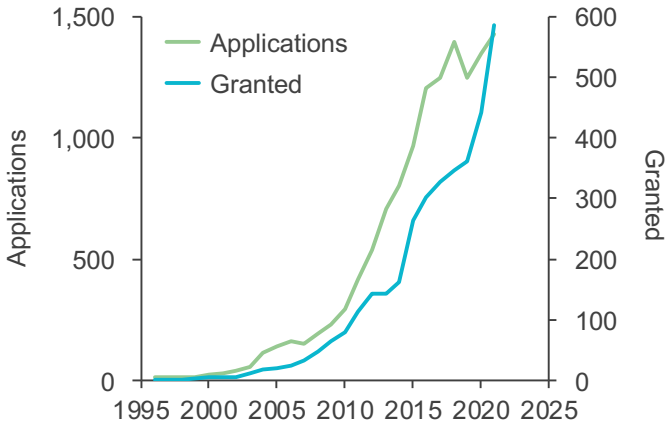
OUTPUTS OF INNOVATION:
PATENT FILINGS AND GRANTS

AFTER IMPLEMENTATION OF THE 2ND AMENDMENT TO PATENT LAW THAT STRENGTHENED IP PROTECTION, THE NUMBER OF PATENT APPLICATIONS INCREASED SIGNIFICANTLY

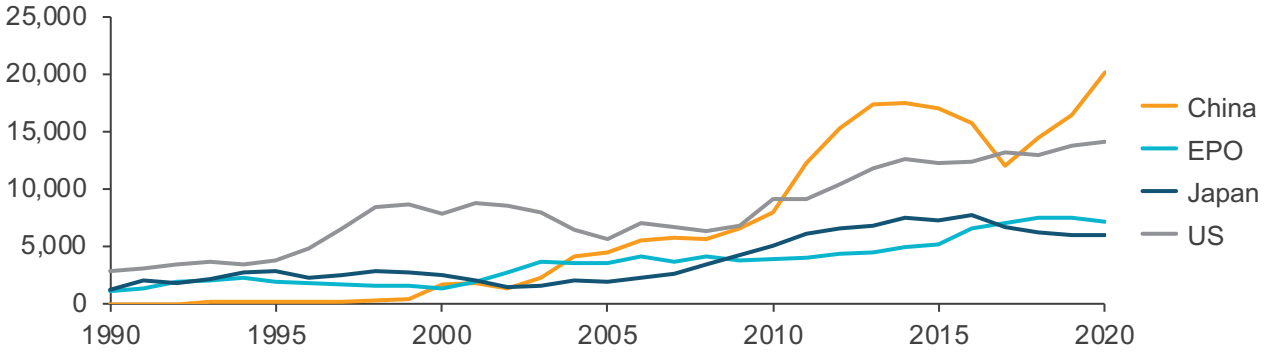
Number of patent applications – Manufacture of medicines[5]



All patent applications and grants (domestic invention patents) ('000)[6]



Number of patent grants – Biotechnology and pharmaceuticals[3]



[3] WIPO
[5] Chinese Statistical Yearbook
[6] CNIPA – Annual Reports

PATENT APPLICATION TRENDS

- The number of patent applications has continuously risen between 1994 and 2007, increasing by over 200-fold.[1] There were more than twice as many patent applications from medicine manufacturers in 2020 compared to 2011.[2]
- A key legislative change during this period was the 2nd Amendment to Patent Law (Aug. 2000), whose provisions strengthened protection for local and foreign patent holders as well as helping the Chinese patent regime conform to WTO standards.[7]
- According to World Intellectual Property Organization (WIPO) data on the number of biotechnology and pharmaceutical patents, China had the highest number of grants in 2020, having lagged behind the US, Europe, and Japan until the mid-2000s.[3]
- However, the quantities of applications have not yet translated into the same quantity of new innovative drugs reaching the market, as Chinese companies may file and acquire patent applications for the purpose of obtaining government subsidies and tax benefits.
    - In 2019, the ratio of granted patents to patent applications in China was 30%, much lower relative to Japan at 63% and South Korea at 57%.[4]

[1] Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

[2] Chemical Abstracts Service. 2022. Global Science & Technology Trends Report: Gene and Cell Therapy R&D

[3] WIPO

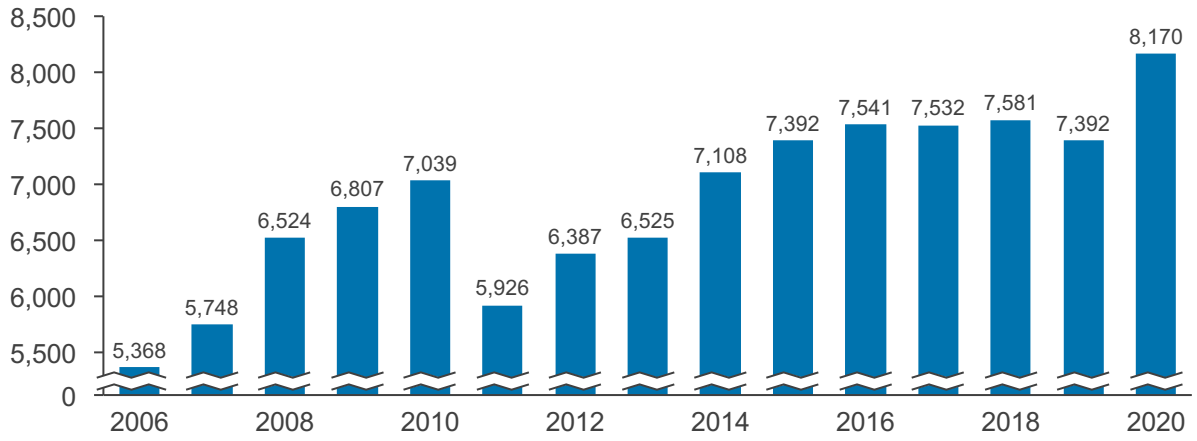
[4] WIPO Statistical Country Profiles cited from He, A. 2021. What Do China's High Patent Numbers Really Mean? https://www.cigionline.org/articles/what-do-chinas-high-patent-numbers-really-mean/

[7] Yu, P. (2020) China's Innovative Turn and the Changing Pharmaceutical Landscape. https://scholarship.law.tamu.edu/facscholar/1441/

ECONOMIC ACTIVITIES:
NUMBER OF ENTERPRISES AND EMPLOYEES

BOTH NUMBER OF ENTERPRISES AND EMPLOYMENT OF R&D PERSONNEL HAVE EXPERIENCED RAPID GROWTH SINCE 2006, STABILISING IN THE TIME PERIOD BETWEEN 2015 AND 2019

Total number of pharmaceutical enterprises*[1]



*Total number of enterprises above designated size including state-controlled

PUBLICATIONS

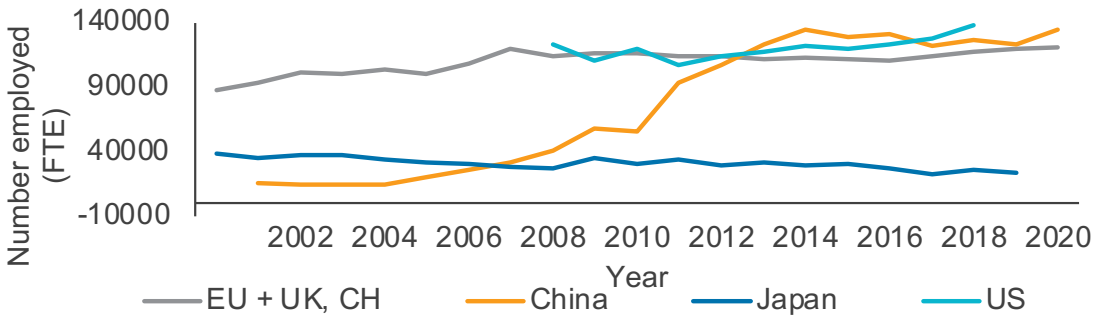
- By 2020 the total number of enterprises manufacturing medicines had reached over 8,000.
    - From 2010 to 2020, more than 140 new biotech companies emerged from China.[5]
- However, policies implemented around 2009–2010, such as the first national drug circulation industry management policy, have encouraged enterprises to "spontaneously merge, restructure, and eliminate systems" to improve industry concentration, potentially contributing to fluctuations in number of enterprises post-2010.[3]

[1] Chinese Statistical Yearbook

[3] Giniat, E. et al. 2011. China's pharmaceutical industry – Poised for the giant leap. KPMG. https://www.elsi-project.eu/fileadmin/user_upload/elsi/brosch%C3%BCren/DD/Chinas_Pharma_Industry_-_KPMG_2011__REPORT_.pdf

[5] Wong, J. et al. 2020. Competing in China's Booming Biopharma Market. BCG. https://www.bcg.com/en-ca/publications/2020/competing-in-chinas-biopharma-market

Employment of medicines R&D personnel (full-time equivalent)[1,4]



R&D PERSONNEL

- With regards to R&D personnel, pharmaceutical companies provided an unprecedented level of labour resources in 2020. Although it has stabilised since around 2015, from 2000 to 2015 there was a surge in the full-time equivalent of R&D personnel working for medicines manufacturers.[1]
    - During this time, total R&D employment has caught up with the EU, Japan, and US[4]

Abbreviations: CH = Switzerland

[1] Chinese Statistical Yearbook

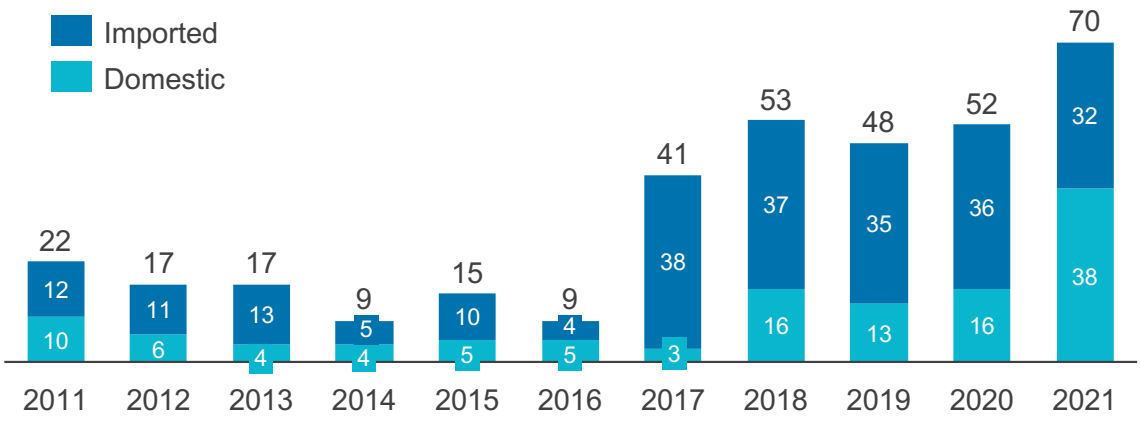
[2] McKinsey

[4] Various sources

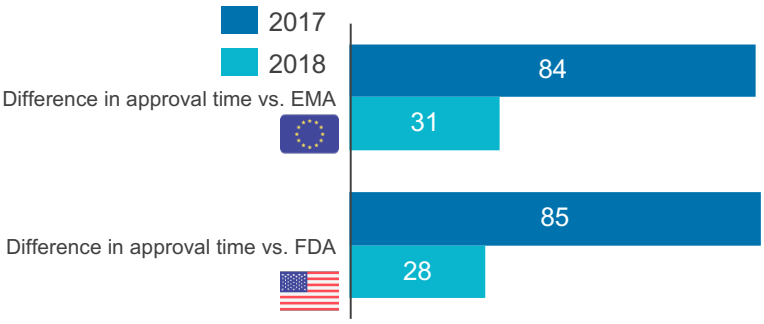
ACCESS TO MEDICINES: NEW DRUG APPROVALS

WHILE NEW DRUG APPROVALS HAVE HISTORICALLY FACED SIGNIFICANT CHALLENGES, THE NUMBER OF APPROVALS FOR INNOVATIVE DRUGS AND APPROVAL TIMES HAVE SHOWN POSITIVE TRENDS IN RECENT YEARS, LARGELY ACCREDITED TO TARGETED REGULATORY REFORMS INTRODUCED BEGINNING 2015

