Copenhagen Economics

REGULATORY DATA PROTECTION FOR PHARMACEUTICALS

How implementing RDP in China will benefit society, industry and the Chinese economy

PhRMA
July 2024

Executive summary

Regulatory Data Protection is a key element towards a successful innovative pharmaceutical industry and increased access to innovative medicines in China

China's ambition of a successful innovative pharmaceutical industry needs more fuel

China has an ambition to strengthen its innovative pharmaceutical industry and improve access to innovative treatments for its population.[1] It has already taken steps towards achieving this such as implementing reforms to accelerate regulatory approvals for innovative medicines.[2]

While these reforms are necessary measures, protecting and incentivising innovation, including the data generated through clinical trials, is key to supporting both the industry growth and access to new medicines to the benefit of patients. If innovation is not protected, companies will lack sufficient incentives to invest in bringing innovative medicines to patients. This limits the growth potential of the industry and may leave patients without much-needed treatments.

Today in China, innovative medicines face competition from generics and biosimilars swiftly after their approval, on average after 4 years. This does not allow companies sufficient time to recoup their investments, thus reducing incentives to invest in bringing innovative medicines to the market.

RDP is pivotal for supporting industry growth and patient access

In this context, implementing Regulatory Data Protection (RDP), protecting the data generated through clinical trials and submitted for regulatory approval, will be key for the development of a successful innovative pharmaceutical industry and to support access to medicines in China.

We estimate that introducing RDP would increase the availability of innovative medicines in China by up to 66% as China would become a more attractive place for companies to launch their innovative medicines. As a result, China could also experience an increase in the number of clinical trials by up to 90%.

Complementing RDP with additional measures will further fuel industry growth and patient access

To build on the benefits of RDP, additional measures should be considered to support patient access to innovative medicines and the industry's growth. In particular, a predictable and science-based regulatory system, a value-based pricing and reimbursement system, and a strong system of protection of innovation are necessary.

A successful pharmaceutical industry would make a significant contribution to the Chinese economy, both in terms of GDP and jobs supported. The industry's contribution to GDP could grow from 100 bn USD to 124 bn USD. This growth will support a whole ecosystem of suppliers and partners adding another 167 bn USD to the Chinese economy effectively driving a total of 563 bn USD of GDP. This can sustain almost 25.8 million local jobs.

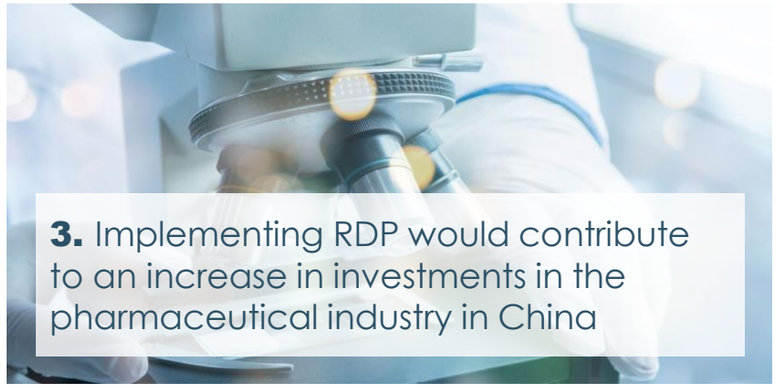
Drawing from our previous research,[3] in this report, we describe the benefits of implementing RDP in China for society, industry and the Chinese economy.

Notes: 1) See Healthy China 2030 and China's 14th five-year plan (2021-2025). / 2) In 2015, China introduced regulatory reforms to accelerate the speed of approval of innovative medicines, Su et al (2023), available at link. / 3) Copenhagen Economics (2023).

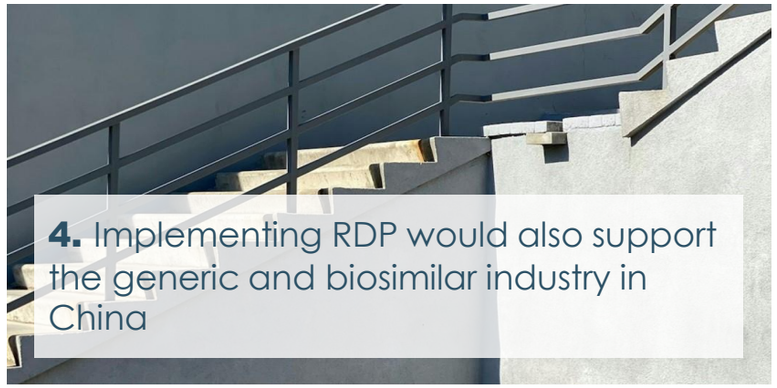
Agenda of the report

1. Innovative medicines are not protected by RDP in China

2. Implementing RDP would increase the availability of innovative medicines In China



3. Implementing RDP would contribute to an increase in investments in the pharmaceutical industry in China



4. Implementing RDP would also support the generic and biosimilar industry in China

5. RDP is a key step towards developing an innovative pharmaceutical industry in China

1. INNOVATIVE MEDICINES ARE NOT PROTECTED BY RDP IN CHINA

RDP protects the data package produced during clinical trials thereby incentivising innovation in pharmaceutical development

China has not implemented RDP for pharmaceuticals

- Regulatory Data Protection (RDP) is an intellectual property right. It protects, for a limited period, the data package that pharmaceutical companies must produce and submit to regulatory authorities to demonstrate the safety and efficacy of an innovative medicine for marketing approval. During this period, other parties are prevented from relying on this data package to obtain marketing authorisation for a generic or biosimilar medicine.
- RDP is in place in many jurisdictions around the world to incentivise innovation in pharmaceutical development.
- RDP runs in parallel and is complementary to other protections such as patents, see Box 1.
- As part of its WTO accession in 2001, China committed to introducing RDP of at least 6 years for pharmaceutical products.
- In the past years, policy-makers discussed proposals for the implementation of RDP in China. Prior proposals also suggest restricting RDP to innovative medicines whose first global launch is in China ("*new to the world*"). This would not be consistent with international standards where RDP applies to all innovative medicines first launched in the country ("*new to the country*").
- To date, China has not implemented RDP.

Box 1. RDP is complementary to patent and crucial for biologic innovation

- RDP and patents are separate and independent protections, see Table 1.
- They are complementary in providing innovators with the certainty that they will have a sufficient period of protection to recoup their investments in developing innovative medicines.
- RDP is particularly important in those situations where either a patent is not available or where the patent may not adequately protect the innovative medicine. For instance, RDP is particularly important for complex biologics.

Table 1. Comparing RDP and patents

	RDP	Patent protection
Protection	Data from clinical trials	Compound previously unknown
Starting point	Marketing Authorization of the medicine	Date of filing patent application
Length	5 to 12 years	20 years

Source: Based on Copenhagen Economics (2018).

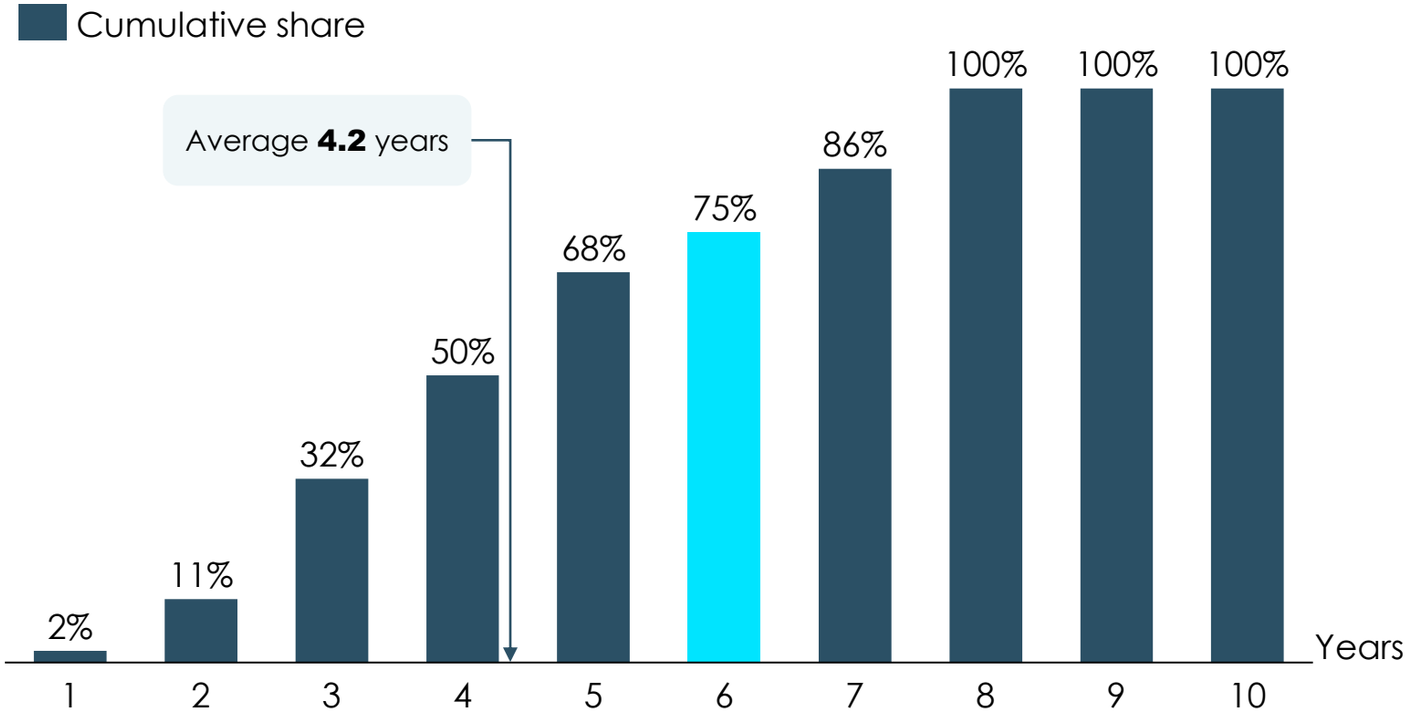
In China, innovative medicines face competition from generics or biosimilars on average 4 years after their approval

This does not allow companies sufficient time to recoup their investments in medicine development

- Often, innovative medicines launched in China face premature competition from generic or biosimilar versions soon after their approval.
- In fact, generics and biosimilars entered the market on average after 4.2 years from the approval of the reference innovative medicine.[1]
- In 75% of cases, entry occurred before or at 6 years from the approval of the innovative medicine, see Figure 1.
- This is the case even though the remaining patent protection at the time of regulatory approval is on average 10.4 years. Although not yet reflected in this data, it is anticipated that patent enforcement will improve in China following the establishment of a patent linkage system in 2021.[2]
- In this context, RDP would be complementary to patents and strengthen the protection of innovative medicines.

Figure 1. Time between the approval of the innovative medicine and its first generic (2013-2022)

Cumulative share of innovative medicines that have a generic approved



Note: the dataset includes 123 innovative medicines approved in 2013-2022 by multinational companies. Out of these, 44 have at least one generic or biosimilar approved. Where a medicine has multiple strengths or mode of delivery approved, we considered the first approval date and the first approval date of generic of the same strength.

