

Value of IP for health and growth

The economic benefits of
strengthening the environment
for innovation in **Mexico**

OCTOBER 2020



KEY
FINDINGS

BACKGROUND AND OBJECTIVES

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

The objective of the study is to:

- 1.** Set out the **policy framework** for supporting innovation in Mexico and the current state of innovative activity.
- 2.** Undertake a **case study analysis** on countries, outside the LATAM region, with potential lessons from other countries which may represent an opportunity for Mexico.
- 3.** Develop **scenarios** as to how innovative activity could change in Mexico, if policies adopted in other countries were pursued.

The approach builds on a similar analysis applied to Argentina in 2018, Brazil in 2019.

THE PROJECT HAD FOUR STEPS

ACTIVITIES

DELIVERABLES

	1 →	2 →	3 →	4 →
	MEXICAN INNOVATION POLICY FRAMEWORK	STAKEHOLDER VIEW OF THE CURRENT IP ENVIRONMENT	COMPARISON TO OTHER MARKETS AND BEST PRACTISE	DEVELOPMENT OF PEER REVIEWED PAPER
ACTIVITIES	<ul style="list-style-type: none"> Review the current IP framework in Mexico, <ul style="list-style-type: none"> 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. Discussion with local academics. 	<ul style="list-style-type: none"> Interviews with INTERPAT members on investment decisions in Latin America and current perception of Mexico. Collection of statistics in terms: <ul style="list-style-type: none"> R&D Investment FDI Clinical trials Patent applications Patents granted Backlog and delays Interviews with policymakers, academics, SMEs, CROs. 	<ul style="list-style-type: none"> Develop comparable country case studies. <ul style="list-style-type: none"> Development of metrics and recent changes. Development of scenarios. <ul style="list-style-type: none"> Application to Mexico. 	<ul style="list-style-type: none"> Draft INTERPAT white paper. <ul style="list-style-type: none"> Incorporate comments. Develop peer-reviewed paper for publication. Participate meeting to disseminate findings.
DELIVERABLES	<ul style="list-style-type: none"> A description of the current regime including challenges and opportunities 	<ul style="list-style-type: none"> Deeper understanding of current challenges Pressure test potential for change 	<ul style="list-style-type: none"> Setting out ranking in terms of Lat Am Case studies on the potential speed of improvement Scenarios 	<ul style="list-style-type: none"> White paper Report with policy implications Published paper on metrics and potential benefits