Annual numbers of new drug approvals[8]



Average NMPA approval time lag in months (2017 to 2018)[9]



The speed of approvals for investigational new drugs has increased substantially since the 2015 reforms: the time to IND approval fell from 501 days in Jan. 2010 to Jun. 2015 to 87 days in Jul. 2015 to Dec. 2020.[4]

Abbreviations: NCE = new chemical entity; NMPA = National Medical Products Administration; EMA = European Medicines Agency; FDA = US Food and Drug Administration; IND = investigational new drug

[4] Su et al. 2020. Trends in innovative drug development in China. Nature reviews drug discovery. https://www.nature.com/articles/d41573-022-00077-3

[8] Su et al. 2022. Trends and Characteristics of New Drug Approvals in China, 2011–2021. Therapeutic Innovation & Regulatory Science. https://link.springer.com/article/10.1007/s43441-022-00472-3

[9] Xie et al. 2019. The rewards of regulatory change: Launching innovative biopharma in China. Deloitte. https://www2.deloitte.com/content/dam/insights/us/articles/R722481_The-rewards-of-regulatory-change/DI_The-rewards-of-regulatory-change.pdf

NEW DRUG APPROVALS

- The new "Provisions for Drug Registration" were enacted in October 2007, and this greatly improved the quality of new drugs.[1]; A series of regulatory reforms was introduced beginning in 2015, aimed at increasing efficiency, reducing backlog, and accelerating the time-to-market of novel medicines.[5]
- Additional limiting factors include capacity restraints at the NMPA: until 2017, the NMPA had a multiyear backlog of drugs awaiting approval.[3]
- In 2017 China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), whose guidelines help drive innovation while protecting patient interests.[5]
- Patient access to innovative therapies in development has also improved as a result of the increasing clinical trial initiations described earlier (from 12.5% of trials initiated in China in 2016, with growth to 21.6% in 2018 – similar to the US).[7]

Abbreviations: NCE = new chemical entity; NMPA = National Medical Products Administration; EMA = European Medicines Agency; FDA = US Food and Drug Administration; IND = investigational new drug

[1] Ding, J. et al. 2011. From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2. https://www.scielo.cl/pdf/jotmi/v6n2/art01.pdf

[2] Zhihua. 2019. Pharma companies move up the value chain. ChinaDaily.com.cn. http://www.chinadaily.com.cn/global/2019-07/26/content_37495602.htm

[3] Atkinson. 2020. The Impact of China's Policies on Global Biopharmaceutical Industry Innovation. Information Technology & Innovation Foundation. https://itif.org/publications/2020/09/08/impact-chinas-policies-global-biopharmaceutical-industry-innovation/

[5] Diao et al. 2019. Unlocking Access To Novel Medicines In China – A Review From A Health System Perspective. Risk Manag Healthc Policy. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6927264/

[6] Jain et al. 2017. Structural and procedural characteristics of international regulatory authorities. Nature reviews drug discovery. https://www.nature.com/articles/nrd.2017.135

[7] GlobalData report cited from Miseta. 2021 Report Reflects Huge Growth of Clinical Trials In China. Clinical Leader. https://www.clinicalleader.com/doc/report-reflects-huge-growth-of-clinical-trials-in-china-0001

DELPHI PANEL OUTPUT: PANELLISTS AGREED THAT METRICS SUCH AS R&D EMPLOYMENT REFLECT PROGRESS AND HAVE CONTRIBUTED TO IMPROVEMENTS IN PATIENT ACCESS

DELPHI STATEMENT
C
Although not the only factors that have led to increased economic and innovative activity, progress in Chinese innovation and IP policy have contributed to a greater than five-fold increase in pharmaceutical R&D employment since 2006, a rise in the number of biopharmaceutical enterprises to over 8,000, a shift from high reliance on government investment to an increasingly active private and venture capital environment, and a doubling of patent applications from medicine manufacturers between 2011 and 2020, which together have led to improved patient access to innovative and more effective therapies.
CONSENSUS LEVEL:
100%

SUMMARY OF DELPHI PANEL RESPONSES:

- Panellists agreed that implementation of improved innovation and IP policy has contributed to the positive trends seen in metrics such as increasing R&D employment, more active venture capital environment, and increase in patent applications, which combined have led to improved patient access
- Other factors noted by respondents that have driven improved patient access includes increased healthcare budget allocated to cover the innovative medicine expenses, generic drug policies, and improvement of physician scientific capabilities
- In future evaluation of the progress and impact of innovation and IP policy, countries such as Japan, Korea, and Singapore were noted as appropriate comparators to the Chinese landscape

3.

Future opportunities for growth in innovation

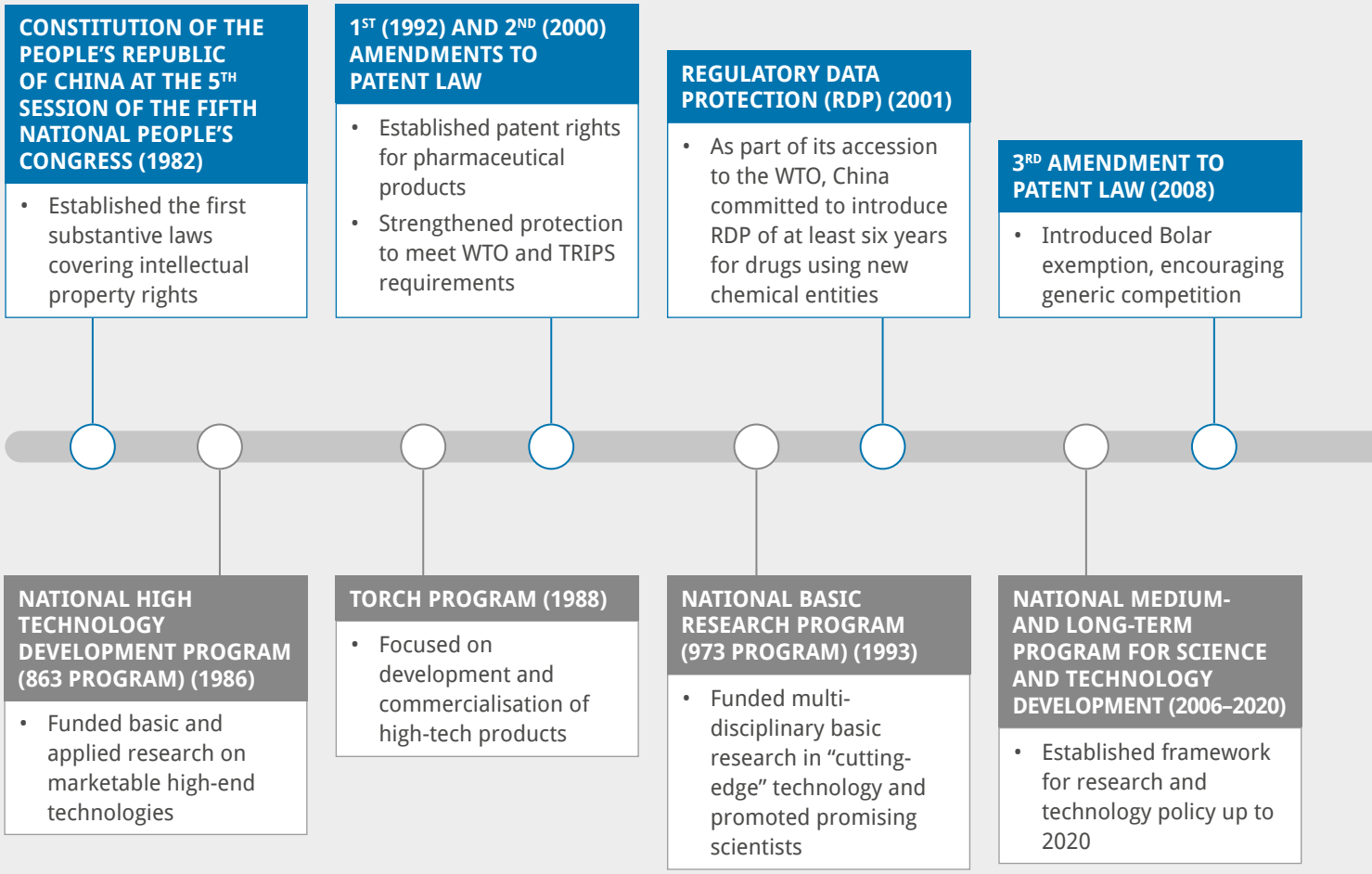
USING THE DELPHI APPROACH, FUTURE OPPORTUNITIES FOR STRENGTHENING THE IP AND INNOVATION ENVIRONMENT HAVE BEEN IDENTIFIED

TWO MAIN QUESTIONS WERE CONSIDERED:

1. Building from the significant progress that has already been made, where are the **opportunities** for increasing the level of innovative and economic activity even further in the future?
2. What **lessons** can be drawn from other countries that have encountered similar challenges?