Source: Copenhagen Economics analysis of data on regulatory approvals and patent information collected from several sources (Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

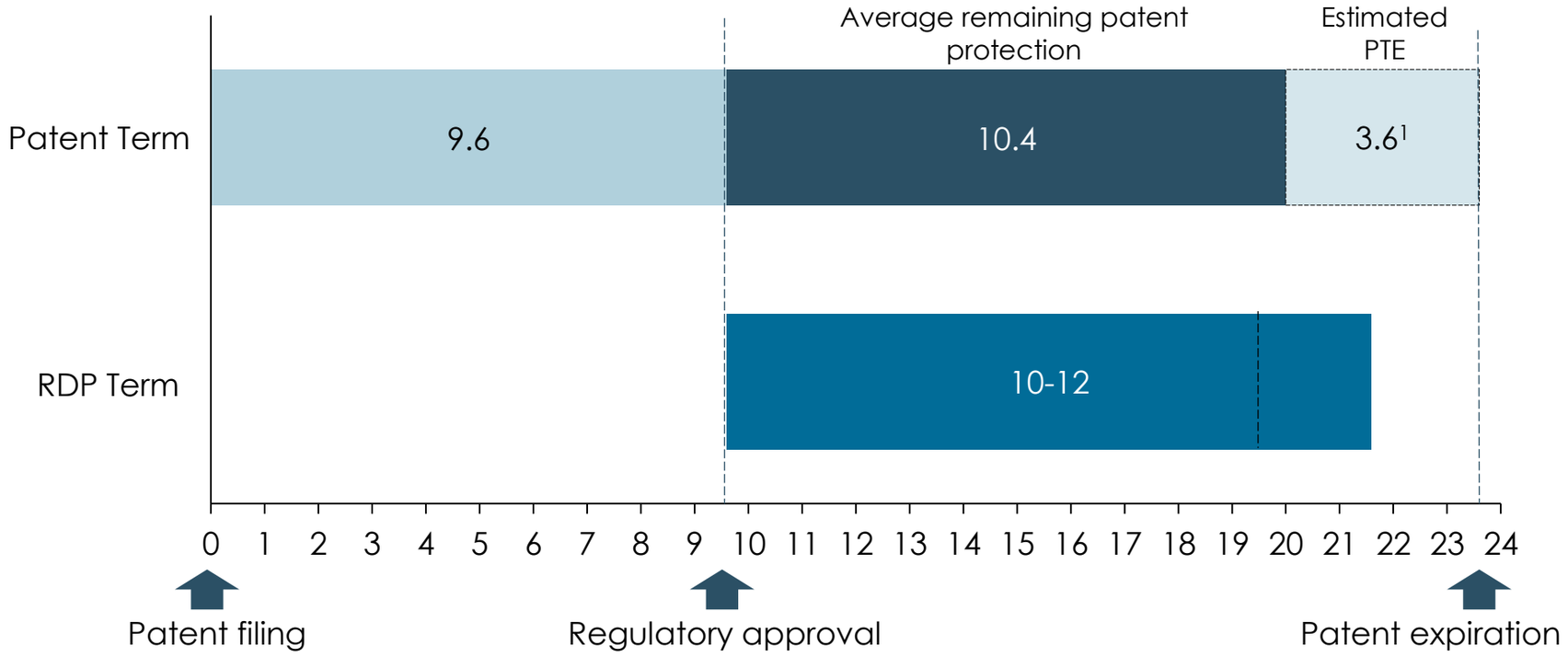
Notes: 1) See Appendix A for more details on the data and methodology. / 2) National Medical Products Administration-China National Intellectual Property Administration Implementation Measures on Early Resolution Mechanisms for Drug Patent Disputes (July 2021) and the Supreme People's Court Judicial Interpretation Regarding Patent Disputes Related to Pharmaceutical Registration Application and Registration (July 2021).

For the average innovative medicine in China, RDP would not extend the period of protection

- For innovative medicines approved in China in 2013-2022, the remaining patent protection at the time of regulatory approval was on average 10.4 years. This time can increase by up to 5 years under China's PTE mechanism.[1]
- This means that, on average, RDP, with terms consistent with international best practice (e.g. 10 years for chemical and 12 years for biological medicines), would not extend the period of protection for innovative medicines, see Figure 2.

Figure 2. Interaction between patent and RDP terms

Time elapsed from patent filing, years



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Source: Copenhagen Economics analysis of data on regulatory approvals and patent information collected from several sources (Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

Notes: 1) Under China's PTE mechanism, an applicant can seek restoration of up to 5 years of the patent term for the lengthy development and regulatory approval process, provided that the total patent term with PTE after market approval is no more than 14 years. As such, the average PTE will be no more than 3.6 years.

2. IMPLEMENTING RDP WOULD INCREASE THE AVAILABILITY OF INNOVATIVE MEDICINES IN CHINA

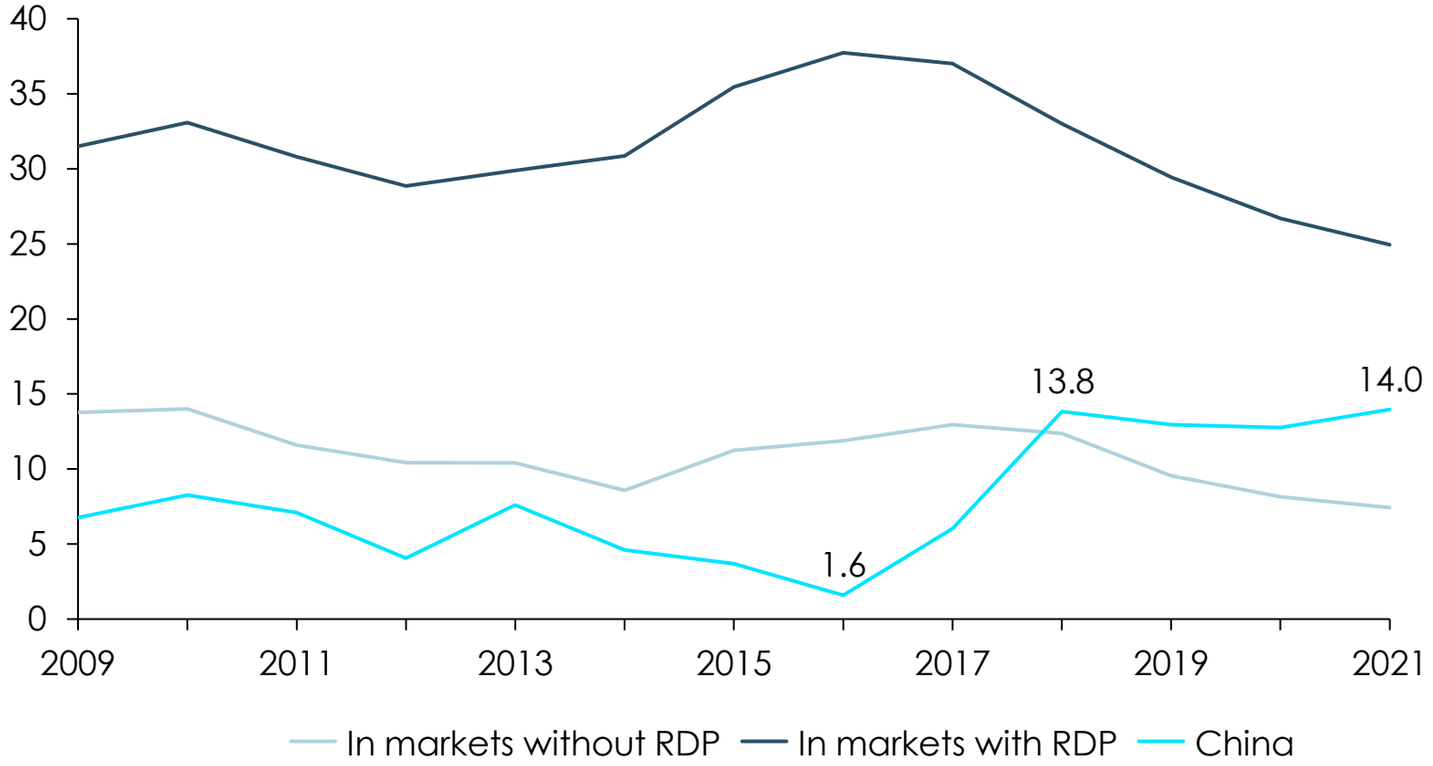
The availability of innovative medicines in China increased significantly in 2016-2018 but has remained stable thereafter

The main drivers of the increase in availability were reforms to accelerate regulatory approval

- Markets with RDP have on average 3 times higher availability of innovative medicines compared to markets without RDP,[1] see Figure 3.
- Historically, the availability of innovative medicines in China has been consistently below the average of markets without RDP.
- Since 2015, China implemented reforms to accelerate regulatory approval.[2] This led to a sharp increase (from 1.6% to 13.8%) in the availability of innovative medicines, bringing China above the average of markets without RDP.
- However, since 2018 the share of innovative medicines available in China has remained at the same level and significantly below the average of markets with RDP.

Figure 3. Availability of innovative medicines in markets with RDP, without RDP and in China, 2009-2021

Share of available innovative medicines out of all launched globally in the past 5 years, 2021[1]



Note: 1) Based on 53 markets, see Copenhagen Economics (2023). Total averages are across markets and years.
Source: Copenhagen Economics analysis of data from PhRMA's Global Access to New Medicines Report

Notes: 1) Copenhagen Economics (2023). / 2) In 2015, China introduced regulatory reforms to accelerate the speed of approval of innovative medicines, Su et al (2023), available at link. This led to the clearing of the backlog of medicines awaiting approval.

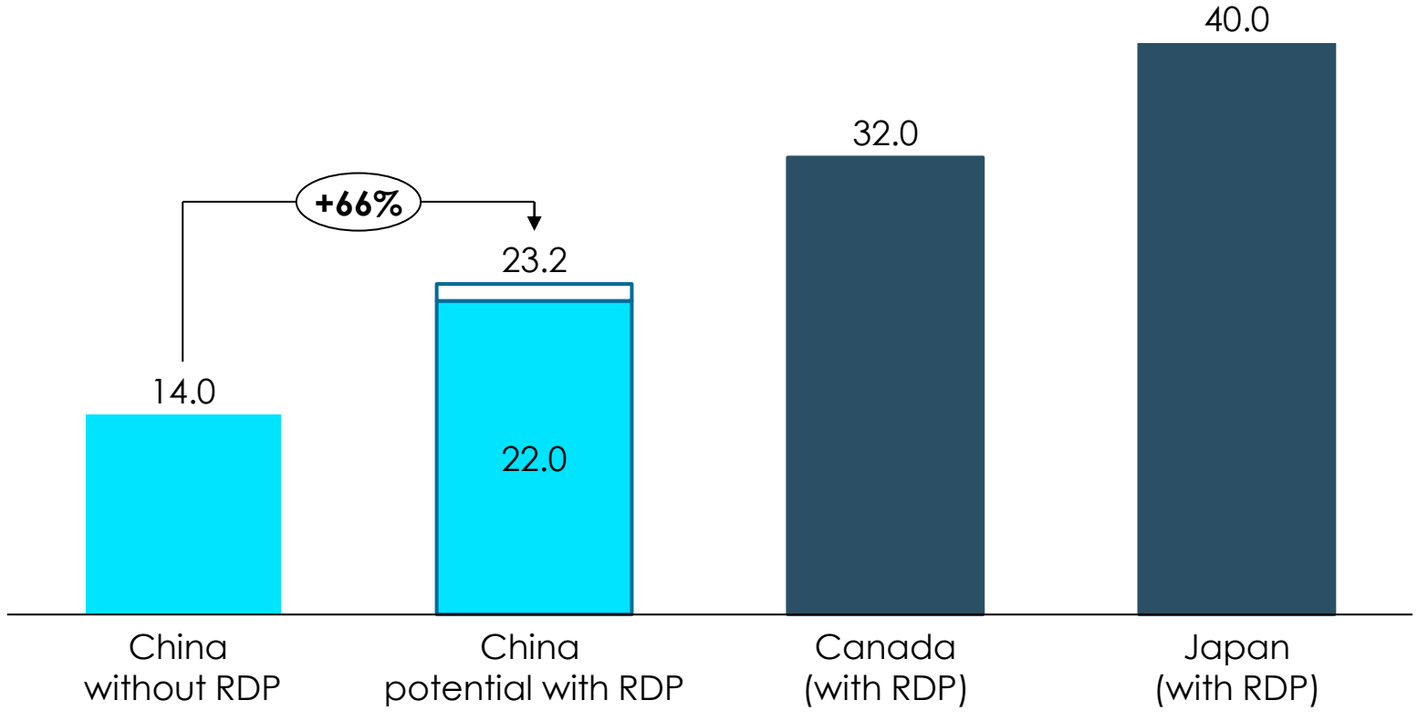
Implementing RDP could increase the availability of innovative medicines in China by up to 66%

Additional measures are needed to reach the average of markets with RDP

- RDP is associated with an 8.0-9.2 percentage point higher availability of innovative medicines.[1]
- For China, this means that RDP could increase the availability of innovative medicines to 22.0-23.2%, corresponding to a 57-66% increase compared to the current level, see Figure 4.
- This would bring the availability of innovative medicines in China close to but lower than other markets with RDP. This suggests that additional measures are needed beyond implementing RDP.