WE HAVE TAKEN INTO ACCOUNT RECENT CHANGES IN LEGISLATION

INNOVATION POLICIES

EQUIVALENCE AGREEMENTS, 2011-2014

TECHNOLOGY TRANSFER OFFICES, 2012

SCIENCE AND TECHNOLOGY COMMISSION (CCYT) ARTICLE 77, MARCH 2003

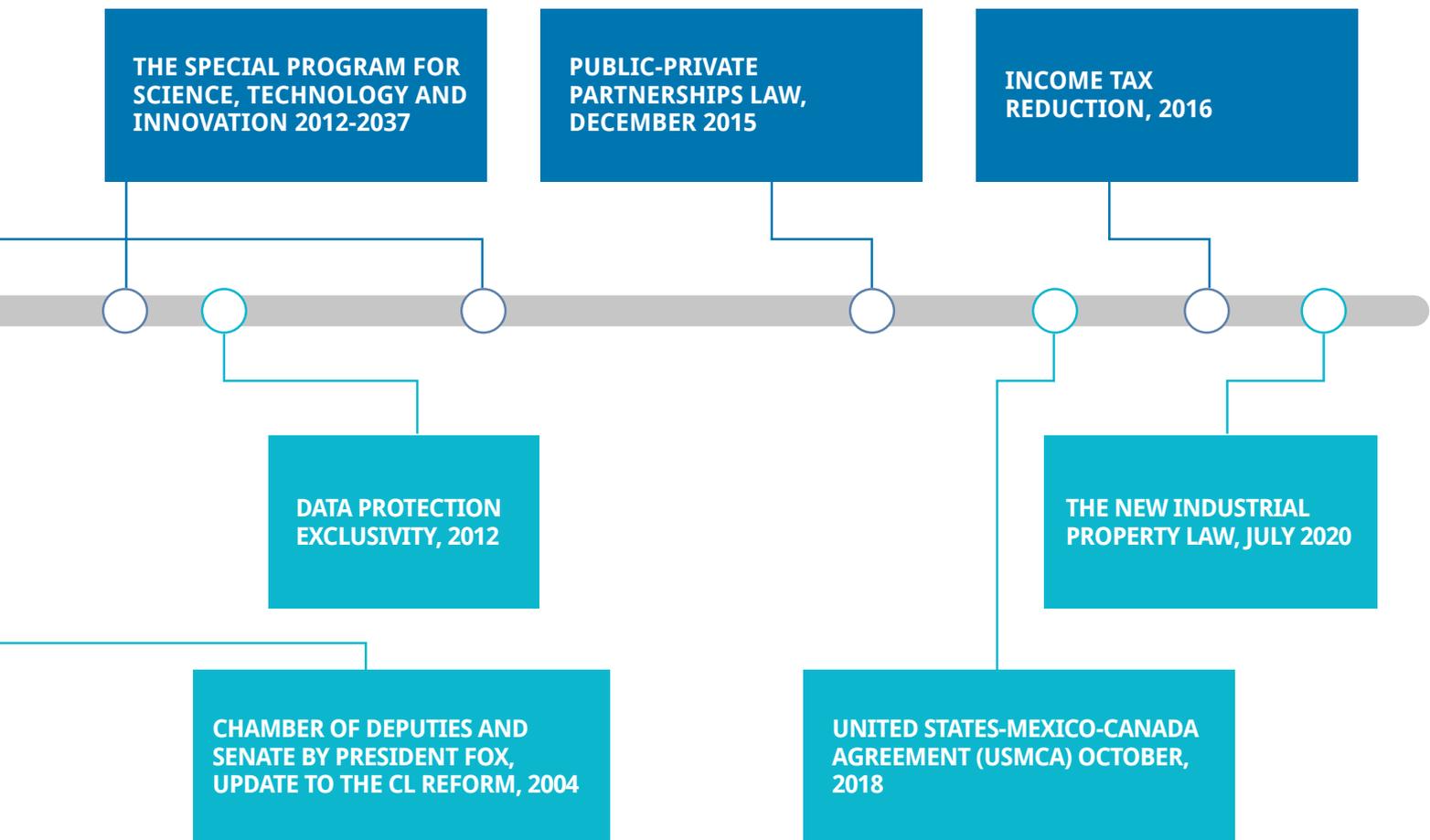
FOX GOVERNMENT INTRODUCED A LINKAGE SYSTEM, 2003

IP PROTECTION AND OTHER IP INCENTIVES

LACK OF IP LEGISLATION ENFORCEMENT

DELAYS AND CUMBERSOME SYSTEM FOR INFRINGEMENT RESOLUTIONS

LACK OF INNOVATION PRIORITISATION



WE GATHERED A BROAD RANGE OF PERSPECTIVES THROUGH THE INTERVIEW PROGRAM

- **INTERVIEWS WITH 9 INTERNAL EXPERTS**

were used to provide industry view of Mexico IP policy and innovation environment and remaining key gaps and challenges.

- AMIIF
- PhRMA
- Novartis
- Pfizer
- UCB
- Roche
- AbbVie
- J&J
- Grünenthal

- Local/ regional teams provided context and validation of findings identified through literature.

- **13 EXTERNAL INTERVIEWS**

with former policymakers, academics, regulatory experts, local bio-techs and influencers of the current innovation environment were used to develop understanding of the broader innovation policy in Mexico.

- Policy experts revealed plans for imminent reforms to innovation policy, while academics and local industry provided suggestions for additional improvements.
- Interviews with experts from other relevant stakeholders were also requested.



Comisión Federal para la Protección