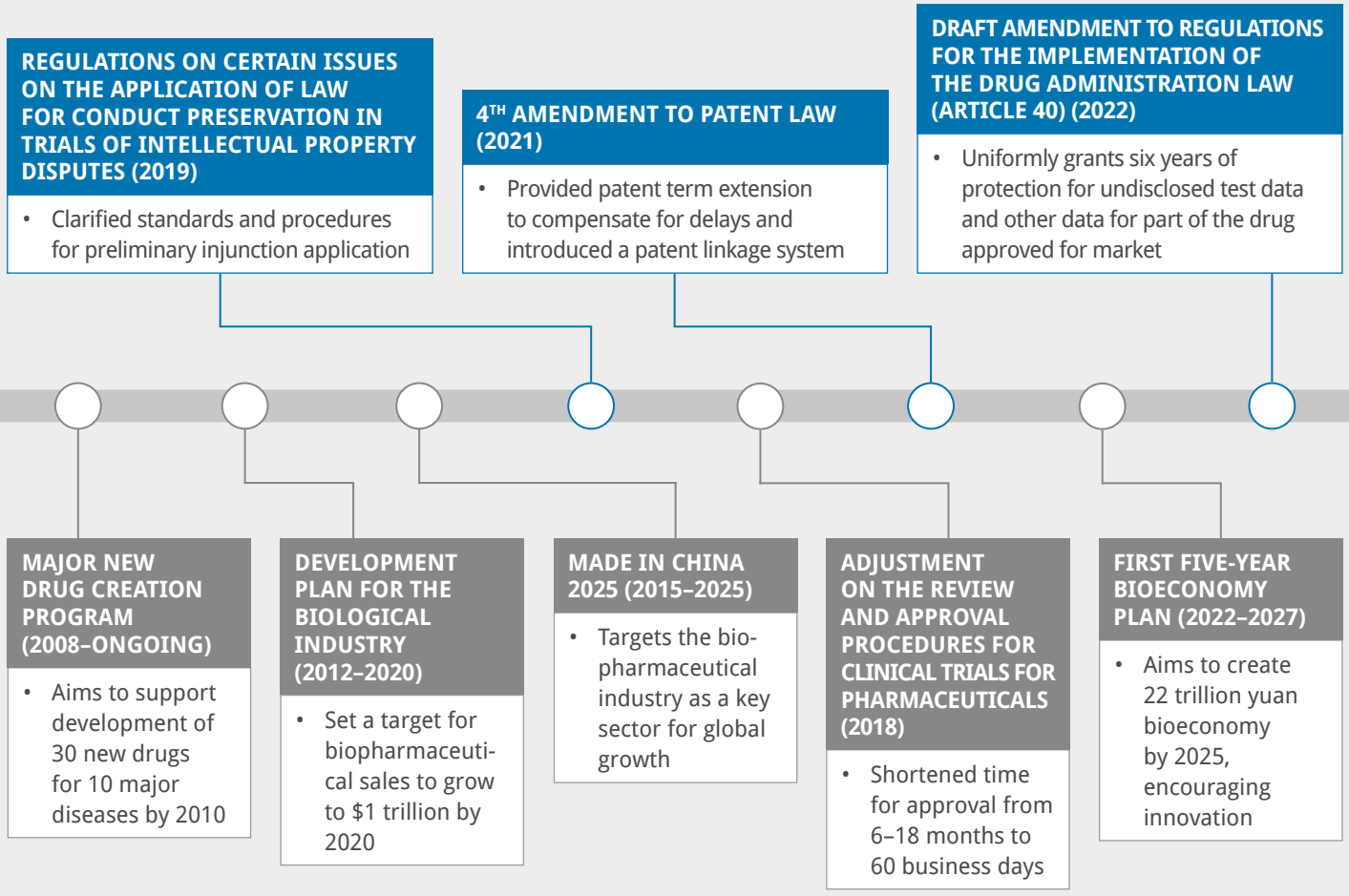
USING THE DELPHI APPROACH, FUTURE OPPORTUNITIES FOR STRENGTHENING THE IP AND INNOVATION ENVIRONMENT HAVE BEEN IDENTIFIED

CHANGES IN THE IP REGIME



CHANGES IN INNOVATION POLICY

2023 AND BEYOND: FUTURE OPPORTUNITIES FOR STRENGTHENING THE IP FRAMEWORK



2023 AND BEYOND: FUTURE OPPORTUNITIES FOR STRENGTHENING THE INNOVATION POLICY ENVIRONMENT

OPPORTUNITIES FOR GROWTH IN INNOVATION POLICY: ATTRACTING FOREIGN INVESTMENT

THE NEGATIVE LIST FOR FOREIGN INVESTMENT DISINCENTIVISES INVESTMENT FROM MULTINATIONAL COMPANIES BY PROHIBITING INVESTMENT IN CELL AND GENE THERAPY TECHNOLOGY

CURRENT POLICY GAP

- The Negative List for Foreign Investment Access contains a list of investment activities that are prohibited for foreign investors; this spans across industries and is regularly updated.[1]
- Although attracting multinational pharmaceutical investment has been an increasing focus in national innovation plans and policies, the Negative List for Foreign Investment prohibits "investment in the development and application of human stem cells, genetic diagnosis, and treatment technologies".[2]
- This limits the extent to which multinational pharmaceutical companies can conduct cell and gene therapy R&D in China, including setting up clinical trial sites for such technologies.
- Although there have been positive signals that some provincial governments would try to open up this area for foreign investment,[3] the restriction remains on the latest version of the Negative List.[1]
- The impact of this is evident: although development of cell and gene therapies has been rapid in China, with strong policy support,[4] none of the 49 cell and gene therapy IND product applications accepted by the NPMA by 2019 had been submitted by foreign companies.[3]

Abbreviations: FDI = foreign direct investment; IND = investigational new drug; NPMA = National Medical Products Administration

[1] The Negative List for Foreign Investment (2021 Edition)

[2] China Briefing

[3] Zhong Lun

[4] Deloitte

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

The case study countries do not have negative lists for foreign investment and attract strong inward foreign investment:

- The US attracts the greatest volume of pharmaceutical FDI projects, with over two times as many projects in 2019-2020 than China (103 and 48 projects respectively).[5]
- The US is also the leading destination for FDI projects in the nuclear acid therapeutics sector, receiving 24 inbound projects in 2021 whilst China received 5.[6]

- Surveys aimed at gathering investor sentiment on the location of investments show that investors have greater confidence investing in Japan than in China (ranked 4th and 10th respectively in 2022).[7]

- Despite its relatively small market size, Singapore attracts a large volume of pharmaceutical FDI.[8]
- This has been attributed to targeted investment promotion activities to attract investment.[9]

Abbreviations: FDI = foreign direct investment; IND = investigational new drug; NPMA = National Medical Products Administration

[5] Pharmaceutical Technology (2022)

[6] Pharmaceutical Technology (2022)

[7] Kearney FDI Confidence Indices

[8] Mercurio, B. and Kim, D. (2015) Foreign Direct Investment in the Pharmaceutical Industry: Why Singapore and not Hong Kong. Asian Journal of Comparative Law. doi:10.1017/asjcl.2015.12

[9] UN ESCAP (2022)

OPPORTUNITIES FOR GROWTH IN INNOVATION POLICY: PROLONGED INNOVATIVE DRUG APPROVALS

MARKETING AUTHORISATION BARRIERS, INCLUDING INSUFFICIENT MANPOWER FOR THE CENTER FOR DRUG EVALUATION AND EXCESSIVE APPLICATIONS OF GENERIC PRODUCTS, LEAD TO PROLONGED INNOVATIVE DRUG APPROVAL TIMES

CURRENT POLICY GAP

- The number of new drugs approved in China has been increasing dramatically, supported by a series of regulatory reforms, leading to significant benefits for patients.[1]
- However, there are notable discrepancies with the rate at which new drugs are approved in China versus the rest of the world even if the extent of the delays is likely to have reduced from that indicated by available data, due to improvements in the regulatory environment:
  - In 2018, China's new drug approval times lagged behind the US and EU by 28 and 31 months respectively.[2]
  - For new foreign drugs (those not manufactured locally), there is on average a five-year lag between their first global approval and their approval in China.[1]
- This has been attributed to a range of hurdles:
  - Limited capacity and resources at the NMPA Center for Drug Evaluation[3]
  - Use of a substantial proportion of the available regulatory resources by the processing of high volumes of generic product applications
  - A regulatory system that has historically applied different processes for domestic and foreign drugs[1]

Abbreviations: NPMA = National Medicinal Products Administration; PMDA = Pharmaceutical and Medical Devices Agency

[1] Su, L. et al. (2023) Trends and Characteristics of New Drug Approvals in China, 2011–2021. Ther Innov Regul Sci; 57(2): 343-351

[2] Deloitte (2019)

[3] Atkinson, R. D. (2020)

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

- The US FDA is widely acknowledged to have world-leading scientific and technical capabilities.
- As a result, median approval times are the shortest of all major regulatory agencies (at 244 days).[4]
- The use of fast track, accelerated approval, and priority review programs has also been steadily increasing since 2000.[5]

- In Japan, the PMDA follows shortly behind the FDA, with median approval times of 313 days.[4]
- New measures to further speed up approval times have been proposed.[6]

- The Health Sciences Authority (HSA) of Singapore, along with four other medium-sized regulatory agencies, is a member of the Access Consortium.
- One element of this collaboration is the New Active Substance Work Sharing Initiative (NASWSI), which aims to share workload, thus increasing efficiency.[5]

Abbreviations: FDA = Food and Drug Administration; PMDA = Pharmaceutical and Medical Devices Agency

[4] CIRS

[5] Batta, A. et al. (2020) Trends in FDA drug approvals over last 2 decades: An observational study. J Family Med Prim Care; 9(1): 105-114

[5] HSA

[6] Pink Sheet

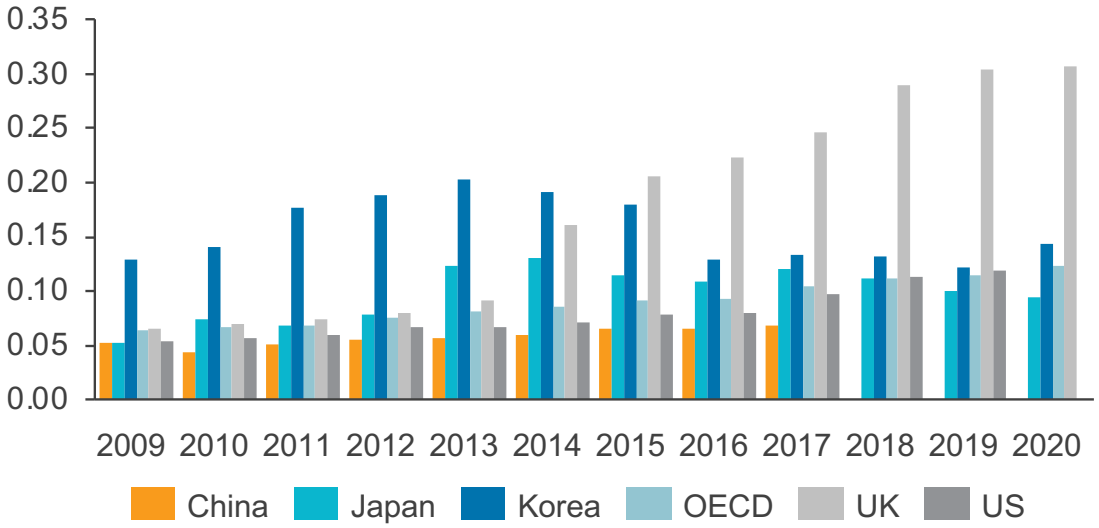
OPPORTUNITIES FOR GROWTH IN INNOVATION POLICY: R&D TAX INCENTIVES

ALTHOUGH LEVELS OF INDIRECT GOVERNMENT SUPPORT THROUGH R&D TAX INCENTIVES HAVE INCREASED, THESE CONTINUE TO LAG BEHIND MARKETS SUCH AS SOUTH KOREA AND JAPAN