Figure 4. Potential increase in the availability of innovative medicines in China with RDP

Share of available innovative medicines out of all launched globally in the past 5 years, 2021



Notes: See page 11 for a discussion on the choice of measuring availability as the share of innovative medicines out of all launched globally in the past 5 years.
Source: Copenhagen Economics analysis of data from PhRMA's Global Access to New Medicines Report

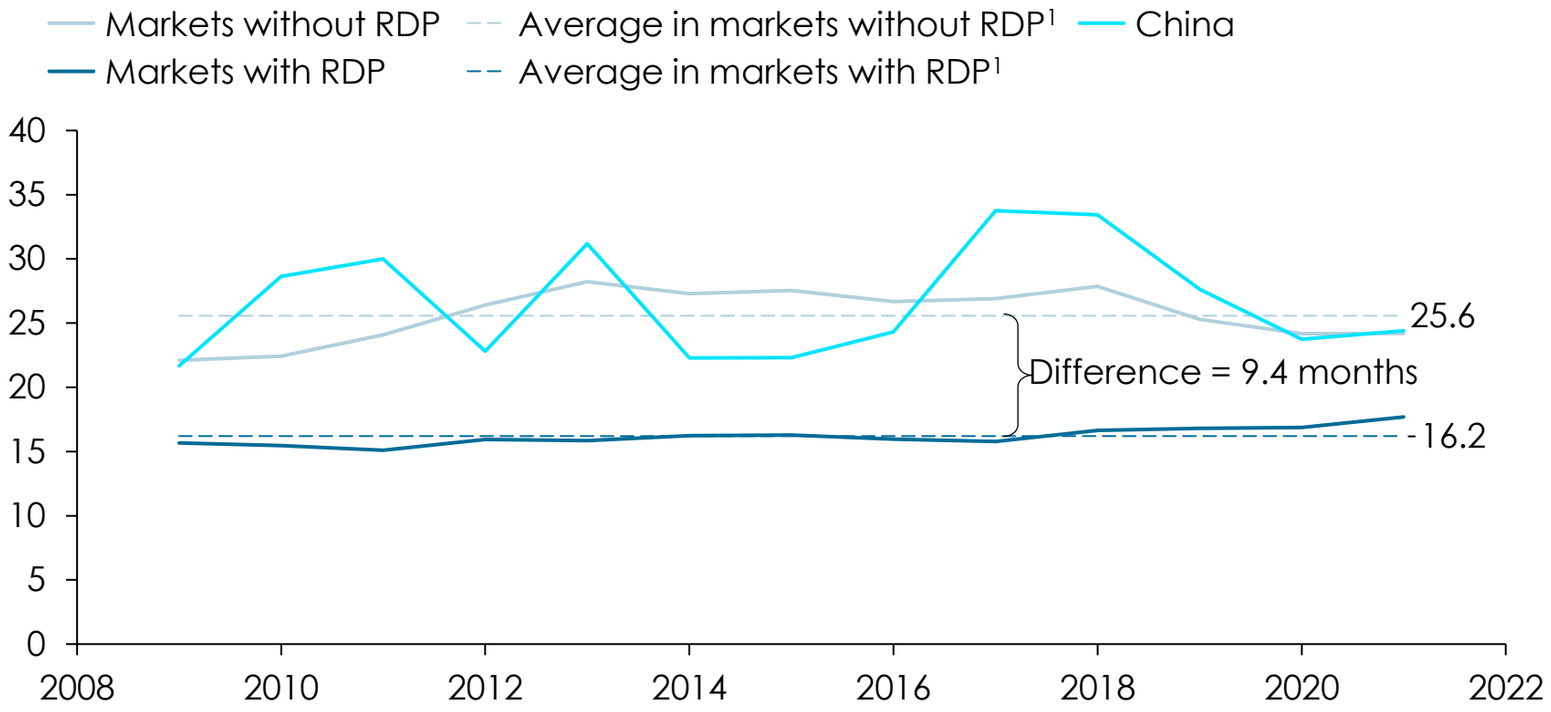
Notes: 1) This corresponds to 45% of the difference in availability of innovative medicines in markets with and without RDP. See Copenhagen Economics (2023) for an in-depth description of the statistical models, set-up, markets included and results. When isolating the effect of RDP, we control for the GDP per capita, population size, healthcare expenditures, share of population aged 65+ as well as year fixed effects.

Medicines are launched faster on average in markets with RDP

- We measure availability as the share of innovative medicines available in a market out of all launched globally in the previous 5 years. When increasing the timeframe, e.g. to 10 years, the share of medicines available naturally increases as medicines launched with a longer time-lag are also captured.
- We use the 5-year timeframe, instead of for instance a 10-year, to reflect a higher ambition for fast launches (and shorter time-lags) of innovative medicines. Medicines are in fact launched on average faster in markets with RDP, see Figure 5.

Figure 5. Time to access

Number of months from first global launch to national launch



Note: Based on average month lag of new and innovative drugs launched (per 5-year time period) in 59 markets observed over 13 years (2009-2021) except Chile, which is only observed 2013-2021.
Source: Copenhagen Economics analysis of data from PhRMA's Global Access to New Medicines Report

3. IMPLEMENTING RDP WOULD CONTRIBUTE TO AN INCREASE IN INVESTMENTS IN THE PHARMACEUTICAL INDUSTRY IN CHINA

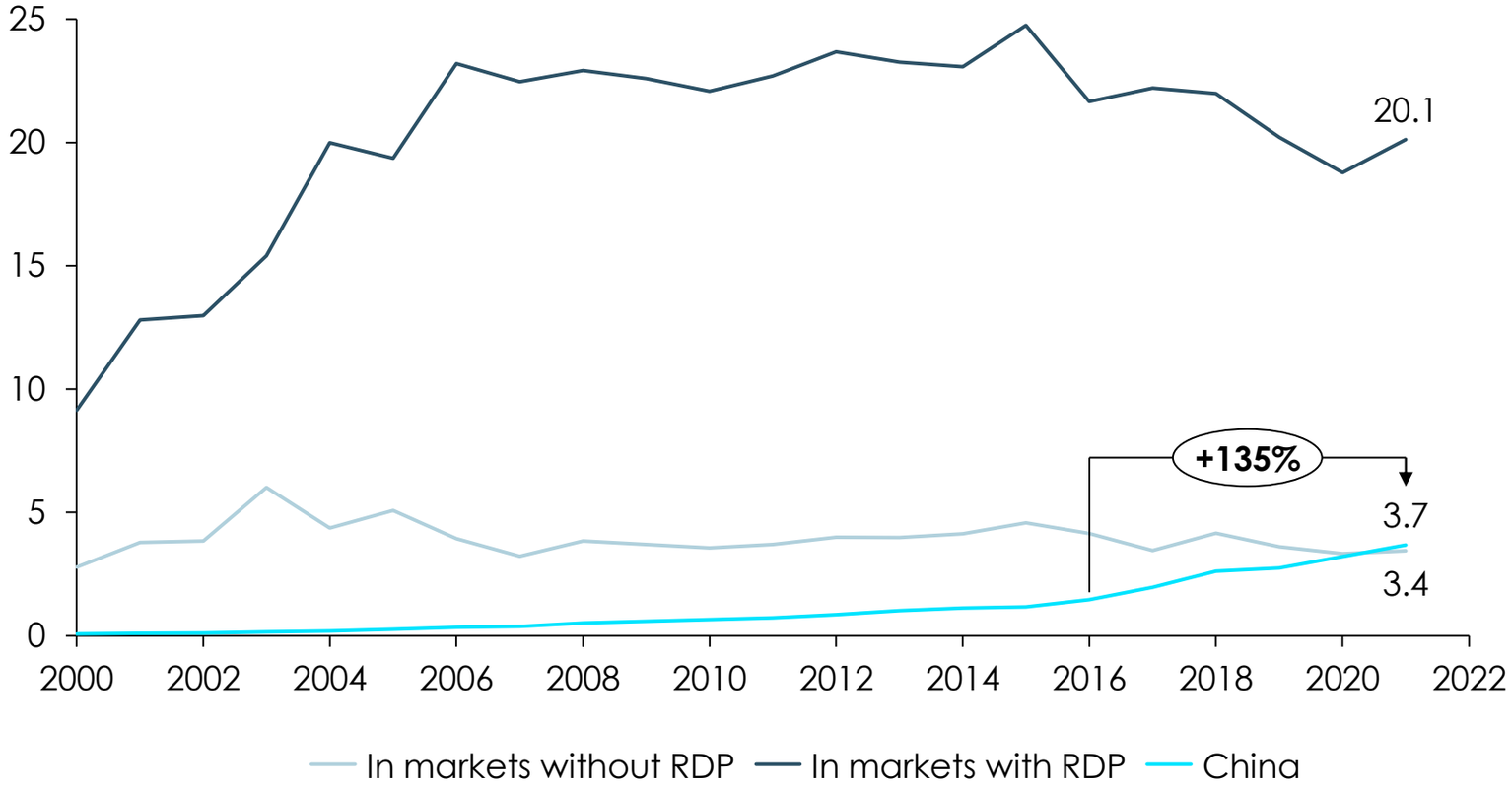
The number of clinical trials in China has been increasing since 2016

The number of clinical trials per capita in China is now in line with the average market without RDP

- Markets with RDP have more clinical trials compared to markets without (17 more per million capita on average)[1] as both local and multinational companies increase their R&D investments, see Figure 6.
- The number of clinical trials per capita in China has historically been significantly lower than the average market without RDP.
- Since 2016, the number of clinical trials per million capita has increased steadily (135%) in China and is now in line with the average market without RDP.
- Many factors contributed to this increased activity, such as increased focus and prioritization of biopharmaceutical research.[2]

Figure 6. Average number of clinical trials in markets with RDP, without RDP and China

Number of clinical trials per million capita[1], 2000-2021



Note: Based on 53 markets, see Copenhagen Economics (2023) for an outline.
Source: Copenhagen Economics (2023)

Notes: 1) See Copenhagen Economics (2023). / 2) Healthy China 2030 and China's 14th Five-year-plan (2021-2025)