contra Riesgos Sanitarios



MEXICO: ASSESSMENT OF PERFORMANCE

- Compared to the LatAm region, Mexico comparatively has strong human resources and a strong healthcare system. The general de-prioritisation of innovation from the government is a significant barrier which limits the level of collaboration between public and private entities. There is limited investment in early stage research in clinical trials and poor implementation of IP laws dis-incentivises FDI. If more investment were to be allocated to innovation, Mexico would experience higher innovative and economic activity.
- With the new Industrial Property Law and the USMCA provisions, Mexico could attract more FDI and pharma confidence to conduct local clinical trials.
 - However, these reforms should be complemented with new innovative policies that foster private-public partnerships.

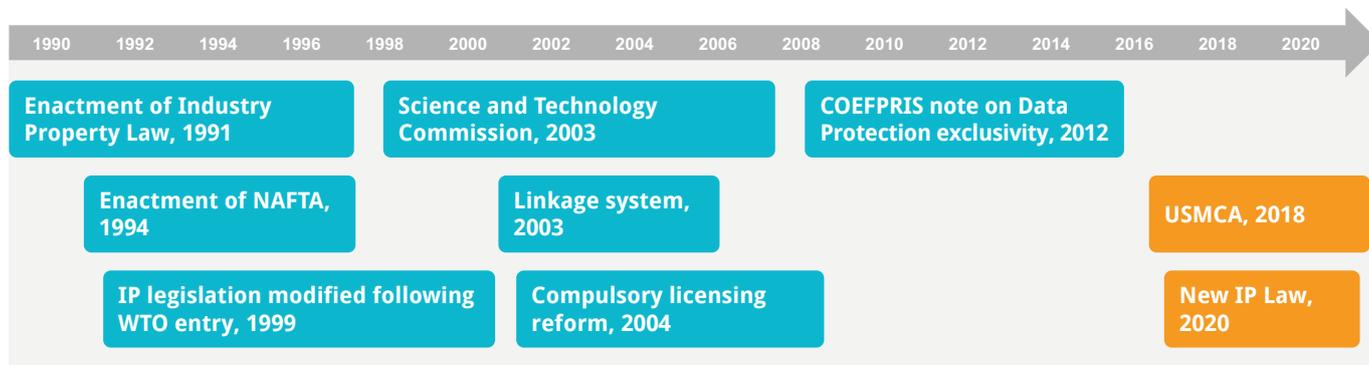
	INDICATORS	COMPARED TO LATAM	COMPARED TO OECD*
HUMAN RESOURCES	Universities		
	Education attainment		
	Collaboration		
	Researchers		
HEALTHCARE SYSTEM STRENGTH	Infrastructure		
	Effective and safe care		
INVESTMENT IN INNOVATION	R&D investment		
	FDI		
INNOVATIVE ACTIVITY	Early research (publications)		
	Clinical trials		
	Patents		
ECONOMIC ACTIVITY	Employment		
	Trade		

Improving performance →



* Where OECD average not available, comparison was made against World: higher income countries average.