CURRENT POLICY GAP

- There have been increasing levels of indirect government support for innovation through R&D tax incentives since 2010, when a series of tax exemption policies were introduced, such as reducing business taxes related to technology innovations, and exemption of income and sales taxes for drug R&D expenses.[2]
- However, China's tax incentives are generally lower compared to other advanced economies.[1]

Government support through R&D tax incentives (% of GDP)[1]



Abbreviations: GDP = gross domestic product; OECD = Organisation for Economic Co-operation and Development

[1] OECD

[2] Ding, J. et al. (2011) From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. Journal of Technology Management & Innovation, 6:2

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

- The tax relief that South Korea provides to business R&D as a percentage of GDP is among the largest levels, at a rate equivalent to 0.29% of GDP. Tax incentives account for 43% of this support.[3]
- In 2021, R&D tax credits were increased by 10% across sectors,[4] and the scope of the R&D tax credit was extended to cover expenses on IP research and analysis.[3]

- Tax credits that benefit the drug industry include the research and experimentation tax credit, the Orphan Drug Act tax credit (which until 2018 covered 50% and now covers 25% of R&D costs), in addition to grants and waived FDA fees.[5]
- The Orphan Drug Credit can also allow tax credits to be claimed for research conducted outside of the US, for example if there is an insufficient US testing population.[6]

Abbreviations: FDA = Food and Drug Administration

[3] OECD

[4] MNE Tax

[5] Kesselheim, A.S. et al. (2019) Pharmaceutical policy in the United States in 2019: An overview of the landscape and avenues for improvement. Stan. L. & Pol'y Rev., 30, p.421

[6] Moss Adams

DELPHI PANEL OUTPUT: THE DELPHI PANELLISTS INDICATED THAT THESE GAPS IN THE INNOVATION POLICY ENVIRONMENT ARE LIMITING FUTURE GROWTH OF INNOVATIVE ACTIVITY

DELPHI STATEMENT
D

Although much less significant than previously, there are still some gaps in innovation policy preventing further progress in increasing economic and innovative activity, with the most impactful gaps being:

a) Negative List for Foreign Investment **disincentivising investment from multinational companies** by prohibiting investment in cell and gene therapy technology

b) Marketing authorisation barriers, including insufficient manpower for the Center for Drug Evaluation and excessive applications of generic products, leading to **prolonged innovative drug approval times**

c) **R&D tax incentives** continuing to lag behind markets such as South Korea and Japan, despite the increasing levels of government support

CONSENSUS LEVEL:
89%

SUMMARY OF DELPHI PANEL RESPONSES:

- There have been significant achievements in the evolution of the innovation policy environment in China, largely catalysed by national innovation plans and streamlining of the regulatory system.
- The speed of growth of innovative and economic activity, whilst already rapid, could be further supported by targeted policy attention in the three areas highlighted in Statement D.

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: REGULATORY DATA PROTECTION

THERE IS A LACK OF CLARIFICATION ON THE SCOPE AND WORDING OF REGULATORY DATA PROTECTION (RDP), AND INADEQUATE IMPLEMENTATION AND ENFORCEMENT OF RDP

CURRENT POLICY GAP

- In 2001, as part of its accession to the WTO, China committed to introduce RDP of at least six years for drugs using new chemical entities. However, there were certain flexibilities to the agreement, such as the definition of "new chemical entities".[1]
- In 2018, the NMPA issued Implementation Measures for Drug Trial Data Protection (for Interim Implementation), which has not been formally promulgated. It provides a six-year data protection period for innovative drugs, orphan drugs, and pediatric drugs, and a 12-year period for innovative therapeutic biological products.[2]
- In mid-2022, a draft legislative amendment uniformly granted 6 years of protection for undisclosed test data and other data for part of the drug approved for market.[2,3]
    - NMPA can also disclose proprietary data during the RDP period as required by public interest, and after taking protective measures to prevent improper use of data.
- Experts believe that further clarification on the scope and conditions is needed, such as on "part of the drug". More explicit statements and removal of exceptions for disclosure have been proposed.[4]

Abbreviations: NPMA = National Medical Products Association; RDP = regulatory data protection; WTO = World Trade Organisation

[1] Cheng, W. (2019) Protection of Data in China: Seventeen Years after China's WTO Accession. European Intellectual Property Review, 41(5):292-297.

[2] Han Kun Law Offices (2022)

[3] Ropes & Gray (2022)

[4] Yang, B. (2022)

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

- Regulatory data protection is relatively well-established in the US.
- In the US, there are five years of data exclusivity for small molecule new chemical entities, three years for a new indication of a previously approved therapy, and four years for biologics, which also has a 12-year market exclusivity period.[6]

- In Europe, there are eight years of data exclusivity provided for all innovative new drugs; one year of additional protection can be provided in case of a new therapeutic indication, which brings significant clinical benefit compared to existing therapies.[5]
- However, it is expected that the European Commission's proposal for revising the general pharmaceutical legislation will contain provisions to reduce baseline RDP from eight to six years.
- This has been met with some criticism based on its potential to harm innovation in Europe.

Abbreviations: RDP = regulatory data protection

[5] Copenhagen Economics (2018)

[6] Hoen, E. (2022)

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENT TERM EXTENSIONS

THERE IS AMBIGUITY IN TERMINOLOGY AND SCOPE AS WELL AS LACK OF EFFECTIVE IMPLEMENTATION OF PATENT TERM EXTENSIONS (PTE)

CURRENT POLICY GAP

- The fourth amendment to Patent Law (in 2021) introduced patent term extensions to compensate for delays caused by regulatory review and approvals of new drugs.[1]
    - Specifically, total compensation term shall not exceed 5 years, and total effective patent term after the new drug is approved shall not exceed 14 years.
- Given the early stages of the implementation of PTE in China, some issues and uncertainties remain:
    - Ambiguity in terminology, particularly in how agencies will define certain parameters such as “new drug” and “scope of rights”
    - Scope of the compound patent during the PTE period is limited to the approved indication of the approved drug product based on which the PTE is requested according to the draft regulations
    - Lack of effective implementation
- The impact of this is that patent holders are not compensated for the time spent on marketing approval.

Abbreviations: PTE = patent term extension

[1] Huang, H. et al. (2020) China Promulgates Fourth Amendment Patent Law

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

- The US has had a patent term restoration mechanism in place since 1984, under the Hatch-Waxman Act, preceding many other countries.[2]
- The scope is well-defined, covering "human drug products" defined as the active ingredient of a new drug or human biologic product first approved in the US.

- In Europe, Supplementary Protection Certificates (SPCs) are used as the primary mechanism to compensate for regulatory review periods. These were introduced in 1992.
- In 2017, the European Commission commissioned a study evaluating the economic impact of SPCs and other elements of the IP framework. This found that the use of SPCs has increased over time, and that longer effective protection periods stimulate further R&D into new medicinal products.[3]

[2] FDA (2020)

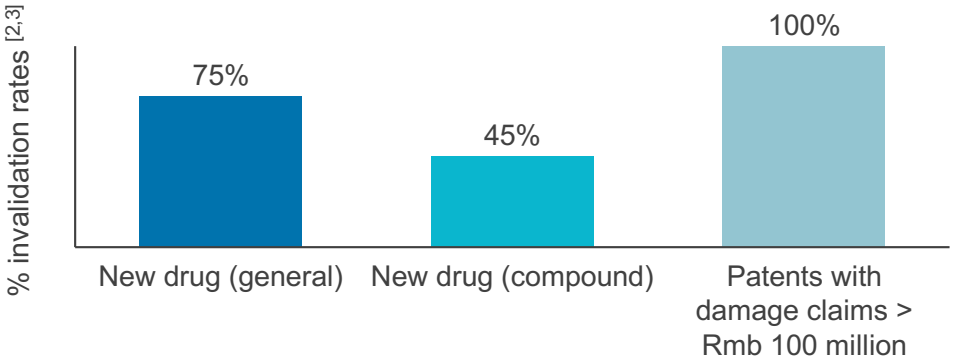
[3] Copenhagen Economics (2018)

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENT INVALIDATION RATES

INNOVATORS ENCOUNTER HIGH PATENT INVALIDATION RATES AND RESTRICTIVE CRITERIA

CURRENT POLICY GAP

- Individuals can request the Patent Reexamination and Invalidation Department (PRD) of CNIPA to declare patent rights invalid following the publication of the grant of the patent[1]
- Some challenges with the system have been highlighted:[2]
  - While the PRD provides a synopsis for each invalidation decision, it lacks detail and clarity.
  - There is a lack of detailed rules on key validity concepts that leaves much to the discretion of each examiner.
  - PRD invalidations move much faster than court proceedings, so a decision will likely be issued before any court judgement. Courts will immediately dismiss a patentee's suit if the patent is invalidated.



Abbreviations: CNIPA = China National Intellectual Property Administration; PRB = patent review board

[1] WIPO, Administrative Revocation and Invalidation Mechanisms: China

[2] IAM (2020)

[3] IAM (2019)

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

- Patent invalidation rates in the US are more balanced.
- The Patent Trial and Appeal Board (PTAB) in the US is similar to the PRD. It is also possible to pursue patent invalidation litigation at district courts.
- At both levels, the rate of invalidations contrasts with that in China:[3]
  - PTAB: 23% of decisions by PTAB invalidated all challenged claims. Zero invalidation of compound patents.
  - District courts: 24% of proceedings invalidated all challenged claims. Very low invalidation rate of compound patents.

Abbreviations: PRB = patent review board

[3] IAM (2019)

[4] Harness IP (2018)

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENTABILITY AND PRELIMINARY INJUNCTIONS

COMPARED TO INTERNATIONAL STANDARDS, PATENTABLE SUBJECT MATTER AND SCOPE OF PROTECTION IS COMPARATIVELY NARROWER IN CHINA

CURRENT POLICY GAP

- Positive steps have been taken to strengthen patentability criteria for pharmaceuticals in China.
    - For example, the Patent Examination Guidelines have been amended such that post-filing data is now considered by the court.[1]
- However, there are a number of additional opportunities in the patentability framework to align with international standards.
    - One outstanding area of concern for innovative companies is that specific therapeutic methods of a treatment of a known indication (e.g. new dosage regimens, treatment of new subgroups of patients or new routes of administration) cannot be protected by patents in China.[1]
- The inability to obtain patents on these inventions undermines the incentives to invest in them, particularly to the extent they are targeted at particular medical and health problems in China.