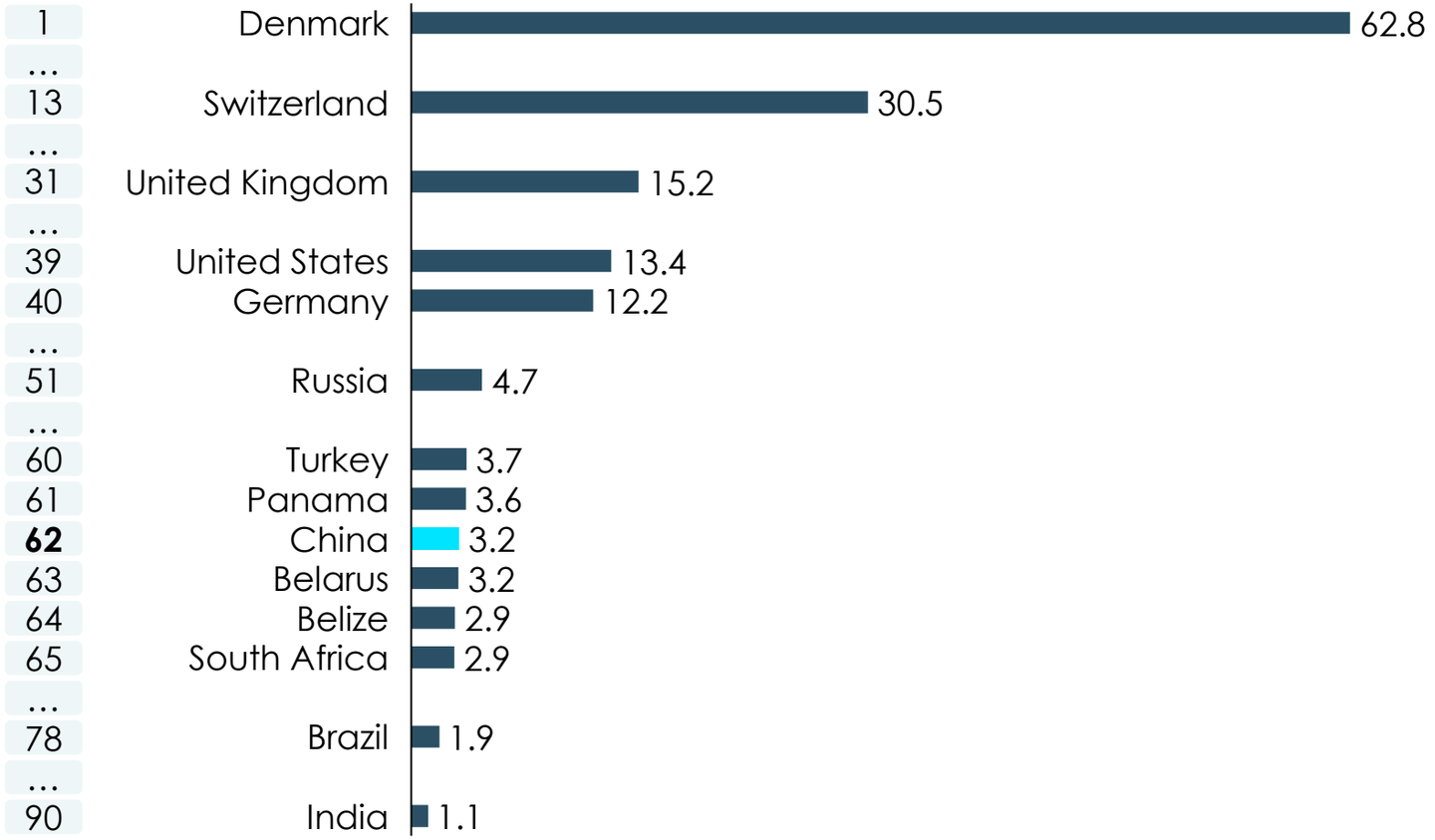
Given its population size, China has the potential to increase the number of clinical trials conducted

China currently ranks 62nd in terms of clinical trials per million capita

- While the absolute number of clinical trials in China is significant[1] and has been increasing, China has the potential to further increase the number of clinical trials given its population size.
- In fact, China ranks 62nd in terms of the average number of clinical trials per million capita, see Figure 7.

Figure 7. Worldwide ranking based on the average yearly number of clinical trials

Average yearly number of clinical trials per million capita, 2013-2023



Note: The yearly average is estimated based on the sum of clinical trials from 2013-2023.
Source: Copenhagen Economics based on data from GlobalData and the World Bank and Copenhagen Economics (2023).

Notes: 1) Data from GlobalData shows that China had 49,428 clinical trials from 1 January 2013 to 31 December 2023.

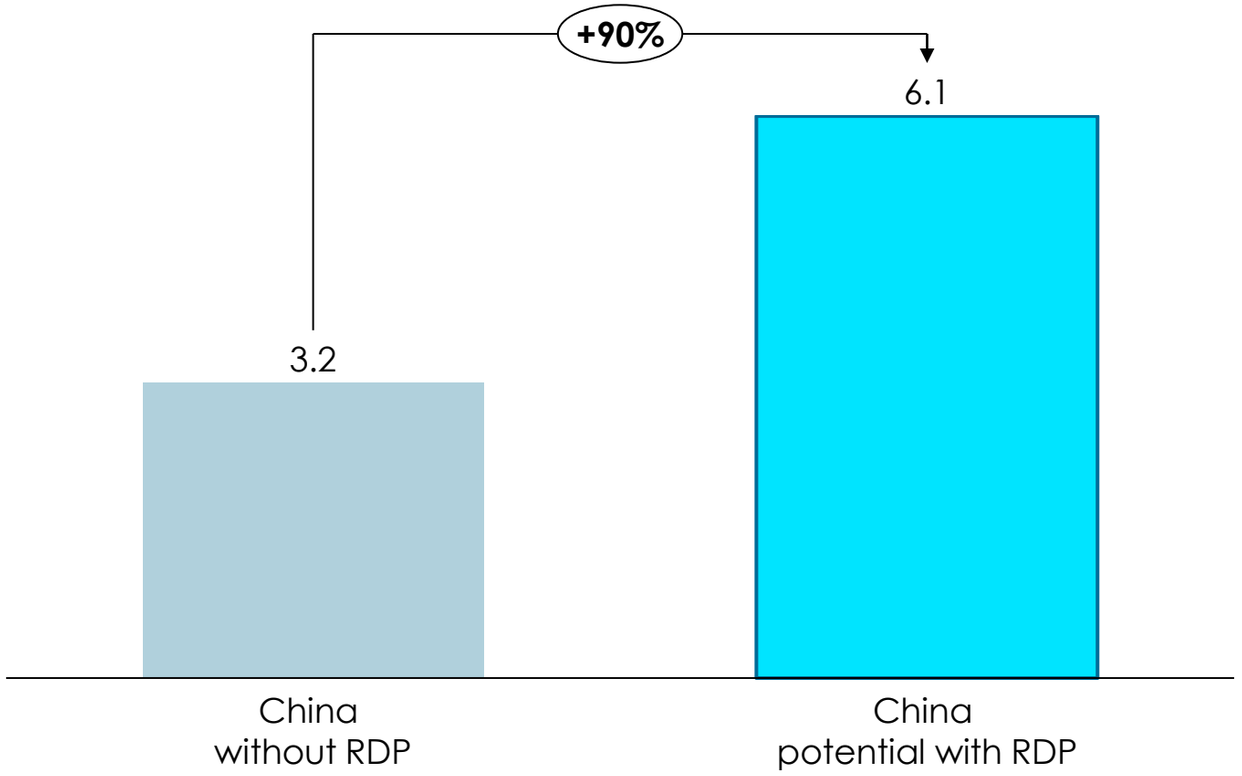
Implementing RDP could increase the number of clinical trials in China by up to 90%

China should develop a strategy for removing barriers to reaching this potential

- RDP could increase the number of clinical trials per million capita by 2.9 to 6.1 clinical trials per million capita per year.[1]
- This means that implementing RDP in China could result in nearly a doubling (+90%) in the number of clinical trials per million capita in the long run, see Figure 8.
- In addition to RDP, other factors may influence the ability to reach this level of clinical trials, including pool of (treatment-naive) patients, medical resources, costs of conducting clinical trials, clinical trial infrastructure, local experience in conducting clinical trials, and local pharmaceutical market.[2,3,4]

Figure 8. Potential increase in number of clinical trials in China

Average yearly number of clinical trials per million capita



Note: The yearly average is estimated based on the sum of clinical trials from 2013-2023.
Source: Copenhagen Economics based on data from GlobalData and the World Bank and Copenhagen Economics (2023).

Notes: 1) See Copenhagen Economics (2023). / 2) Clinical Trials Arena (2022), see link. / 3) Zhao et al. (2019), see link. / 4) CGTN (2024), see link and McKinsey (2021)

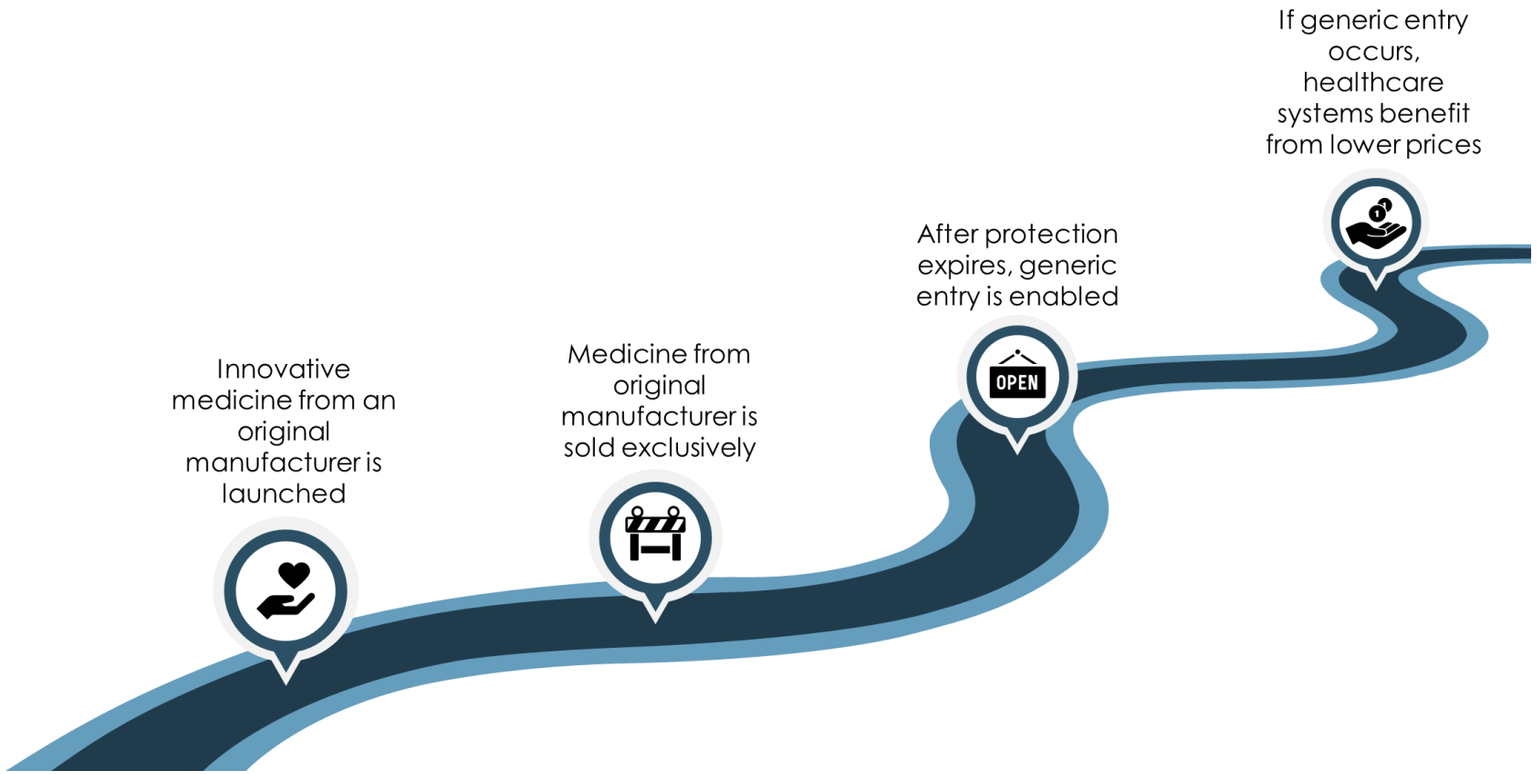
4. IMPLEMENTING RDP WOULD ALSO SUPPORT THE GENERIC AND BIOSIMILAR INDUSTRY IN CHINA

RDP represents an opportunity for generics and biosimilars

Innovative medicines are the building block of the pharmaceutical ecosystem

- The pharmaceutical ecosystem is driven by the efforts of innovative medicine developers.
- Once the exclusivity period expires, generic or biosimilar manufacturers may seek marketing authorisation for their versions of the medicine based in full or in part on the data created and submitted by the innovator showing that the medicine is safe and effective.
- Given that generic/biosimilar manufacturers incur significantly less cost and risk to launch their products, they are able to sell their products at a lower price, thereby reducing healthcare spending for that particular medicine, see Figure 9.