RECENT LEGISLATION HAS BEEN INTRODUCED TO IMPROVE THE IP REGIME, HOWEVER EFFECTIVENESS OF IMPLEMENTATION REMAINS UNCLEAR



The literature review identified six main weaknesses in Mexico's IP regime. Some have since been addressed through the IP law*:

<p>* DELAYS IN IP INFRINGEMENT RESOLUTIONS</p>	<p>It could take between 5 to 8 years for a company to access reparation due to IP infringement. Through the new IP Law, the rules to claim damages have been modified in order to make it easier and to expedite the corresponding proceedings.</p>
<p>* LACK OF ROBUST REGULATORY DATA PROTECTION FRAMEWORK</p>	<p>In 2012, COFEPRIS issued guidelines to implement RDP for new chemical entities for five years. Under the USMCA, Mexico will extend the term for RDP of new agricultural chemical products, new pharmaceutical products and new indications.</p>
<p>EXCLUSION OF BIOLOGICS IN THE USMCA</p>	<p>The assurance of 10 years' data exclusivity for biologics in the USMCA was removed from the tri-lateral trade agreement in late 2019.</p>
<p>* WEAK PATENT LINKAGE</p>	<p>COFEPRIS appears to apply patent linkage inconsistently. Through the new IP Law the scope of linkage will be broadened to include patents of inventions susceptible to be used in a pharmaceutical product.</p>
<p>* NO PROVISIONS FOR PATENT TERM EXTENSION</p>	<p>As of end 2020, the Supreme Court ruled that patent term restoration must be made available to a pharmaceutical company. The rule was not conditioned on the delay being greater than five years and compensation was not based on "one day for two of delay". However, the resolution does not automatically apply to all patents granted that have been delayed.</p>
<p>POTENTIAL ABUSE OF THE BOLAR EXEMPTION</p>	<p>Mexico fails to impose any limits on the amount of raw materials that can be imported in a patented pharmaceutical for "experimental use" (the Bolar Exemption). The controls on the Bolar exemption will be covered through secondary regulations.</p>

Latest developments

CHALLENGES IN THE IMPLEMENTATION OF USMCA EXTEND BEYOND IP AND INCLUDE CHALLENGES IN GOVERNMENT PROCUREMENT PROCESS

DIVERSION OF PROVISIONS IN GOVERNMENT PROCUREMENT AWAY FROM USMCA COMMITMENTS

- In April 2020, a bill was introduced to Congress to amend the **Government Procurement Law**.²⁸ This new bill **fails to meet the standards and, in some cases, is in contradiction to what is agreed in the USMCA**.
- Provisions in the new Bill which contradict the USMCA include:
 1. The introduction of **'market research'** which enables different suppliers to make auctions, reducing the original price offered by suppliers and enables greater scope for negotiation.
 - This would essentially act as a summary proceeding for the open tendering which does not need to comply with the deadlines, timeframes and procedural stages agreed in USMCA.
 2. Broader definition of **'limited tendering'** where entities can directly contact a supplier of their choice.
 - The new Bill exceeds USMCA grounds by enabling limited tendering of a greater number of goods and hence, prevents fair competition.
 3. **National treatment and preference** in the instance where there are two finalists for a tendering procedure, the national supplier will be awarded the tender even if the price offered is 15% higher. This goes against the national treatment principle of USMCA.
 4. **Lack of domestic review** whereby the new Bill fails to designate one impartial administrative authority to implement the USMCA as agreed in the treaty.

IMPLICATIONS

- The Bill represents an example of Mexico's **inaccurate interpretation of the USMCA's provisions**.
- The Bill is contributing to **uncertainty around the procurement process**.
- Industry efforts to address the inefficient procurement process is a **trade-off of investment into innovation**.
- Nationalistic policies may **discourage foreign investment** in Mexico and could ultimately **harm patient access to medicines**.
- The Mexican government should take an informed, **"do no harm" approach** when considering implementation of legislation of the USMCA. Policies which fail to achieve the true goals of the USCMA could have **significant negative unintended consequences**.