[1] PhRMA (2021)

INNOVATIVE COMPANIES REPORT INSUFFICIENT ACTION TAKEN BY CHINESE COURTS IN ISSUING PRELIMINARY INJUNCTIONS

CURRENT POLICY GAP

- Courts in China have been historically conservative in issuing preliminary injunctions, particularly when compared to the US and Europe.
- In 2019, new regulations were enforced that are hoped to encourage a more liberal approach to issuing preliminary injunctions in the future.[2]
- However, certain aspects may pose a high risk to applicants for a preliminary injunction:[2]
    - The need to post a bond equal to the damages the defendant may suffer from implementing the injunction
    - The newly introduced and broad concept of "wrongful applications" for injunctions, creating a risk of compensation paid to the other party

[2] Hogan Lovells (2019)

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENT LINKAGE

THERE ARE REPORTS OF PATENT LINKAGE PROCEDURAL ISSUES AND LACK OF ENFORCEMENT OF PATENT LINKAGE RULES

CURRENT POLICY GAP

- The fourth amendment to Patent Law (in 2021) introduced a patent linkage system for early resolution of patent disputes, before the marketing and sale of the generic or biosimilar drug.
    - This is facilitated by a marketed drug patent information registration platform which lists all active and qualified patents.
- Whilst this represents a positive milestone in the development of the IP framework in China, there are some outstanding areas of concern regarding the new legislation:[1]
    - When patent linkage actions are commenced within 45 days after the filing of chemical generic drug applications, generic drugs are granted an automatic nine-month stay of marketing authorisation. This is also shorter than is typical in other countries.
    - At present cases are generally closed within nine months
- Other problems (i.e. limited types of listable patents , unconditional approval of drugs when no marketing until patent expiry is declared, and no stay of biosimilar approval) are bigger challenges than filing within 45 days, the 9-month stay and originators' liability.
    - Innovative companies can be liable for compensatory damages if they know or should have known the patent is invalid or the patent has been declared invalidated (i.e. no further appeal available)
    - No remedies are available when generics/biosimilars make false patent declarations.
    - Also, patents on manufacturing processes or on pharamceutical intermdiates, metabolities, crystalline patents or diagnostic patents cannot be listed on the Chinese Patent Linkage System.[1]

[1] Wexler, B., Zhou, M. and Sperling, M. (2021)

OPPORTUNITIES FOR GROWTH

CASE STUDY LESSONS

- Under the US Hatch-Waxman act:[2]
  - The first generic able to obtain approval is granted 180 days of market exclusivity. This is subject to detailed criteria and regulations.
  - Generic small molecule drugs are granted an automatic 30-month stay of marketing authorisation after commencement of the patent linkage process. This protects the IP rights of the patented drug.
- The Hatch-Waxman act aimed to strike a balance between promoting innovation whilst supporting market entry of generics. It is largely considered to have met this goal.[3]

- In South Korea, the free trade agreement signed with the US (KORUS FTA) catalysed the introduction of a patent linkage system.[2]

Abbreviations: KORUS FTA = US-Korean Free Trade Agreement

[2] Raju, K. D. (2022) Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries. Access to Medicines and Vaccines. https://doi.org/10.1007/978-3-030-83114-1_12

[3] Shepherd, J. (2016) Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review. JIPEL, 6(1)

DELPHI PANEL OUTPUT: PANELLISTS CONFIRMED THAT DESPITE THE MAJOR PROGRESS THAT HAS BEEN MADE IN STRENGTHENING THE CHINESE IP FRAMEWORK, SOME CONCERNS REMAIN

DELPHI STATEMENT

E

Despite the progress that has been made, innovative activity could be further stimulated by addressing shortcomings in the Chinese IP regime, specifically:

a) Lack of clarification on the scope and wording of **regulatory data protection (RDP),** e.g. on the definition of "new chemical entity" and "certain drugs", and inadequate implementation and enforcement of RDP

b) Ambiguity in terminology and scope as well as lack of effective implementation of **patent term extensions (PTE)**

c) High **patent invalidation rate and restrictive criteria,** including lack of clear standards for post-filing data, no presumption of validity after patent grant, and repeated invalidation requests based on the same or similar reasons

d) Scope of the compound patent during the patent term extension period is **limited to the approved indication** of the approved drug product according to the draft regulations

e) Insufficient action taken by Chinese courts in issuing **preliminary injunctions**

f) Patent linkage procedural issues and lack of enforcement of patent linkage rules

g) Limited patentable subject matter and scope of protection: e.g. dosing regimen is not patentable; biological patents are sequence-specific

CONSENSUS LEVEL:

100%

DELPHI PANEL OUTPUT: FROM THE PERSPECTIVES OF THE DELPHI PANELLISTS, THE CURRENT RDP FRAMEWORK AND PATENT REGIME LIMIT THE GROWTH OF INNOVATION IN CHINA

DELPHI STATEMENT

F

The most significant barriers preventing further progress in stimulating biopharmaceutical innovation are the lack of implementation and enforcement of **regulatory data protection** and **shortcomings in the patent regime** around patent term extensions, high invalidation rates, patent linkage issues, and insufficient preliminary injunctions.

CONSENSUS LEVEL:

90%

SUMMARY OF DELPHI PANEL RESPONSES:

- Major improvements to the IP framework in China have catalysed a rapid expansion of innovative and economic activity and led to new innovative medicines being brought to patients in China.
- Some challenges remain, particularly when comparing the strength of RDP and IP in China to international standards.
- Where such barriers have already been addressed in other countries and regions, there are some directional policy lessons that can be taken from these countries and tailored to the local legal framework in China.

DELPHI PANEL OUTPUT: THE US, EUROPE AND JAPAN ARE SEEN AS MARKETS IN WHICH RDP POLICY IS MORE SUPPORTIVE OF BIOPHARMACEUTICAL INNOVATION

DELPHI STATEMENT
G
Fully implemented and enforced regulatory data protection with clarification on scope and wording, and with rules which are in line with best practices from the US, EU and Japan, would increase incentives for biopharmaceutical companies to make the significant investments necessary to develop new medicines in China.
CONSENSUS LEVEL:
80%

SUMMARY OF DELPHI PANEL RESPONSES:

- Panellists reported that some ambiguities and uncertainties in current RDP policy have prevented some biopharmaceutical companies from investing or increasing their investments in China.
- Other advanced economies, namely the US, Europe and Japan, are seen as benchmarks; panellists identified opportunities for further growth in innovative activity in China if RDP policy were altered to be more in line with these regions' approaches, for example allowing foreign data and published data to also fall under the scope of protections as well as granting RDP to drugs first approved in China regardless of their registration status in other countries.

DELPHI PANEL OUTPUT: PANELLISTS SAW SIGNIFICANT OPPORTUNITIES FOR GROWTH IN INNOVATIVE ACTIVITY IF THESE ELEMENTS OF THE PATENT FRAMEWORK WERE STRENGTHENED

DELPHI STATEMENT
H
A strengthening of the patent system to better align with international best practices such that patent linkage procedural issues are resolved and the rules enforced, valid patents are robustly protected, preliminary injunctions are increased, and the scope of patent term extension is broadened, would significantly encourage innovative activities in the biopharmaceutical sector, likely leading to increased research and development as well as launch of new medicines.
CONSENSUS LEVEL:
100%

SUMMARY OF DELPHI PANEL RESPONSES:

- Specific countries and regions highlighted as sources of potential "international best practices" in terms of the strength of their IP frameworks were the US, Europe and Japan.
- It was not considered realistic nor appropriate for Chinese patent legislation to mirror that of these regions, but instead to learn from the progress that has been made and identify ways in which similar elements (such as robust defence of valid patents and broad and transparent PTE) could also serve to accelerate the growth of innovative activity in China.

4.

Innovation policy implications for China

BENEFITS OF FURTHER IMPROVEMENTS IN THE INNOVATION ENVIRONMENT

WHAT IF CHINA CONTINUES ON A POSITIVE TRAJECTORY?

- As has already been demonstrated, there have been major improvements in the innovation environment in China, resulting in rapid increases in innovative and economic activity and patient access to novel therapies.
- Despite these improvements, however, some notable gaps remain in the innovation environment, particularly with regards to intellectual property. The panel agreed with Statement I that further improvements that address the remaining barriers would lead to substantial benefits across the innovation pathway, from early research through to patient health outcomes.

DELPHI STATEMENT

I

If the innovation policy environment was improved in a way that addresses the remaining barriers (e.g. enforcement of regulatory data protection, high invalidation rates, patent linkage issues etc.) in China, the impact would be to encourage innovation from domestic and international pharmaceutical companies, with the following benefits:

a) Innovative activity in the biopharmaceutical industry would increase, likely leading to higher numbers of scientific publications, patent applications, and clinical trials.

b) Increased innovative activity would have economic benefits by attracting greater foreign direct investment, supporting the growth of local companies and their contribution to China's economy, and increasing employment in the biopharmaceutical sector.

c) Patients would subsequently benefit from new, improved medicines as a result of these innovative activities.

CONSENSUS LEVEL:

100%

APPROACH TO QUANTIFYING MAGNITUDE OF FURTHER IMPROVEMENTS

- To estimate the potential magnitude of benefits of further improvements in the innovation environment, we applied an approach which uses data from case study comparator countries. This builds on a similar approach previously employed in INTERPAT reports on the innovation environment in Latin America.
- The premise of the approach was captured in **Statement J,** which the panel reached consensus on, that further improvements could lead to China's growth rate for key metrics increasing in line with the increases seen in comparable markets where improvements to innovation and IP policy have been implemented.

DELPHI STATEMENT
J
If the innovation environment in China was further improved and the remaining barriers were addressed, the relative increase in growth rates for innovative activity, economic activity, and patient access could approximate those achieved in comparable markets where significant improvements to innovation and IP policy have been implemented.