Figure 9. The role of innovative medicines in the pharmaceutical ecosystem



Source: Copenhagen Economics.

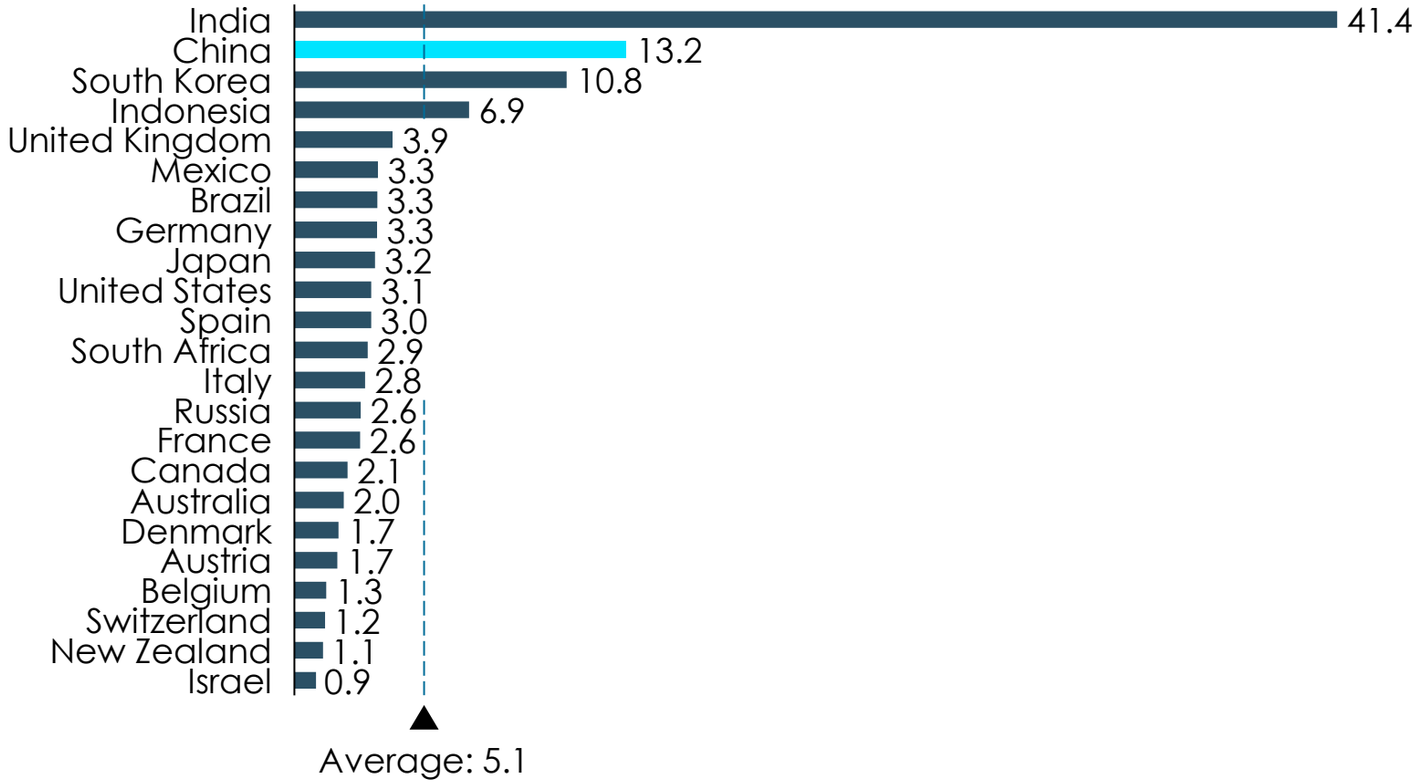
For every innovative medicine in China, 13 generics or biosimilars are available on average

This suggests a strong generic industry in China able to benefit from the increase in the number of innovative medicines

- Generally, for each innovative medicine available on the global market, 5.1 generic or biosimilars (lower without India and China) become available over time, see Figure 10.
- The number for China is larger than the average, with a ratio of 13.2 generics or biosimilars per innovative medicine.
- This is evidence that China currently has a relatively strong generic industry. In fact, generic medicines accounted for 54% of China's pharmaceutical market in 2020.[1]
- Through increased availability of innovative medicines (i.e. products to which generic and biosimilar manufacturers can refer), RDP would further support the generic and biosimilar industry in China.

Figure 10. Implication of presence of original products for availability of generics

Ratio between marketed generic medicines (and biosimilars) available and marketed innovator medicines



Note: Innovators include both NME medicines and non-NME. All markets with available data are included. Data is downloaded on 8 February 2024.
Source: Copenhagen Economics based on GlobalData.

Notes: 1) See Daxue Consulting (2023)

5. RDP IS A KEY STEP TOWARDS DEVELOPING AN INNOVATIVE PHARMACEUTICAL INDUSTRY IN CHINA

RDP can support China's ambition to develop its innovative pharmaceutical industry

Outlining two scenarios for the future growth of the pharmaceutical industry in China

- China has an ambition to develop its pharmaceutical industry into a successful innovative industry, as set out in its strategy Healthy China 2030 and China's 14th five-year plan (2021-2025).
- In line with this strategy, China's plan includes measures to support research and innovation, e.g. the promotion of innovation clusters, increase in research efforts, improving quality standards and international competitiveness. Based on this ambition, we estimate how this may affect the innovative industry in China in two scenarios.
- *Scenario 1 - Current trajectory:* while these are necessary elements towards reaching its ambition, they are not likely to prove sufficient. We find that the current trajectory will not allow the innovative pharmaceutical industry in China to reach its potential.
- *Scenario 2 - Potential for the Chinese pharmaceutical industry:* in this scenario, China implements *R*DP, which is a key step towards developing an innovative pharmaceutical industry in China, within a strong system of protection of innovation. China also implements additional measures related to the market access environment. These allow China's industry to reach its potential.
- Being an R&D-intensive industry, the pharmaceutical industry directly and indirectly contributes to a market's economy through high value-added activities. This means that by reaching its potential, the pharmaceutical industry in China would make a significant contribution to the Chinese economy.
- In the following, we describe these 2 scenarios and estimate the potential contribution of the pharmaceutical industry to the Chinese economy.

> *By 2030, the international market share of new drugs and diagnostic and treatment equipment with intellectual property rights will be substantially increased, and high-end.*

Source: Healthy China 2030, Copenhagen Economics' translation to English.

Scenario 1 - Current trajectory

The pharmaceutical industry maintains its level of contribution to the Chinese economy

Policies implemented:

- Sustaining investments and innovation at the current level, RDP is not implemented, dominant focus on cheaper, generic medicines.

Effects on the industry:

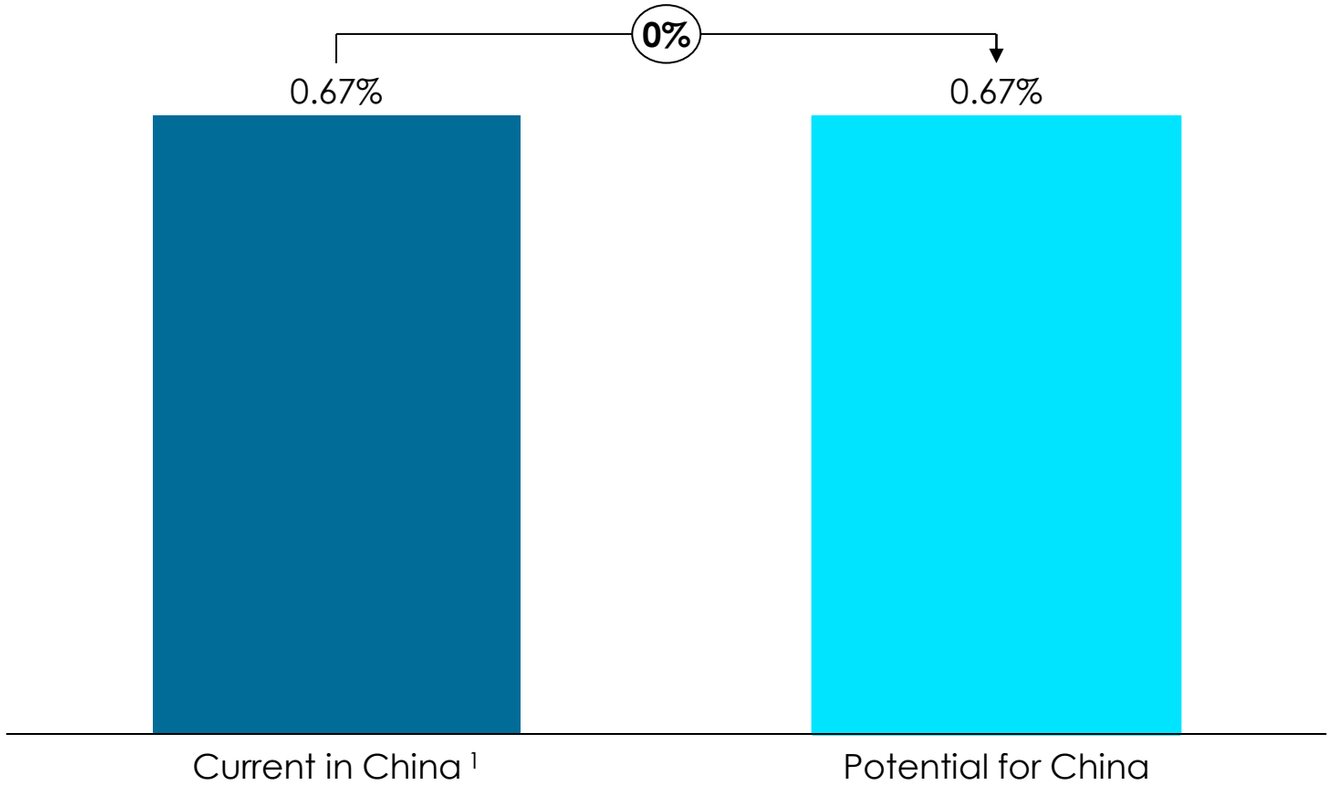
- Investments and innovation continue at the current pace. However, without a strong system to protect innovation and an access environment that rewards innovation, growth is stunted as additional investments into the most advanced technologies cannot be recouped.

Outcome for the industry and economy:

- The contribution of the pharmaceutical industry grows at the same pace as the national economy. Therefore, the share of GDP that the industry contributes to remains constant, see Figure 11.