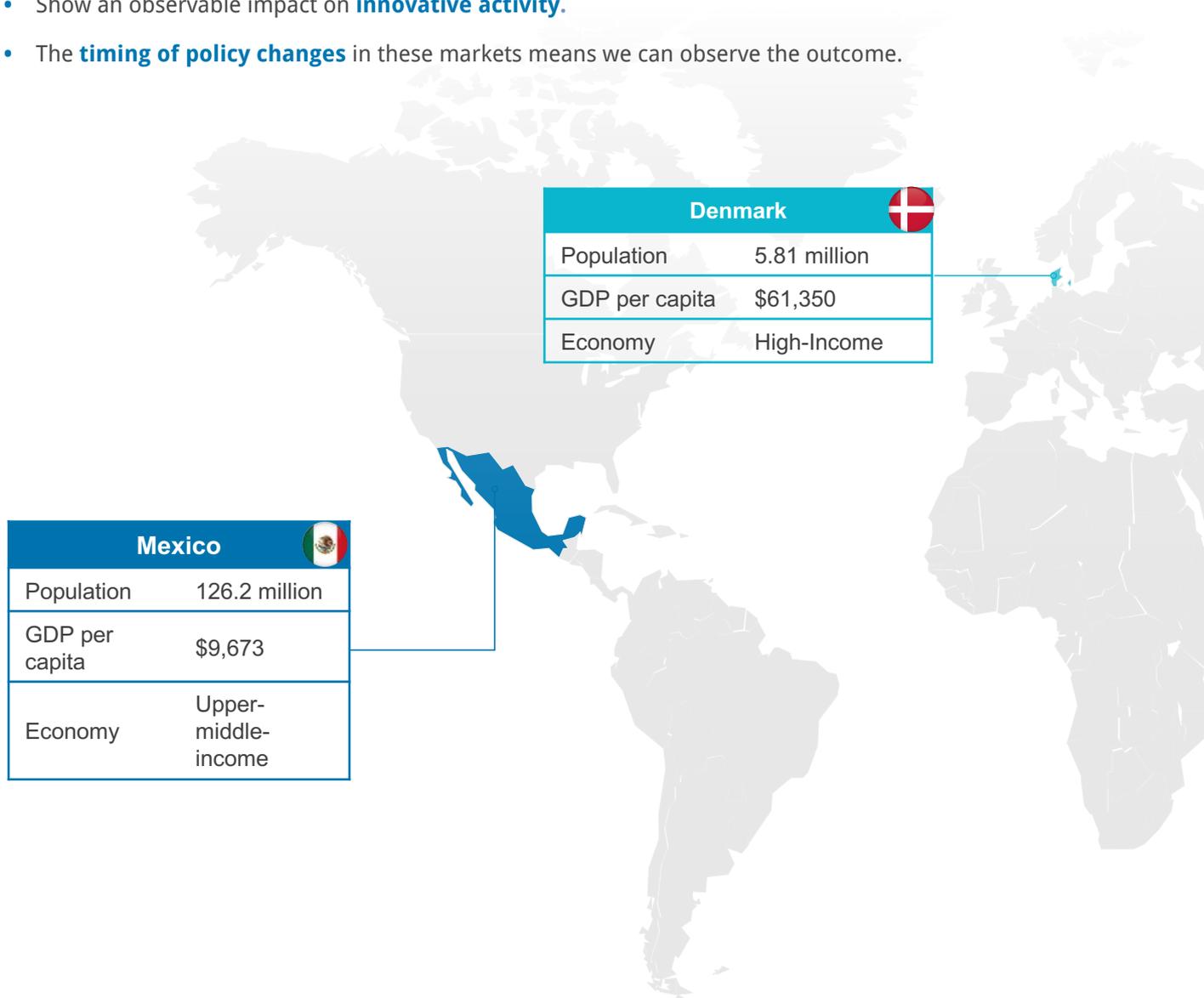
APPROACH TO CASE STUDY ANALYSIS AND SCENARIOS

Our research and interview insights reveal that Mexico's key innovation policy gaps are:

1. Government de-prioritisation of innovation together with a lack of incentives and legal certainty for companies to invest in innovation and collaborations.
2. Lack of enforcement of legislation and delays in infringement resolutions.
3. Patent Linkage is being applied inconsistently and this is attributed to the poor communication between government bodies.
4. Inconsistencies in the granting of RDP and no legal instrument available to ensure RDP protection.

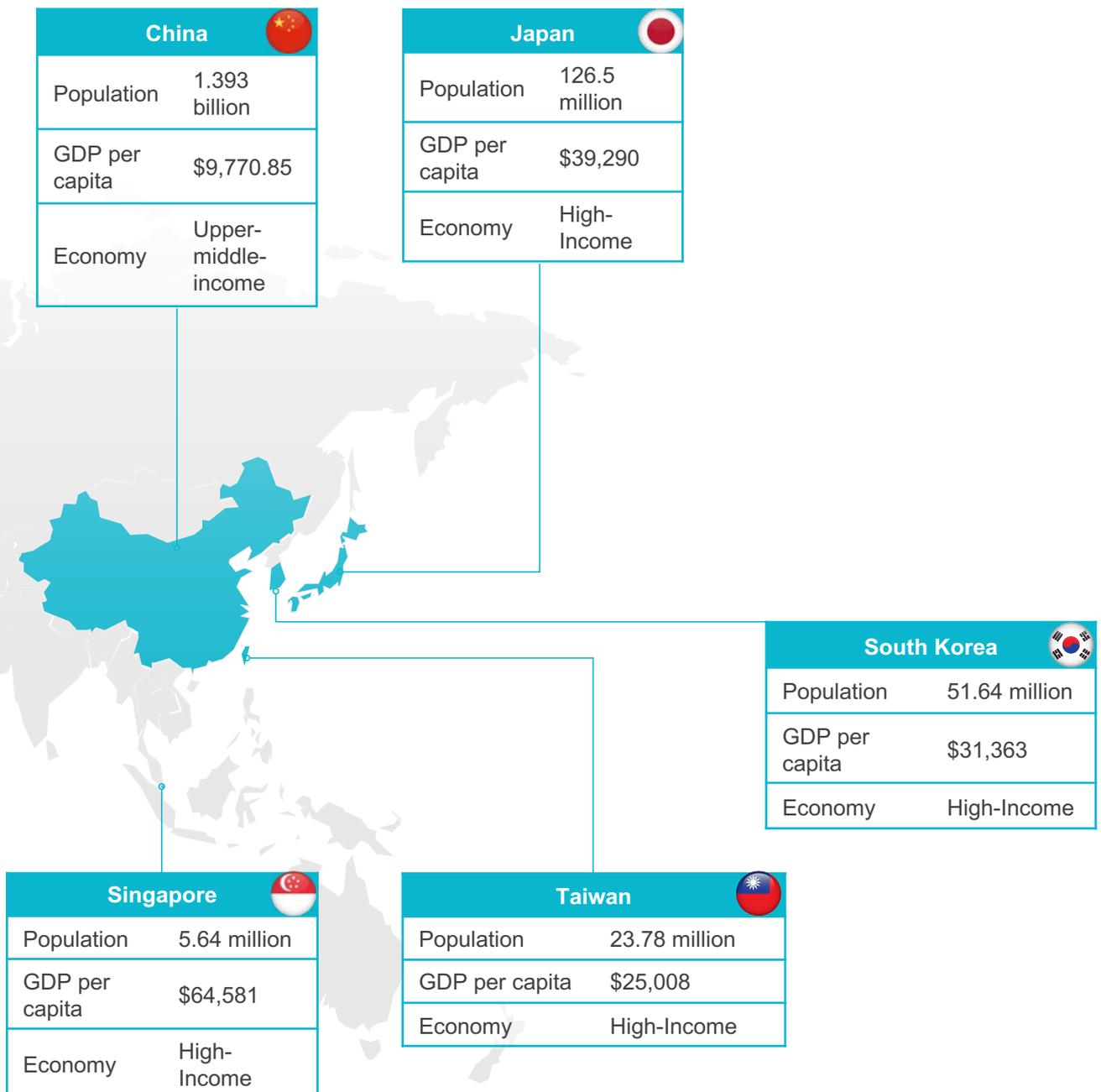
Our selection criteria for our case study markets include:

- Have shown a **focus on strengthening innovative environment**, particularly the IP protection.
- Placed **broadly in the same income, size and development category as Mexico** when started focusing on innovation.
- Show an observable impact on **innovative activity**.
- The **timing of policy changes** in these markets means we can observe the outcome.



Our research and interview insights reveal that Mexico's key innovation policy gaps are:

- 1. Denmark and China's** government prioritisation of innovation and implementation of incentives to secure innovation environment:
- 2. Singapore's** implementation of legislation to enforce international agreements and provisions for infringement resolutions.
- 3. Taiwan and South Korea's** implementation of a robust patent linkage system:
- 4. South Korea, Japan, Taiwan, Singapore's** implementation of RDP through legislation.



THE FOLLOWING INDICATORS WERE ASSESSED TO UNDERSTAND THE OVERALL INNOVATIVE ENVIRONMENT

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 e.g. the USMCA.

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

EARLY AND BASIC RESEARCH

- Publications.
- Public private collaborations.

PRODUCT DEVELOPMENT

- Clinical trials by phase, type and funder.

OUTPUTS OF INNOVATION

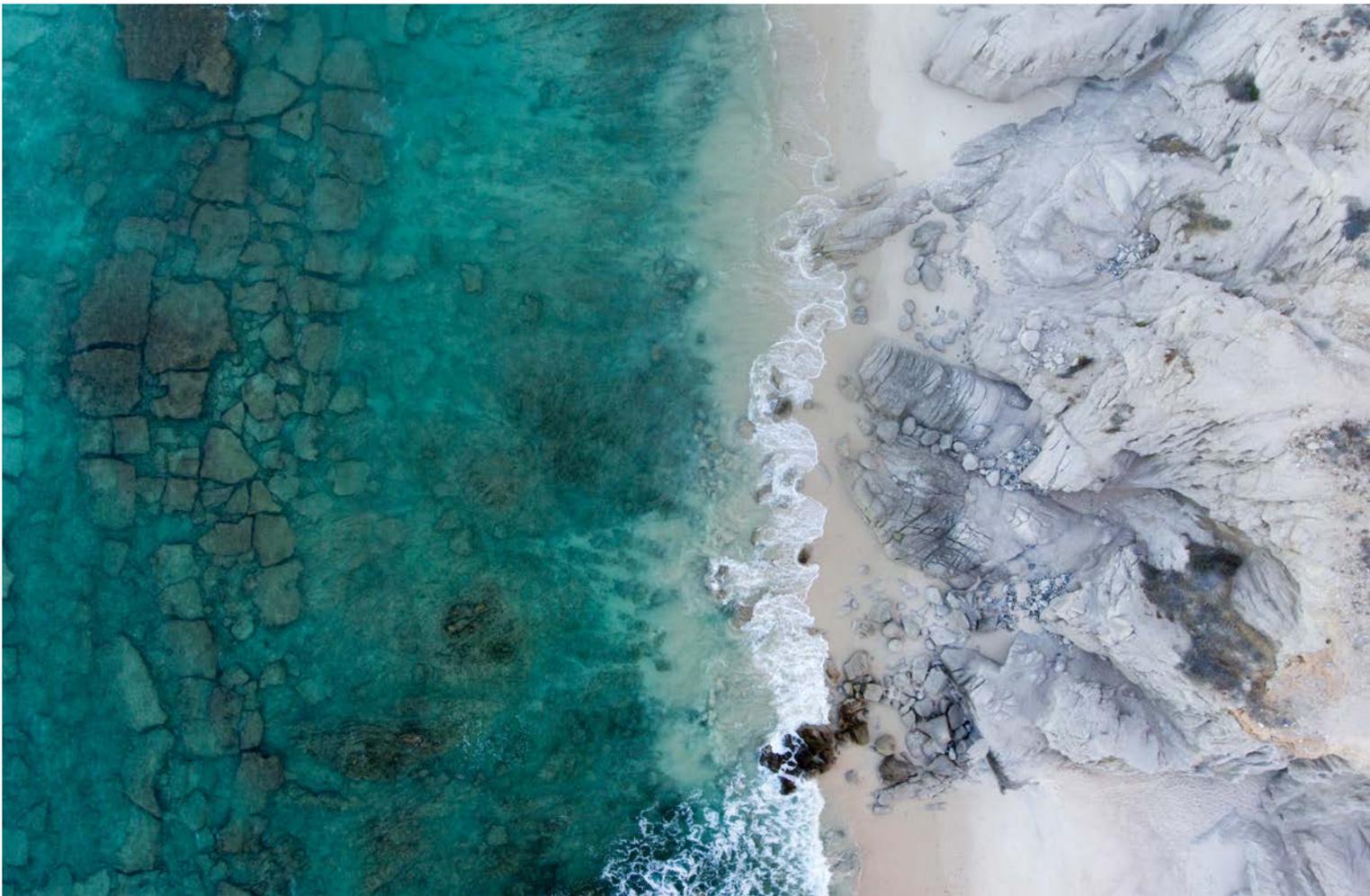
- Number of patents filed, granted both domestic and international.