CONSENSUS LEVEL:
100%

METHOD FOR ESTIMATING GROWTH SCENARIOS FOR CHINA

STEP 1

China baseline growth

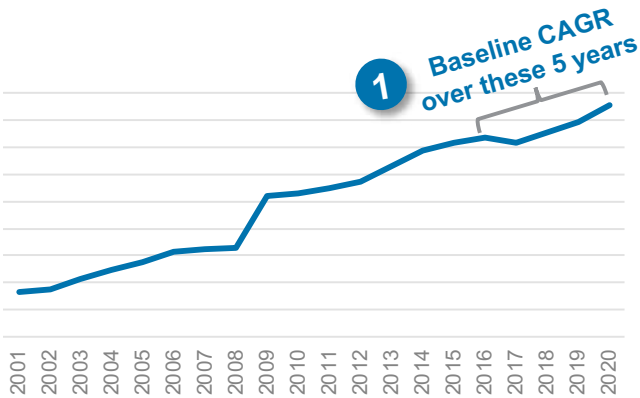
- Construct baseline scenario in which China continues on its current growth rate for key metrics
- Specifically, we calculate the compound annual growth rate (CAGR) over the previous five years for which data is available

STEP 2

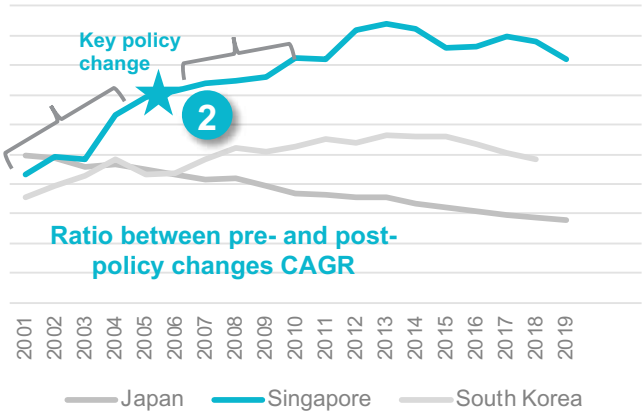
Case study growth rate changes

- Calculate the change in the five-year CAGR before and after the implementation of key policy changes beneficial to the innovation environment for three case study comparator countries

Number of publications: China



Number of publications: Other countries



Abbreviations: CAGR = Compound annual growth rate

STEP 3

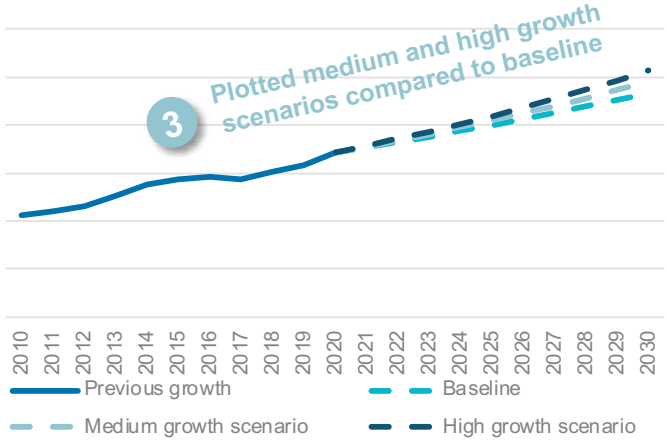
China growth scenarios

Estimate two scenarios for China:

a) Medium growth scenario in which China's growth rate increases in line with the average of case study CAGR differences

b) High growth scenario in which it increases in line with the highest increase for a case study country

Number of publications: Scenarios



Abbreviations: CAGR = Compound annual growth rate

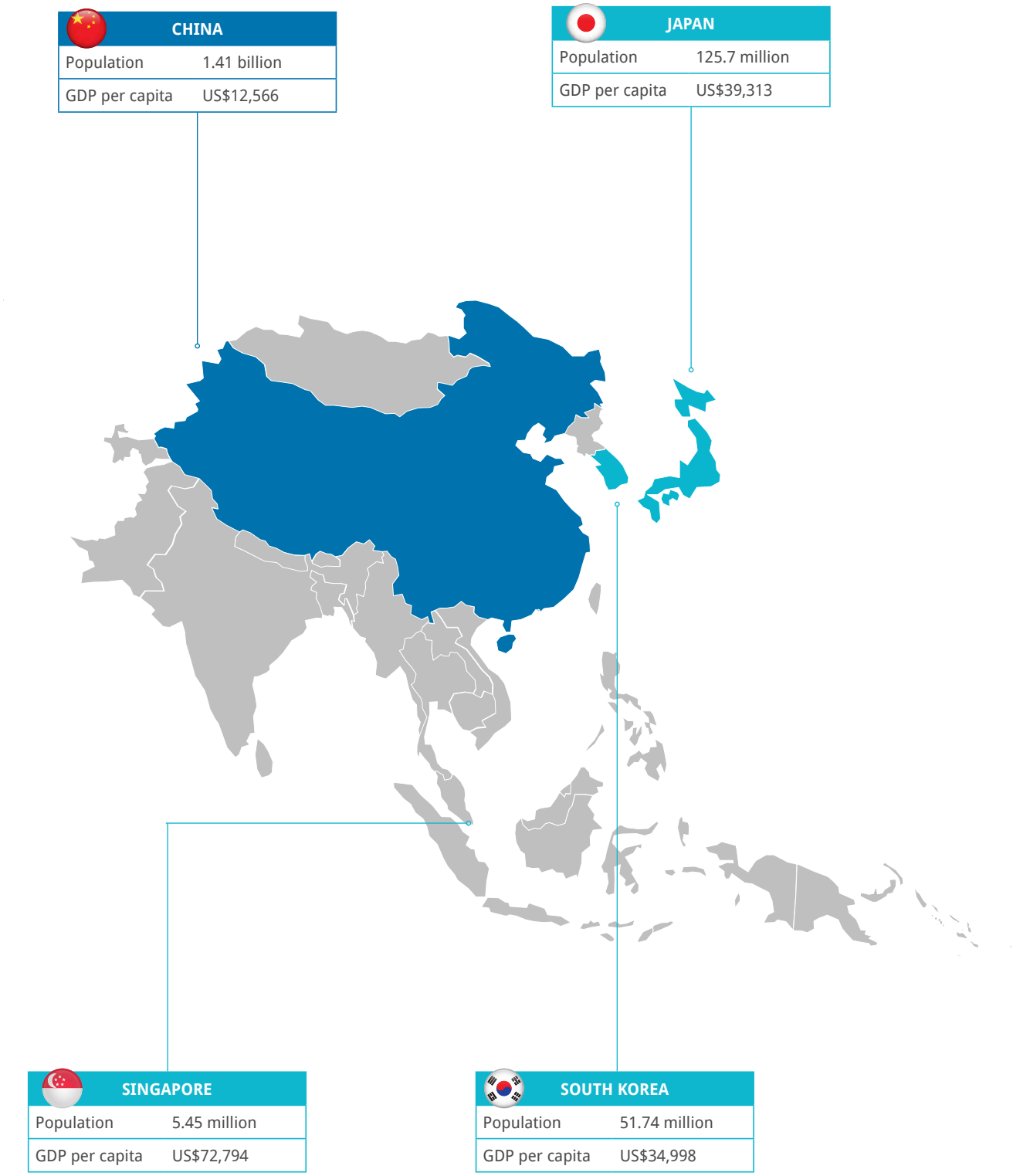
CRITERIA FOR THE SELECTED CASE STUDY MARKETS INCLUDED HAVING OBSERVABLE OUTCOMES FROM INNOVATION AND IP POLICY CHANGES

THE SELECTION CRITERIA FOR OUR CASE STUDY MARKETS INCLUDE:

1. Have shown a focus on **strengthening innovative environment,** particularly the IP protection
2. Is placed **broadly in the same region and development category as China**
3. Shows an observable impact on **innovative activity**
4. Policy changes **occurred recently enough** in this market that we can observe the outcome (this was the reason why the US and EU were not included, as the relevant policy changes occurred too long ago for reliable data to be available)

KEY POLICY CHANGES

SINGAPORE	SOUTH KOREA	JAPAN
• Establishment of IP courts, 2002 • Singapore-US Free Trade agreement (2004), strengthening the IP regime • The Patents (Amendment) Act, 2004	• Pharmaceutical Affairs Act of 2007, strengthening RDP • 2nd Framework plan for Promotion of Biotechnology ("Bio-Vision 2016") (2006) • "577 Initiative" (2008)	• Extension of de-facto RDP from six to eight years in 2007 (Notification No. 0401001) • Policies targeted at the patent backlog (2004-2007) • Innovation 25 initiative (2006)


CHINA
Population 1.41 billion
GDP per capita US$12,566
JAPAN
Population 125.7 million
GDP per capita US$39,313
SINGAPORE
Population 5.45 million
GDP per capita US$72,794
SOUTH KOREA
Population 51.74 million
GDP per capita US$34,998

SCENARIOS ANALYSIS:
ESTIMATED MEDIUM AND HIGH GROWTH RATES FOR EACH METRIC

SCENARIO DETAILS	BASIC RESEARCH	R&D EXPENDITURE
	CAGR of biological and biomedical sciences publications per 1000 researchers	CAGR of pharmaceutical R&D expenditure per 1000 persons
BASELINE GROWTH IN CHINA		
• China's current five-year compound annual growth rate (CAGR); latest five years of available data	**3.1%**	**9.6%****
IP REGIME AND INNOVATION POLICY – MEDIUM GROWTH		
• Paced growth scenario based on an improvement of the IP regime and other innovation incentives but with limitations in implementation • Based on average of changes in growth rates for case study countries	**3.7%*** ▲	**11.5%** ▲
IP REGIME AND INNOVATION POLICY – HIGH GROWTH		
• Escalated growth scenario based on an improvement of the IP regime and other innovation incentives with good implementation • Based on highest change in growth rate for the three case study countries	**4.1%** ▲▲	**13.4%** ▲▲

Abbreviations: CAGR = Compound annual growth rate

*Excludes Japan due to lack of available data

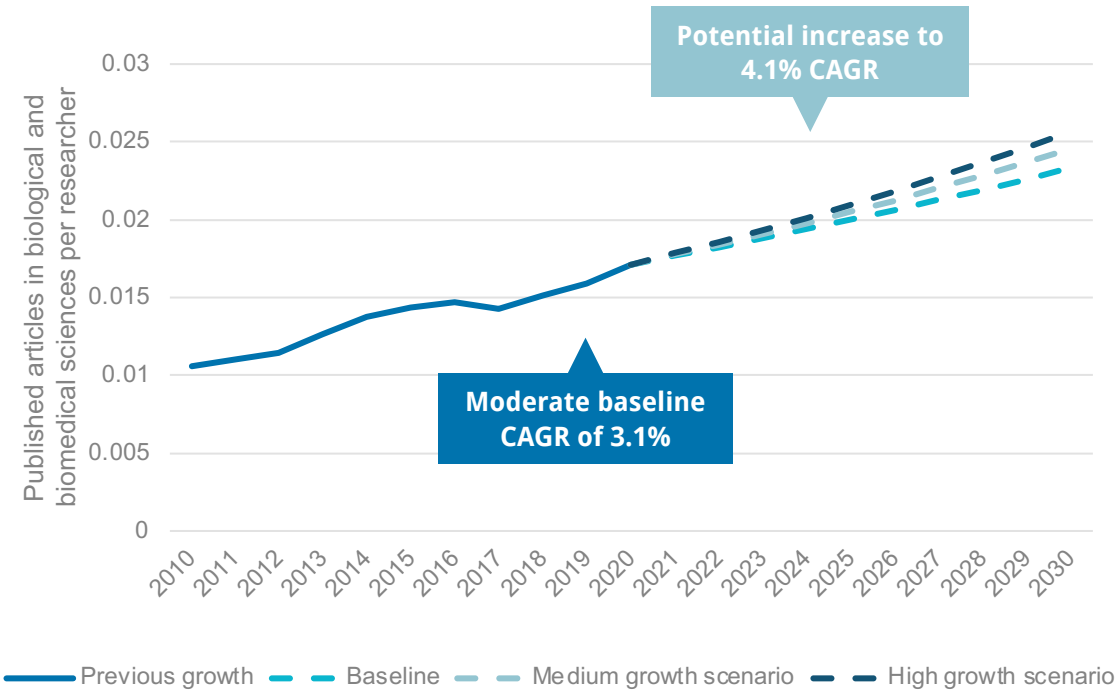
**As growth has been very high in recent years, we divided the scenario growth rates by two to provide a more realistic projection