Figure 11. The share of gross value added by pharmaceuticals in China in Scenario 1 would remain in line with the current level

Per cent of gross value added, western medicine



Source: Copenhagen Economics based on OECD (2023), Chinese Ministry of Commerce (2022).

Notes: 1) The GDP contribution of the pharmaceutical industry in China was 0.84% in 2020. This includes the contribution of Traditional Chinese Medicine (TCM). Western medicine represents 80% of the Chinese pharmaceutical industry. Copenhagen Economics based on the Report from the Ministry of Commerce (2022), see link.

Scenario 2 – Potential for the Chinese pharmaceutical industry

The Chinese pharmaceutical industry grows to meet the demand for innovative medicines in China

Policies implemented

- China implements RDP and addresses barriers to access: the market access system is predictable and a timely, value-based reimbursement system that rewards innovation is implemented.

Effects on the industry:

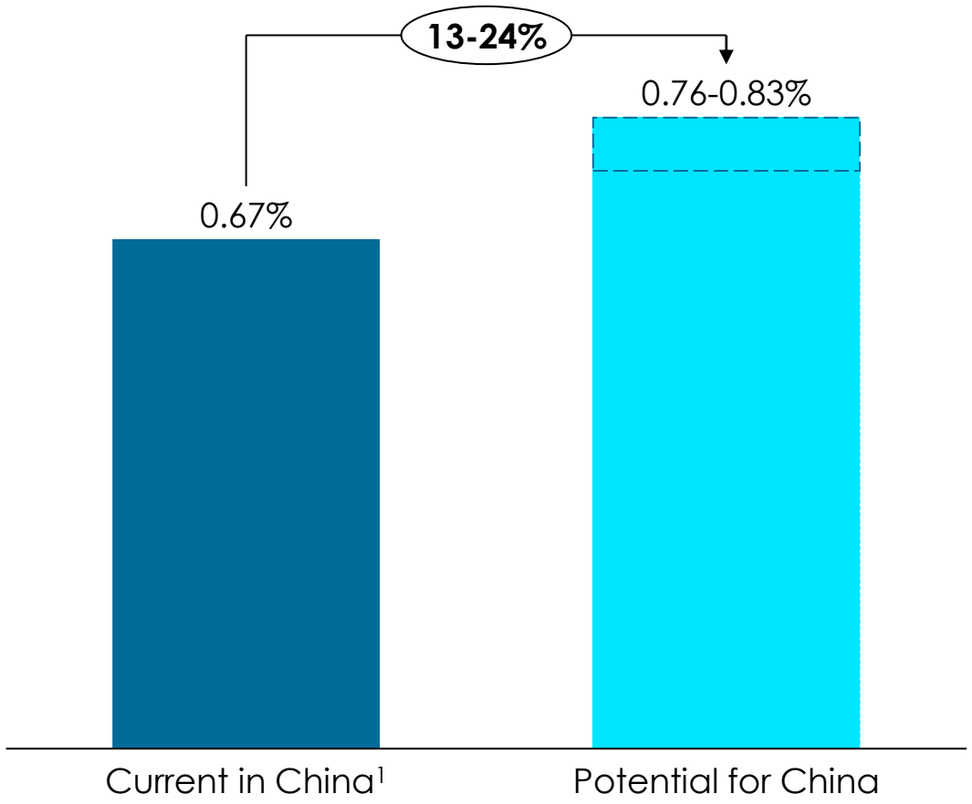
- With a strong system of protection of innovation and an access environment that rewards innovation, investments increase.
- China is an attractive market for multinational companies to launch their innovative medicines in. Multinational companies therefore increase their level of investments in China. National pharmaceutical companies also benefit from the presence of multinational companies through knowledge/ skills spillovers and collaboration.
- At the global level, China remains behind the EU or reaches the level of the EU in terms of R&D investments (assumptions, see Appendix B).

Outcome for industry and economy

- The contribution of the industry to the Chinese economy grows by 13-24%. This is comparable to a lower bound and upper bound of EU countries with a successful pharmaceutical industry but a diversified economy, e.g. the UK and Germany, see Figure 12.

Figure 12. The share of gross value added by pharmaceuticals in China could increase by 13-24%

Per cent of gross value added, western medicine



Source: Copenhagen Economics based on OECD (2023), Chinese Ministry of Commerce (2022).

Notes: 1) The GDP contribution of the pharmaceutical industry in China was 0.84% in 2020. This includes the contribution of Traditional Chinese Medicine (TCM). Western medicine represents 80% of the Chinese pharmaceutical industry. Copenhagen Economics based on the Report from the Ministry of Commerce (2022), see link.

A successful innovative pharmaceutical industry would make a significant contribution to the Chinese economy

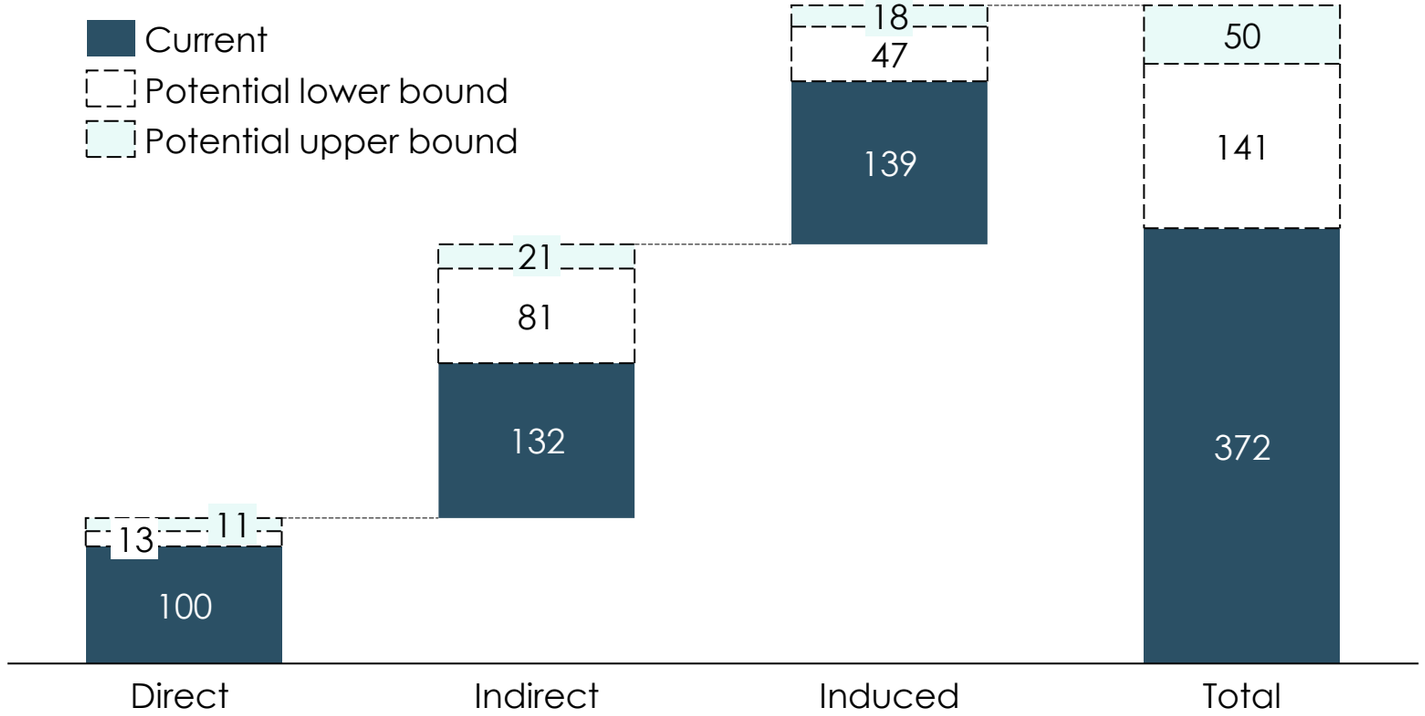
The industry's contribution to the national GDP would increase

- Currently, the pharmaceutical industry in China directly supports the economy's GDP for 100 bn USD, see Figure 13. When including indirect and induced effects, the supported GDP contribution is 372 bn USD.
- If the industry achieves its potential outlined in scenario 2 (see page 22), the directly supported GDP could increase to between 113 and 124 bn USD. When including indirect and induced effects (see Box 2), the total supported GDP can range between 513 and 563 bn USD.

Box 2. Economic footprint explained

An industry's economic footprint measures the direct, indirect and induced economic activity derived from said industry. The direct effect measures the economic activity in the pharmaceutical industry itself. The indirect effect arises along the pharmaceutical industry's value chain through the economic activity of its suppliers. Induced effect arises through spending of the employees, suppliers' employees and sub-suppliers' employees, see Appendix C for a more detailed description.

Figure 13. The economic footprint of the pharmaceutical industry
Supported GDP, billion USD, 2023 values, western medicine



Note: Rounding causes differences in totals./ 1) Potential effect is modelled based on achieving China's strategic potential estimated as an average of the pharmaceutical industry in China using the input shares of Germany, Spain and the UK.
Source: Copenhagen Economics based on OECD (2022), IMF (2023) and WIOD.

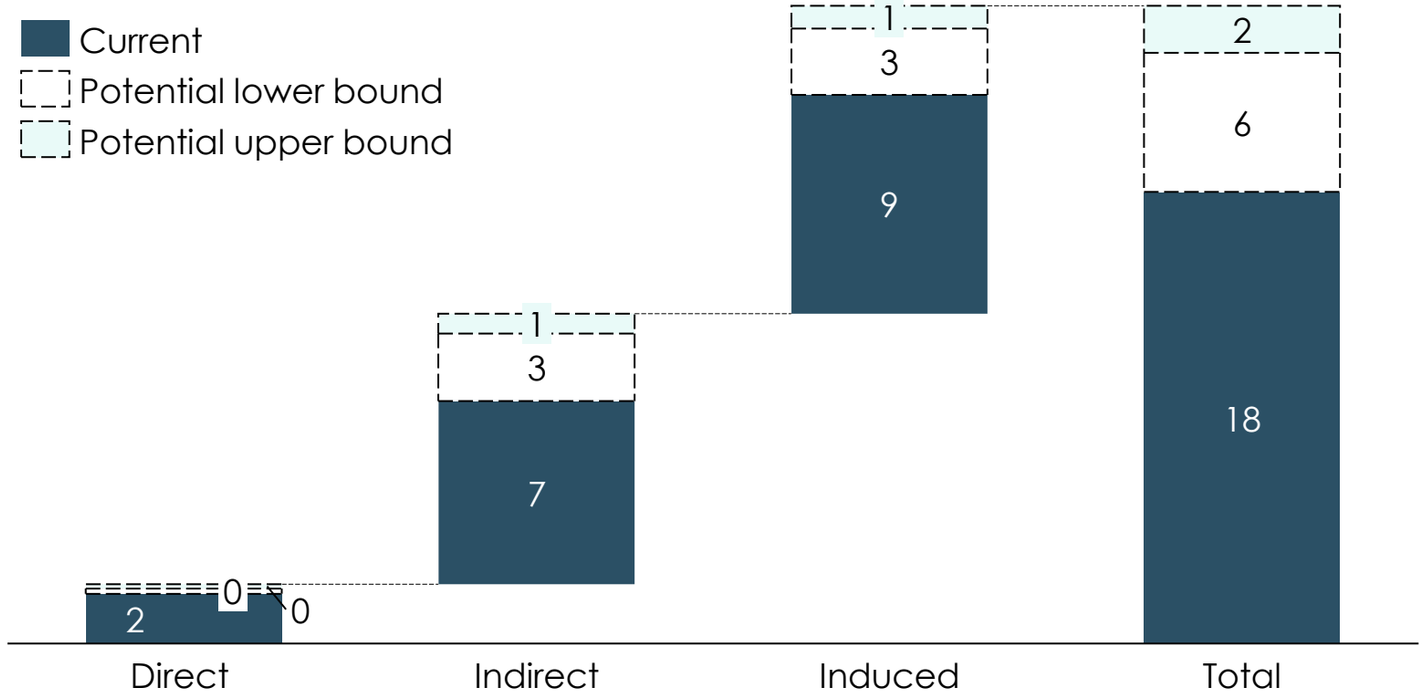
A successful innovative pharmaceutical industry would support jobs in China

The number of job supported by the industry would increase

- The increase in supported GDP also implies an increase in employment.
- The pharmaceutical sector in China directly supports 2 million jobs, and 18.3 million when including indirect and induced effects, see Figure 14.
- In the outlined scenario 2 (see page 22), we estimate that the direct number of supported jobs in the pharmaceutical industry could increase to between 2.2 and 2.4 million. When including indirect and induced effects, the number of supported jobs ranges between 23.9 and 25.8 million.

Figure 14. Current employment gain in the innovative, generic and biosimilar industry

Number of jobs supported, millions



Note: Rounding causes differences in totals.
Source: Copenhagen Economics based on OECD (2022) and WIOD.

APPENDICES AND REFERENCES

APPENDIX A

Analysis of entry of generics and biosimilars

APPENDIX B

Estimating the potential increase in the industry's contribution to the economy

APPENDIX C

Footprint analysis

REFERENCES

APPENDIX A

ANALYSIS OF ENTRY OF GENERICS AND BIOSIMILARS

Analysis of the timing of generic and biosimilar entry and the interaction between RDP and patent protection

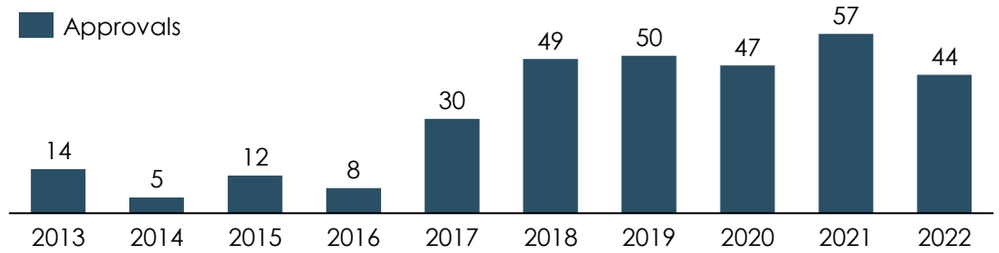
This analysis is based on data on launches of innovative medicines in China in 2012-2022 and their generics and biosimilars. The data includes 371 unique medicines considered originators in the Chinese regulatory approval system. Based on the category assigned to each medicine in the regulatory approval process, we identified 54 medicines that by international standards would be classified as generics or biosimilars. We excluded these from our analysis, see page 28-29. Our final sample included 317 unique medicines. We summarise some characteristics of the medicines included in the sample, see Figures A1-A3.

Of these 317 medicines, 76 of these have at least one generic or biosimilar approved. For 83% of these medicine for which a generic is available, the first generic was approved 6 years or less after the originator's approval. The average time between originator and first generic approval was 2.9 years.

PhRMA collected information on the patent status of the innovative medicines in this sample launched by multinational companies. This restriction is due to challenges in identifying the correct patent information for the medicines launched by local companies. We assume that the constraining patent is the one with the latest expiry date. This data included 123 unique innovative medicines, 44 of these have at least one generic or biosimilar approved.

Figure A1. Approvals of unique originators by year (2013-2022)

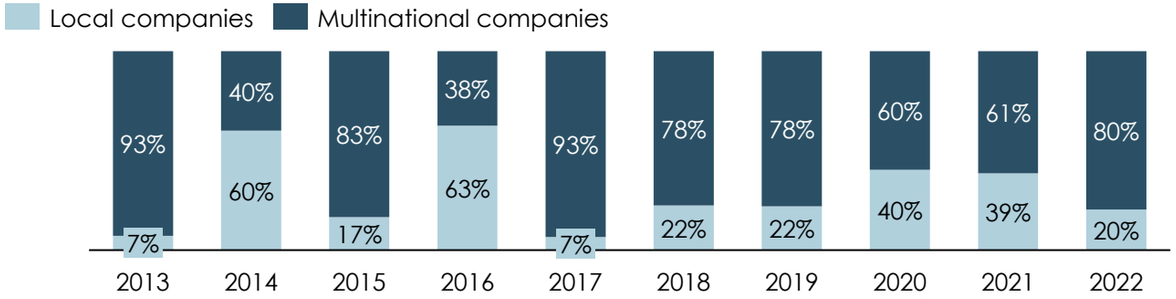
Number of unique originator approvals



Notes: In case of a same original drug with multiple strengths approved, we considered the first approval date and the approval date of its generic counterpart.

Source: Copenhagen Economics analysis of data on regulatory approvals and patent information collected from several sources (Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

Figure A2. Approvals of unique originators by global and local companies (2013-2022)

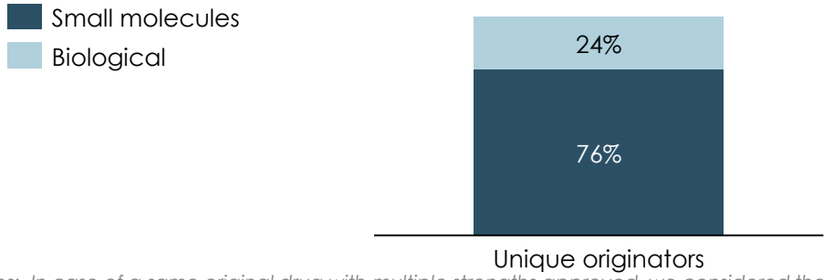


Notes: In case of a same original drug with multiple strengths approved, we considered the first approval date and the approval date of its generic counterpart.

Source: Copenhagen Economics analysis of data on regulatory approvals and patent information collected from several sources (Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

Figure A3. Approvals of unique originators by drug type (2013-2023)

Share of unique originators approved



Notes: In case of a same original drug with multiple strengths approved, we considered the first approval date and the approval date of its generic counterpart.

Source: Copenhagen Economics analysis of data on regulatory approvals and patent information collected from several sources (Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

Small molecule medicines – registration categories

Categories in red are excluded from the analysis

	A: 2007- March 2016	B: April 2016- June 2020	C: July 2020 -
New innovative drugs	1. New drugs that were never marketed in any country.	1. Innovative drugs never marketed in China or abroad: APIs and their preparations containing new chemical compounds with clear structures, pharmacological effects, and clinical value.	1. Innovative drugs that have not been marketed in China or overseas. They refer to drugs that contain new compounds with clear structures and pharmacological effects that have clinical value.
	1.1 New drugs that were never marketed in any country: Active pharmaceutical ingredients (APIs) and their preparations produced through synthesis or semi-synthesis.		
	1.2 New drugs that were never marketed in any country: New chemical monomers and their preparations extracted from natural substances or by fermentation.		
		5.1 Drugs marketed abroad applying for market authorization in China: **Originators** (including APIs and their preparations) marketed abroad applying for market authorization in China	5.1 Drugs that have been marketed overseas and are under application for being marketed in China: **Original drugs** and **modified drugs** that have been marketed overseas and are under application for being marketed in China
Improved new drugs		2. Improved new drugs never marketed in China or abroad	2. Improved new drugs that have not been marketed in China or overseas
	1.3 New drugs that were never marketed in any country: Optical isomers and their preparations in known drugs prepared by separation or synthesis.	2.1 APIs and their preparations with significant clinical advantages that a) contain optical isomers of known active ingredients prepared with resolution or synthesis methods, b) esterify known active ingredients, or salified known active ingredients (including salt with hydrogen bonds or coordinate bonds), c) **change the acid radicals, basic groups, or metal elements of known salt active ingredients or d) form other non-covalent bond derivatives** (such as complexes, chelates, or clathrate compounds).	2.1 Drugs that contain an optical isomer of known active ingredients obtained by resolution or synthesis, esterification of known active ingredients, salification of known active ingredients (including salt containing hydrogen bonds or coordination bonds), **changes in the acid group, basic group, or metallic element of known active ingredients of salt, or formation of other non-covalent bond derivatives** (e.g., complex, chelate or clathrate), which also have significant clinical advantages.
	1.4 New drugs that were never marketed in any country: Drugs with **fewer components derived from marketed multi-component drugs.**		
	4. APIs and their preparations approved in China applying for changing their acid or alkaline radicals (or metallic elements), but without any pharmacological changes		
	2. Drug preparations not marketed in any country applying to change their routes of administration	2.2 Preparations containing known active ingredients with significant clinical advantages applying for **new dosage forms** (including new drug administration systems), **new formulation technologies, and new routes of administration**.	2.2 Drugs that contain known active ingredients with **new dosage forms** (including new drug administration systems), **new formulation technologies**, or **new routes of administration**, which also have significant clinical advantages.
	5. Preparations approved in China applying to change dosage forms, but without changing their routes of administration		
	1.5 New drugs that were never marketed in any country: **New compound** preparations.	2.3 **New compound preparations** with significant clinical advantages containing known active ingredients	2.3 **New compound** preparations that contain known active ingredients and have significant clinical advantages
	1.6 New drugs that were never marketed in any country: Preparations already marketed in China applying to add **new indications** not yet approved in any country.	2.4 Preparations containing known active ingredients applying for **new indications**.	2.4 Drugs for **new indications** that contain known active ingredients
Generic drugs	3. Drugs that have been marketed abroad but have not been marketed in China, including	3. **Generic drugs** produced based on originators marketed abroad but not yet in China	3. Drugs manufactured by domestic applicants by imitating original drugs that have been marketed overseas but not yet in China. Such drugs should have quality and efficacy consistent with the reference listed drug.
	3.1 Drugs that have been marketed abroad but have not been marketed in China, including: APIs and their preparations with the same active ingredients, dosage forms, specifications, indications, routes of administration, and administration instructions as originators.		
	6. APIs or preparations for which there are already existing national drug standards	4. **Generic drugs** produced based on originators marketed in China	4. Drugs manufactured by domestic applicants by imitating the original drugs that have been marketed in China. Such drugs should have quality and efficacy consistent with the reference formulations.
		5.2 Drugs marketed abroad applying for market authorization in China: **Non-originators** (including APIs and their preparations) marketed abroad applying for market authorization in China	5.2 Drugs that have been marketed overseas and are under application for being marketed in China: **Generic drugs** that have been marketed overseas and are under application for being marketed in China