SCENARIO DETAILS	EMPLOYMENT	R&D EXPENDITURE
	CAGR of medicines R&D personnel	CAGR of biopharmaceutical patent grants
BASELINE GROWTH IN CHINA		
• China's current five-year compound annual growth rate (CAGR); latest five years of available data	**0.6%**	**5.0%**
IP REGIME AND INNOVATION POLICY – MEDIUM GROWTH		
• Paced growth scenario based on an improvement of the IP regime and other innovation incentives but with limitations in implementation • Based on average of changes in growth rates for case study countries	**0.9%** ▲	**7.3%** ▲
IP REGIME AND INNOVATION POLICY – HIGH GROWTH		
• Escalated growth scenario based on an improvement of the IP regime and other innovation incentives with good implementation • Based on highest change in growth rate for the three case study countries	**1.4%** ▲▲	**8.1%** ▲▲

Abbreviations: CAGR = Compound annual growth rate

SCENARIOS ANALYSIS: RESULTS (1/2)

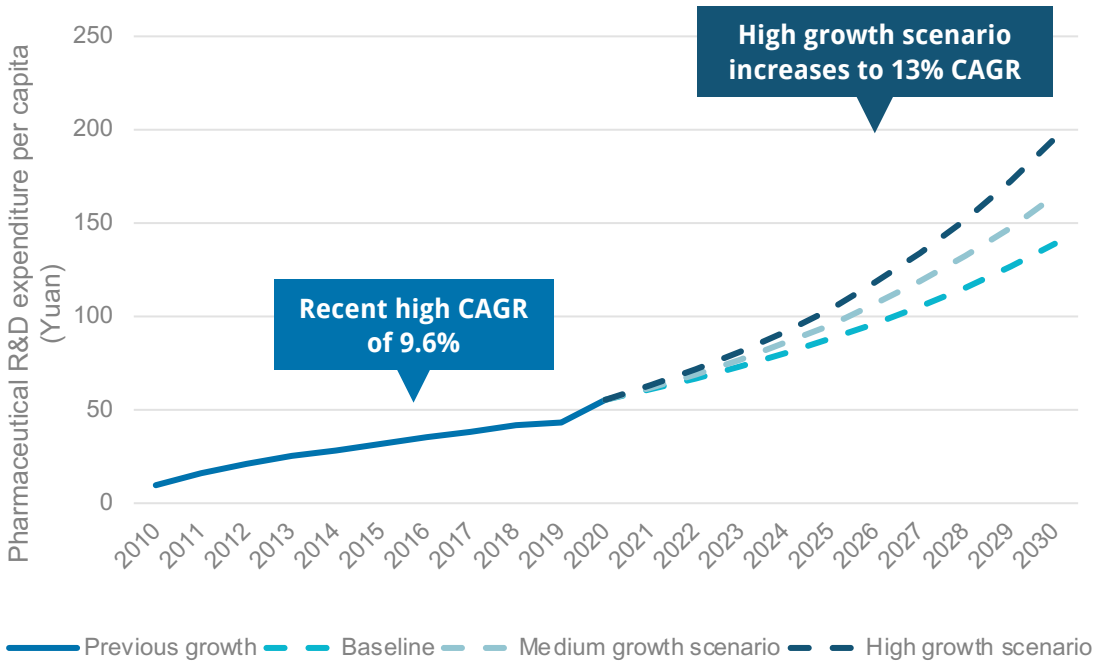
BASIC RESEARCH GAINS



- Previous growth in biological and biomedical sciences publications has been relatively moderate in China
- The medium and high growth scenarios suggest that there certainly could be improvements but these may be limited by relatively slow underlying growth

Abbreviations: CAGR = Compound annual growth rate

PHARMACEUTICAL R&D EXPENDITURE GAINS

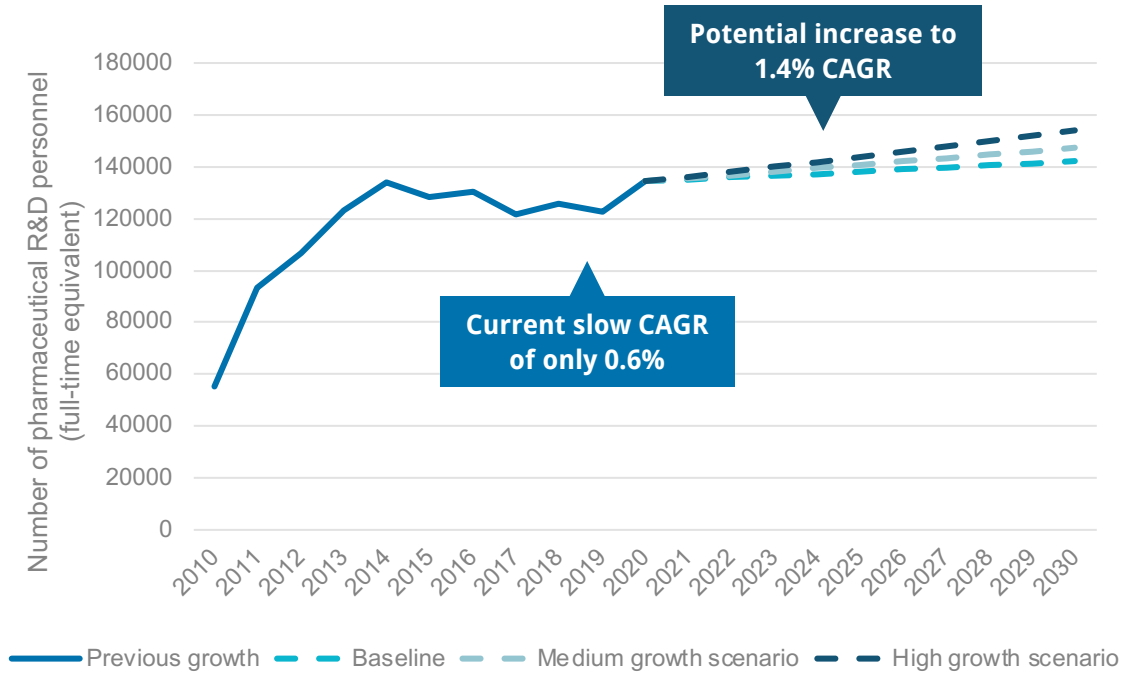


- Pharmaceutical R&D expenditure in China is already rapidly growing, so further changes based on case study markets make it appear that growth in China would increase much faster

Abbreviations: CAGR = Compound annual growth rate

SCENARIOS ANALYSIS: RESULTS (2/2)

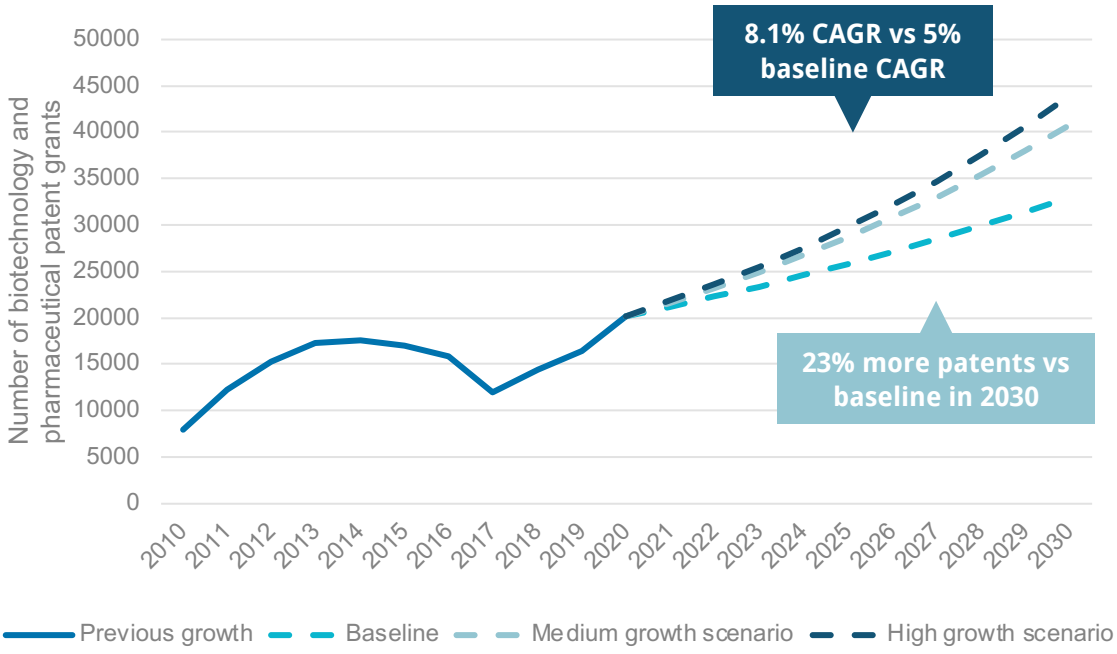
PHARMACEUTICAL EMPLOYMENT GAINS



- In recent years there has been limited growth in Chinese pharmaceutical employment, so even with a high growth scenario the gains for China appear modest.
- However, this is more reflective of the low baseline growth, and demonstrates the need for improvements to the innovation environment if growth in pharmaceutical employment is to return to pre-2014 levels