Biological medicines – registration categories

Categories in red are excluded from the analysis

	D: 2007- September 2020	E: October 2020 -
New innovative drug	1. Biological products not yet marketed either in China or abroad.	1. Innovative therapeutic biological products that have not been granted marketing authorization in or outside China.
	2. Monoclonal antibodies.	
	3. Gene therapies, somatic cell therapies, and their preparations.	
	4. Allergenic products.	
	5. Multi-component products with bioactivity extracted from human and/or animal tissues and/or body fluids, or by fermentation.	
	8. Micro-ecological products prepared using microorganism strains not yet approved.	
	7. Biological products already marketed overseas but not yet marketed in China.	3.1. Biological products that have obtained marketing authorization in China or abroad: Biological products that are a) manufactured overseas; b) only marketed abroad and not in China and c) applying for marketing authorization in China.
		3.2. Biological products that have obtained marketing authorization in China or abroad: Biological products that are a) marketed abroad but not in China and b) applying for either manufacturing or marketing authorizations in China.
		3.4. Biological products that have obtained marketing authorization in China or abroad: Other biological products.
Improved new drug		2. Improved biological products based on biologics that have been granted marketing authorization in or outside China. The new therapeutic biological products have improvements in safety, efficacy, and quality control, and distinct advantages.
	10. Products with different preparation methods from already marketed products, (such as those that use different expression systems or host cells).	2.1: Improved biological products based on biologics that have been granted marketing authorization in or outside China. The new therapeutic biological products have improvements in safety, efficacy, and quality control, and distinct advantages. Biologics that have distinct clinical advantages with improvements in dosage forms, routes of administration, and other aspects compared with existing products.
	14. Products applying to change their routes of administration (excluding the above Category 12).	
		2.2. Improved biological products based on biologics that have been granted marketing authorization in or outside China. The new therapeutic biological products have improvements in safety, efficacy, and quality control, and distinct advantages. Biologics adding a new indication that has not been approved in or outside China, or changing the intended patient groups.
	6. New compound products of already marketed biological products.	2.3. Improved biological products based on biologics that have been granted marketing authorization in or outside China. The new therapeutic biological products have improvements in safety, efficacy, and quality control, and distinct advantages. New compound products of biological products as which there are already other same type of products being marketed.
	9. Products with similar but not completely the same chemical structure as already marketed products and not yet marketed products in China or abroad. (i.e., products with amino acid locus mutation/absence, modification caused by a different expression system, deletion, changed interpretation, as well as chemical modifications of the product).	2.4. Improved biological products based on biologics that have been granted marketing authorization in or outside China. The new therapeutic biological products have improvements in safety, efficacy, and quality control, and distinct advantages. Biological products with major technical improvements compared with approved products such as those that use recombinant technology instead of bio-tissue extraction technology or those that change the amino acid sites, amino acid expression systems, or host cells allowing the new products to have distinct clinical advantages over the approved ones.
Biosimilar		3.3. Biological products that have obtained marketing authorization in China or abroad: Biosimilars.

APPENDIX B

ESTIMATING THE POTENTIAL INCREASE IN THE INDUSTRY'S CONTRIBUTION TO THE ECONOMY

Estimating the potential increase in the contribution to the economy

In our scenario analysis (see page 22), we estimated the potential increase in the share of gross value added by pharmaceuticals in China in two steps.

Step 1. Ratio of R&D investments increase to GDP contribution increase

First, we calculate a ratio of R&D investments increase to GDP contribution increase. We based this ratio on the development of R&D investments in the pharmaceutical industry in China and the GDP contribution of the pharmaceutical industry in China in 2015-2020.[1] We calculate a ratio of R&D investments increase to GDP contribution increase of 0.08.

Step 2. Growth in GDP contribution of the pharmaceutical industry in China

Second, we estimated the increase in GDP contribution of the pharmaceutical industry in China in scenario 2. We assumed that in this scenario R&D investments in China will reach 2/3 of or the same level as the EU's (157 to 285% increase). [1] This assumption seems plausible given the development in the shares of global R&D investments represented by the US, the EU, China and Japan in the past 2 decades.[2]

Using the ratio identified in step 1, we estimated that the GDP contribution of the pharmaceutical industry in China will increase by 13 to 24% following an increase in R&D investments by 157 to 285%.

Notes: 1) Copenhagen Economics calculation based on OECD (2023), CRA (2022). / 2) See CRA (2022) Figure 2.

APPENDIX C
FOOTPRINT ANALYSIS

Footprint analysis using input-output modelling (1/2)

Data sources, assumptions and methodology

In this study, we assess the pharmaceutical industry's contribution to the Chinese economy in terms of value added and jobs supported. We analyse the contribution through three effects: direct, indirect and induced.

The **direct contribution** measures the economic activity generated directly in the Chinese pharmaceutical industry. The **indirect contribution** measures contribution arising along the value chain of the industry. **Induced contribution** captures consumer spending in the Chinese market funded by wages paid in the pharmaceutical industry and those employed in its value chain. The indirect and induced effects are calculated using so-called **multipliers**.

We build an input-output (IO) model using an IO table from the OECD.[1] An IO tables is built around industries and contains information on inter- and intra-industry purchases. Thus, the table captures the flow of purchases throughout the value chain in an economy – i.e., who buys from whom, and what the wider upstream effects are. In this analysis, we follow the standard IO model assumptions[2] with several additional assumptions listed below.

Current footprint of the Chinese pharmaceutical sector

We base our estimate of the current footprint of the pharmaceutical sector on the IO table from the OECD. The Chinese pharmaceutical sector consists Western-medicine and Traditional Chinese Medicine (TCM). OECD IO tables do not distinguish between the two and present them as a single sector.[3]

RDP would impact the western pharmaceutical industry, we therefore split the industry into western and traditional according to their respective share of sales in value, based on data from the Chinese ministry of commerce.[4] We calculate that the western medicine accounts for 80% and TCM 20% of the industry.

The OECD provides data in 2020 USD values and we transformed it to 2023 USD values by correcting for Chinese inflation. The transformation assumes unchanged productivity in the period. We note that our measure for total GDP contribution in 2023 is 16% lower than the 2023 GDP reported by the National Bureau of Statistics of China. This difference is due to the fact that we use value added plus taxes based on the IO tables to proxy GDP. This is a close but not perfect approximation. This discrepancy does not lead to an overestimation of the multipliers. As a result, our estimates are conservative.

The OECD IO tables do not include the number of employees in the sector. Hence, we estimate the number of jobs supported by the pharmaceutical industry using IO tables from WIOD.[4] The data from WIOD are from 2014 and we use it to estimate the 2020 value in the following way. The OECD IO tables classify the economy into agriculture, industry and services. The growth of employee numbers in these three sectors is calculated using data from the World Bank. These growth rates are applied to WIOD data to obtain the estimates of employees in 2020.

Estimating China's strategic potential

To calculate the potential of the Chinese pharmaceutical industry, we start from the assumptions to the baseline IO model and apply the following assumptions to estimate the increase in direct contribution:

First, we estimate that the direct GDP contribution of the Chinese pharmaceutical industry would increase by 13-24% (see slide 22).

Second, we correct for the fact that the Chinese pharmaceutical sector makes more significant purchases from the agricultural sector compared to other countries as this affects the multipliers.[5,6] We

Notes: 1) OECD (2022). / 2) Standard assumptions of an input-output model are that it is a static model implying no constraints on capital or labour, and that the model does not clear and there are no price effects. In addition, an input-output model uses sector averages for interregional purchases, number of jobs, etc. Impacts are measured linearly from the current economic situation. / 3) Pharmaceutical sector in listed as "C21 - Pharmaceuticals, medicinal chemical and botanical products". / 4) Statistical report on pharmaceutical circulation industry (2022). / 4) World Input-Output Database (WIOD). / 5) 30% of the pharmaceutical purchases are from the agricultural and forestry sector. / 6) We assume that the high agricultural purchase is due to TCM and hence use other country's input shares to calculate the strategic potential.

Footprint analysis using input-output modelling (2/2)

Data sources, assumptions and methodology

correct for this by modifying China's IO model using the input shares of the pharmaceutical industries of three countries – Germany, Spain and The UK. This correction allows us to use the multipliers from the average of the three countries to calculate the indirect and induced effects

Effect on employment in the pharmaceutical industry

To estimate the impact on employment, we assume that an increase in GDP does not lead to a proportional increase in the number of jobs supported due to economies of scale and increased productivity. We instead assume that an increase in GDP by 1% leads to an increase in the number of supported jobs by 0.8%.[1] We therefore use the increase in GDP of 13-24% to estimate the potential increase in employment.

The potential indirect and induced employment multipliers are calculated based on the same methodology described for the GDP contribution.

Notes: 1) Based on PwC (2009).

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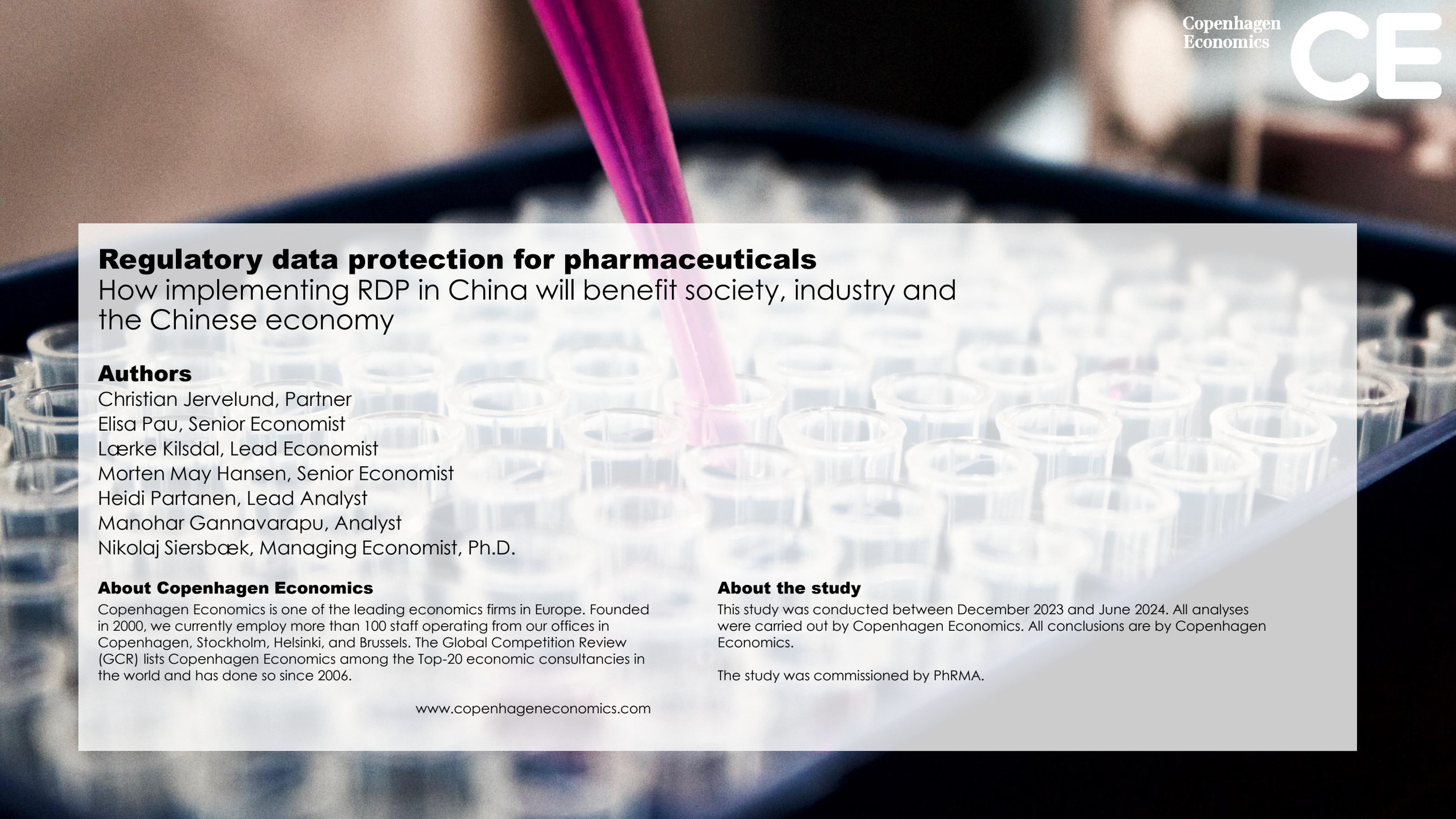

Regulatory data protection for pharmaceuticals

How implementing RDP in China will benefit society, industry and the Chinese economy

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About the study

This study was conducted between December 2023 and June 2024. All analyses were carried out by Copenhagen Economics. All conclusions are by Copenhagen Economics.

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