Abbreviations: CAGR = Compound annual growth rate

PATENT GRANT GAINS

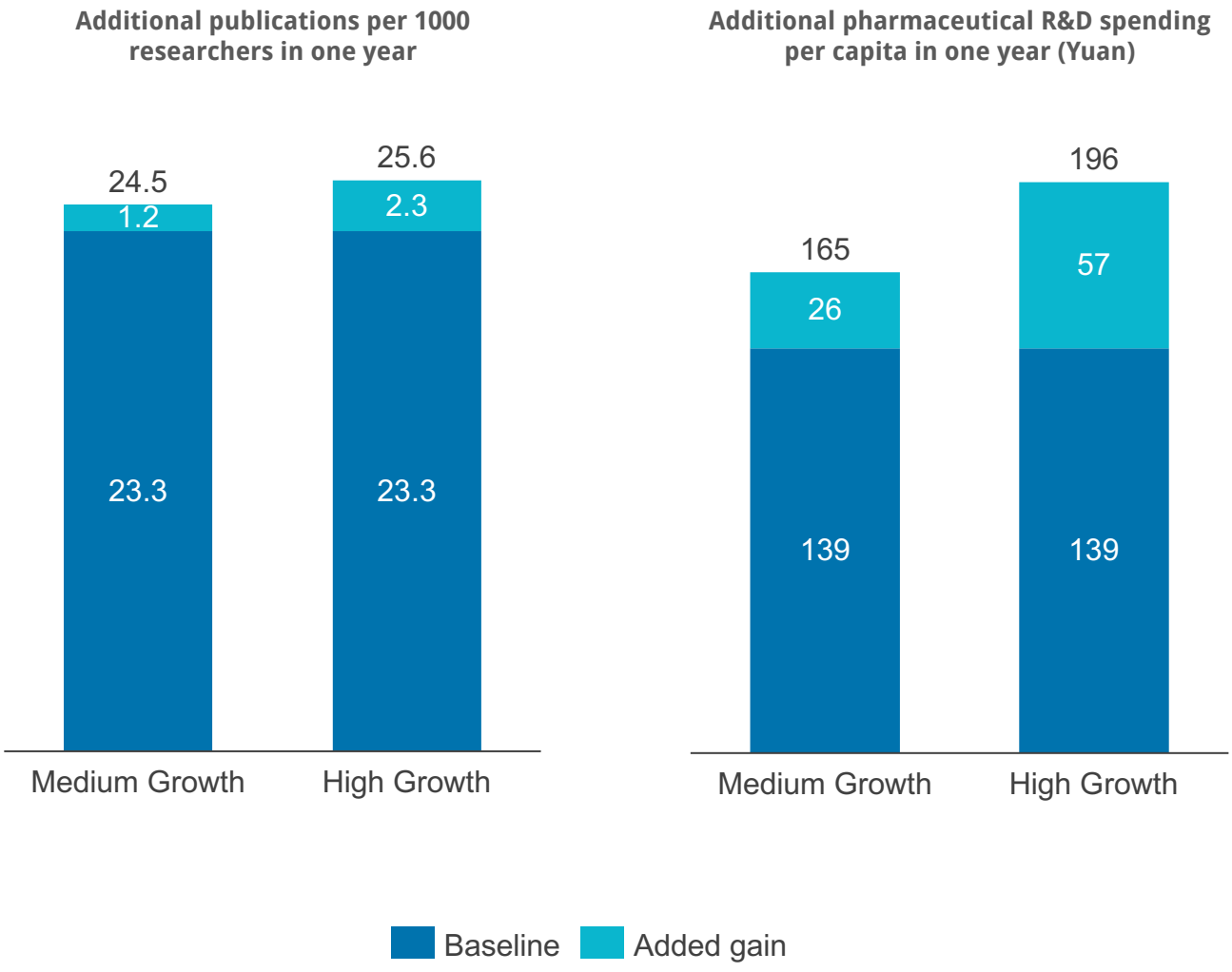


- In all case study countries, improvements in the innovation environment led to a significant increase in patent grants, so the possible magnitude of gains for China is substantial even in a medium growth scenario.

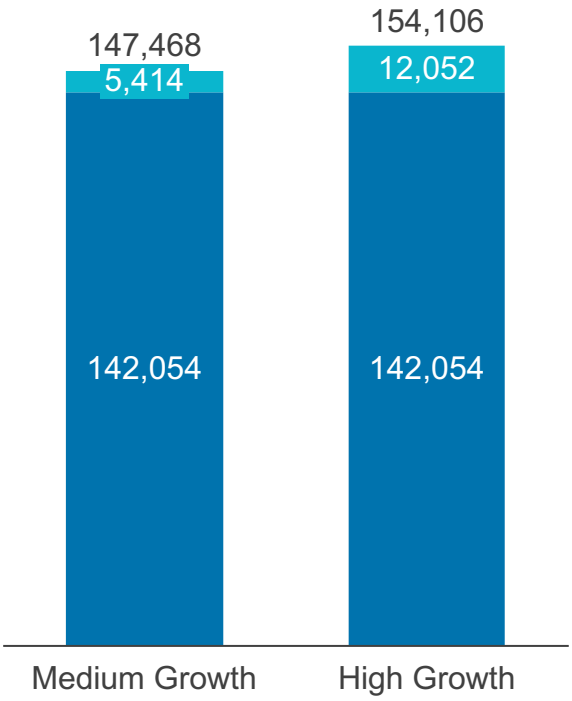
Abbreviations: CAGR = Compound annual growth rate

ILLUSTRATION OF GAINS FOR CHINA (ABSOLUTE GAINS)

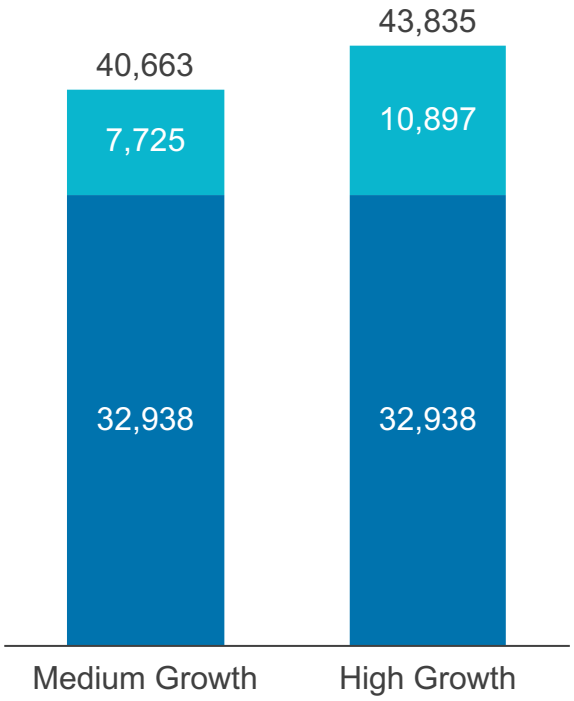
BASED ON THE SCENARIOS ANALYSIS, WE ARE ABLE TO PROJECT THE POTENTIAL ABSOLUTE GAINS AFTER 10 YEARS COMPARED TO CHINA'S BASELINE GROWTH RATE FOR THE MEDIUM GROWTH AND HIGH GROWTH SCENARIOS.



Additional new pharma R&D employees in one year



Additional new patents in one year



CONCLUSIONS

1. THE SCALE OF CHINA'S PROGRESS TO DATE

China has become a much more favourable environment for supporting biopharmaceutical innovation

- China's biopharmaceutical sector is in a sustained period of rapid growth and has been supported by ongoing progress in innovation and IP policy since the 1980s.

- Several national innovation plans and amendments to the IP regime – including but not limited to the successive Amendments to Patent Law, the Major New Drug Creation Program (2008–ongoing) and the Development Plan for the Biological Industry (2012–2020) – have been a major contributor to these improvements.

Improvements in the innovation environment have led to substantial and rapid growth in innovative and economic activities

- Across key metrics in innovative and economic activity, China has demonstrated extensive growth in the previous 20 years or so. It has narrowed the gap to the global leaders – particularly the US – in terms of investment in R&D, educational attainment, and clinical trials.

2. REMAINING GAPS IN THE INNOVATION ENVIRONMENT

There remain some notable shortcomings to the innovation environment in China

- Although China has made substantial progress in terms of the innovation environment and resulting innovative and economic activities, there are still some significant areas for further improvement.

- This is especially the case with regards to the IP regime, and innovative activity could be further stimulated if the Chinese IP regime were improved in line with the US, EU, and Japan.

The most significant gaps include provisions around regulatory data protection and patent term extensions

- A key barrier to investment in China has been the lack of transparency, and ambiguities in RDP-related policy. Fully implemented and enforced RDP with clarification on scope and wording would be a significant enabler of further innovative activities in China.

- There is also a need to strengthen the patent system to better align with international best practices. While this includes several issues (including patent linkage procedural issues and the protection of valid patents), there is a particular gap around patent term extensions

CONCLUSIONS

3. THE BENEFITS OF FURTHER IMPROVEMENTS

Addressing the remaining gaps in the innovation environment would lead to substantial benefits for China

- If the innovation policy environment were improved in a way that addresses the remaining barriers, the impact would be to encourage innovation from domestic and international pharmaceutical companies.

- This would deliver benefits across the innovation pathway, from early innovative activity around scientific publications and basic research, through to investment in R&D and employment of researchers, and ultimately leading to more clinical trials, patent applications, and new innovative therapies for patients.

Based on the experience of other countries, our conclusion is that further improvements in China could lead to an acceleration in innovative and economic activity

- In order to assess potential gains from an improvement in the enablers of innovation, we applied the change in growth rates from case study countries where positive changes in the IP and innovation regime were introduced, to China's current baseline growth rate.

- While there are some significant challenges with this methodology, it nevertheless illustrated that the potential gains in China could be substantial for key metrics including pharmaceutical R&D expenditure and biopharma patent grants.

4. KEY POLICY IMPLICATIONS

Strengthening the IP regime could lead to further progress in China

- China already has a significantly improved policy environment for biopharmaceutical innovation. It is crucial that China remains on this positive trajectory and that the risk of regressing towards a less favourable environment is minimised.

- To ensure this, there are a number of specific policy implications for how further progress in China could be brought about:

A patent regime to match China's aspirations for world-leading innovation

- China has already become close to – or in some cases is – the global leader in terms of key metrics of economic and innovative activity. A patent regime that is as supportive of innovation as those in the EU, US, and Japan will likely be necessary if China is to attain consistently world-leading levels of innovative activity.

- This should include addressing ambiguity in terminology and scope and lack of effective implementation of patent term extensions, and the high patent invalidation rate and restrictive criteria.

Implemented RDP as a prerequisite for further international investment

- The lack of strong RDP in China has discouraged some biopharmaceutical companies from investing more there. Fully implemented and enforced RDP is needed for China to become more attractive to international investment.

Innovation policy that enables accelerated future growth

- Although gaps in innovation policy are less significant than in the past, the speed of future growth could be supported by targeted policy attention regarding the Negative List for Foreign Investment, prolonged innovative drug approval times, and comparatively low R&D tax incentives.

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