EMPLOYMENT

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

TRADE

- Imports vs exports in pharma and biotech.



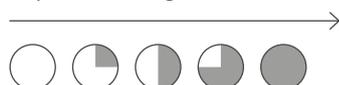
Aerial views from the beach and reef of Cabo Pulmo, Mexico, [shutterstock.com/it/g/photonatura](https://www.shutterstock.com/it/g/photonatura).

IMPACT ATTRIBUTABLE TO THE CHANGE IN REGULATION IN A 5-YEAR PERIOD: SUMMARY (2/1)

	DENMARK	SINGAPORE	SOUTH KOREA
KEY INNOVATION POLICY CHANGES	Globalization Strategy, "Denmark – Building on Tradition" 2006.	Biomedical Sciences Initiative, 2000.	"Bio-Vision 2016" Plan of 2007 "577 Initiative" of 2008.
KEY IP REGULATION CHANGES	Act on Inventions at Public Research Institutions, 2000.	Singapore-US Free Trade agreement, 2004.	Pharmaceutical Affairs Act of 2007: Grant of RDP.
OTHER KEY REGULATION CHANGES	Technology Transfer Offices, 2000.	Establishment of IP courts, 2002.	Dosage patent decision 2015.

		Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation
Innovative Activity	BERD / GERD	3%		70%		11%	
	Early research (publications)	7%		4%		4%	
	Clinical trials (All)	4%		7%		7%	
	Patents (local residents)	0%		4%		25%	
	Patents (local non-residents)	0%		4%		16%	
	Patents (USPTO)	17%		22%		29%	
Economic Activity	Employment in biopharmaceuticals	3%		6%		7%	

Impact of the regulation →

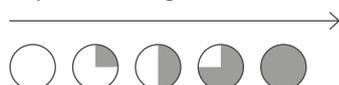


IMPACT ATTRIBUTABLE TO THE CHANGE IN REGULATION IN A 5-YEAR PERIOD: SUMMARY (2/2)

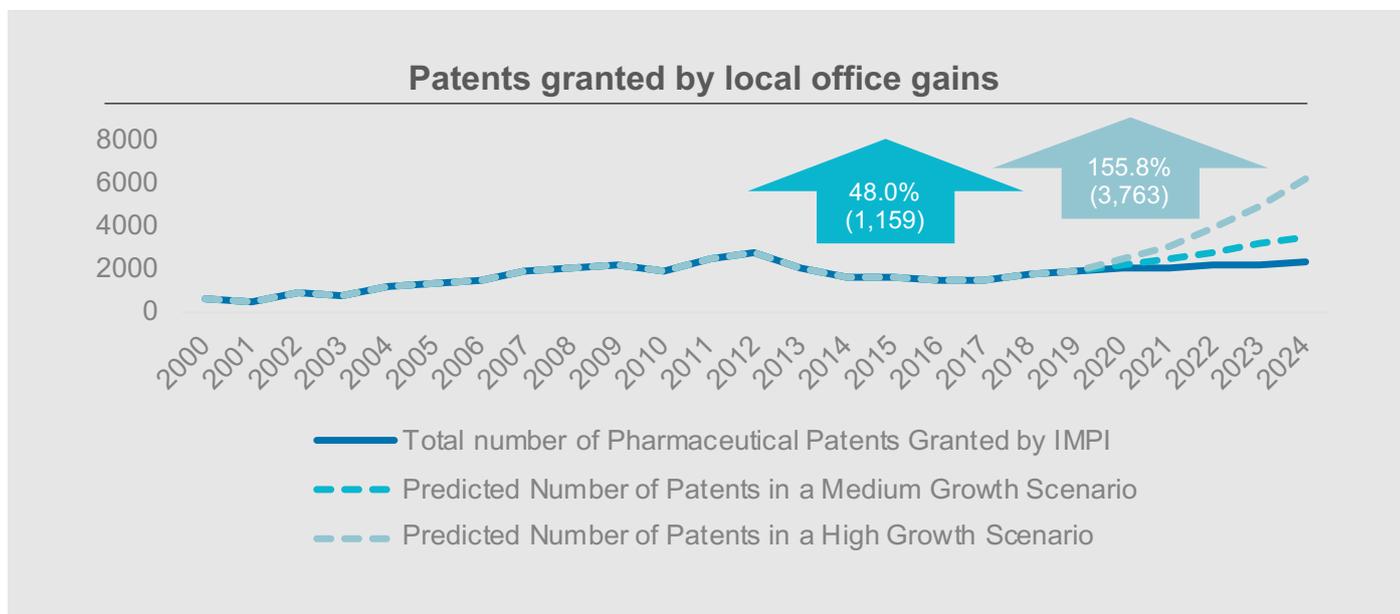
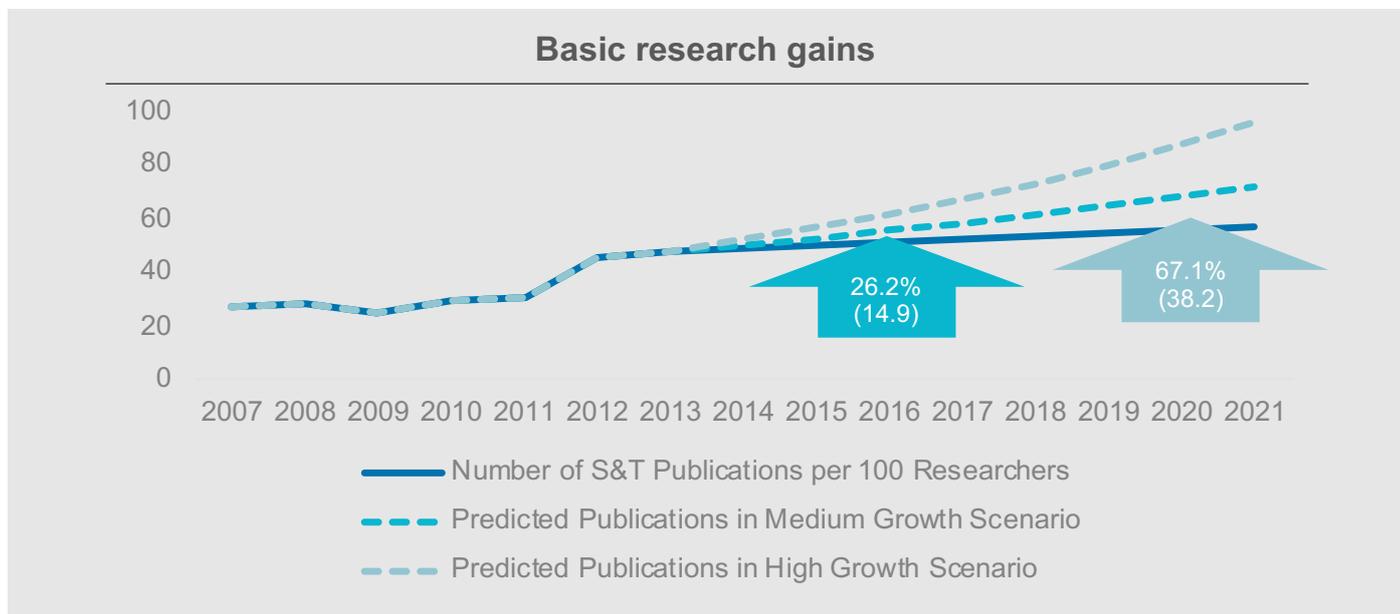
	TAIWAN	CHINA	JAPAN
KEY INNOVATION POLICY CHANGES	Biotech and New Pharmaceutical Development Act (2007).	Program for Science and Technology Development (2006).	Science & Technology Basic Plan (1996 – 2016).
KEY IP REGULATION CHANGES	Revision of Pharmaceutical Affairs Law (2005): Grant of RDP.	Regulatory Data Protection (RDP) (2001).	Notice extending the RDP term (2007).
OTHER KEY REGULATION CHANGES	Backlog Reduction Program, 2010-2017.	National Intellectual Property Strategy (2008).	Policies targeted at the patent backlog (2004 – 2007).

		Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation
Innovative Activity	BERD	14%		26%		4%	
	Early research (publications)	4%		12%		-1%	N/A
	Clinical trials (All)	17%		16%		-3%	N/A
	Patents (local residents)	23%		35%		0.6%	
	Patents (local non-residents)	11%					
	Patents (USPTO)	20%		-2%	N/A	-31%	N/A
Economic Activity	Employment in biopharmaceuticals	8%		17%		-1%	N/A

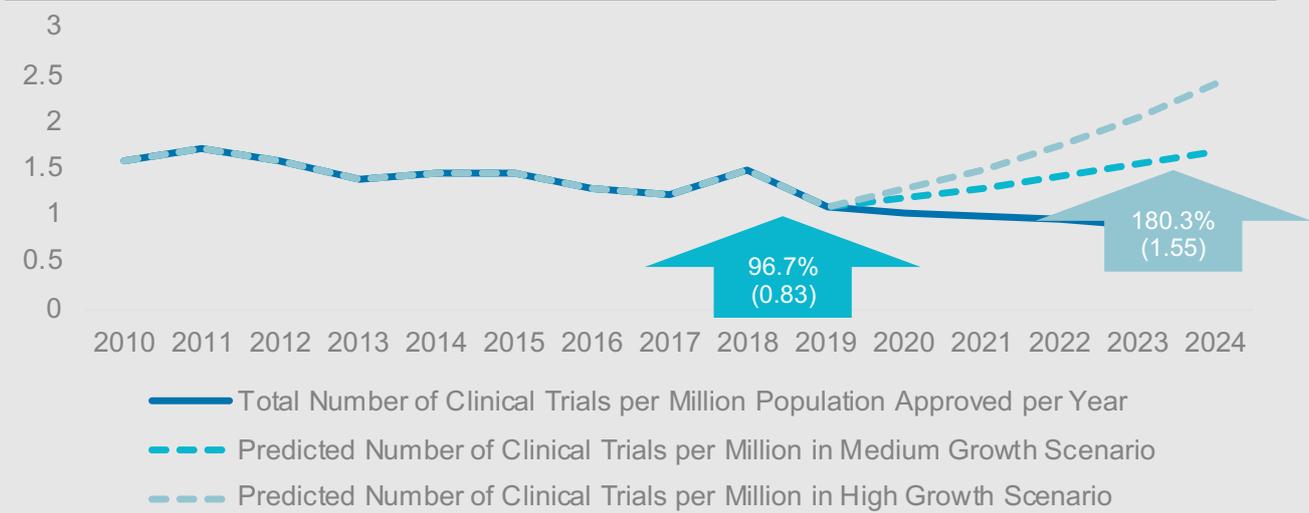
Impact of the regulation →



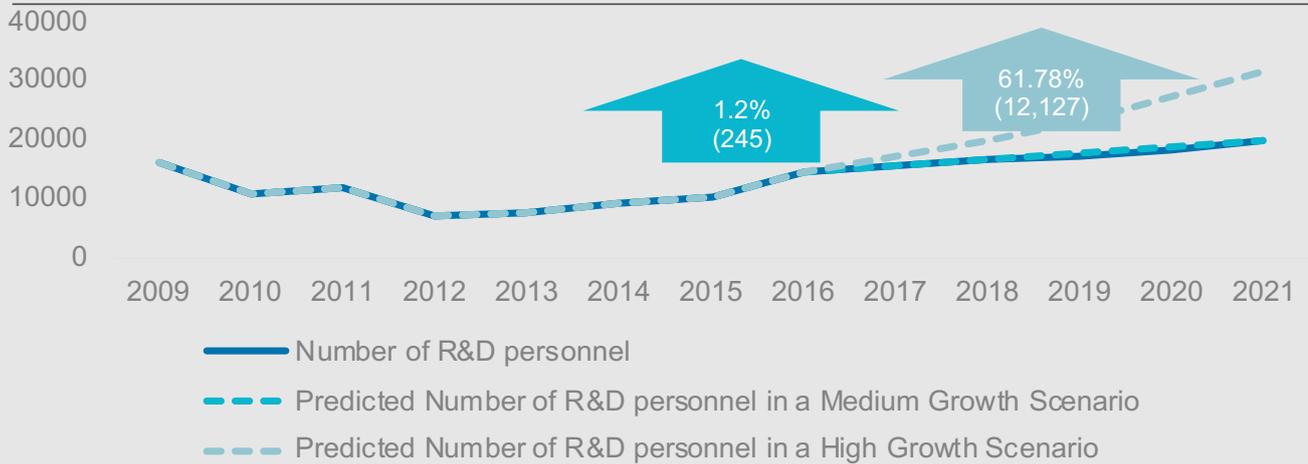
SCENARIO ANALYSIS ACROSS INNOVATIVE AND ECONOMIC ACTIVITY IN MEXICO: ABSOLUTE GAINS AND GROWTH POTENTIAL (ON AVERAGE)



Clinical trials gains



Employment in pharma gains



Note:

The number of employees in the pharmaceutical industry was estimated based on the number of R&D personnel. The employment ratio of pharmaceutical to total knowledge intensive industries is assumed constant throughout the years.

FINDINGS (1/3)

1. Mexico's current innovation capacity and potential.

Mexico has many of the factors required to be successful in encouraging biopharmaceutical innovation.

- This includes: a skilled workforce; a large, treatment-naïve population; strategic placement next to the US and established treaties to attract foreign investment.
- The market has also developed a relatively comprehensive IPR framework, a strong foundation in academic research and several regional innovation clusters.

There is room for improvement however when compared to OECD and Asia markets in many innovation activities.

- There are several weaknesses in Mexico's innovation framework : Weak enforcement of existing IP legislation; the bifurcated IP infringement resolution system; loopholes which allows for IPR infringement to be exploited and create uncertainty for innovative industry.
- Additionally, patent linkage is applied inconsistently and there is a lack of regulatory data protection. Although both of these IP regime limitations have the potential to be addressed through the new Industrial Property Law, the extent to which the Law will be implemented effectively remains unclear.

Gaps in Mexico's innovation framework have constrained innovative activity in Mexico, especially in terms of lower basic research, clinical trial activity, patent filings and employment.

- University regulations prevent researchers from collaborating with the private industry and the private industry is not provided with sufficient incentives to partner with the public industry.
- There is limited research funds available and public funds are not allocated on the basis of commercialisation potential.
- Furthermore, there is a limited number of Technology Transfer Offices across the country, resulting in only a few patents being commercialised.

FINDINGS (2/3)

2. Implications for Mexico's innovation and economic policy.

Immediate need for enforcement of IP laws with a “do no harm” approach.

- Mexico has made several recent efforts to strengthen its IP environment such as through the USMCA (October 2018) and the new Industrial Property Law (July 2020). However implementing regulations are lacking. Lessons from Singapore highlight how amendments to local law created the assurance for multinational companies to choose Singapore as a location for innovation.
- There is immediate need for Mexico to implement legal rules to enforce its commitment to the USMCA. The government has already set a precedent for capitalizing on the USMCA's transition period by implementing early provisions related to the Agreement's copyright and trademark commitments. Mexico should avoid repeating the failure to implement RDP following ratification of NAFTA.
- In addition, the government should ensure an informed, “do no harm” approach to implementation and consider the true objectives of the IP law to avoid any negative unintended consequences on the incentives to innovate.

Regulatory Data Protection.

- Since 1994, under NAFTA and now through the USMCA Mexico has the legal foundation to provide RDP however COFEPRIS has failed to implement any associated legal instruments. Findings from comparable Asian markets reveal the benefits of strong protection for clinical trial test data. The Singapore-US Free Trade agreement was the impetus for updates to Singapore's IP framework including the implementation of RDP and the enforcement of patient linkage and Bolar exemption through the Patent Act. New pharma investment in Singapore has since been linked to these updates to IPR.
- Mexico should ensure implementing legislation to recognise RDP for biologics and new formulations and indications. Mexico could amend the IP Law or include a provision in the national Health Law, to domestically implement legislative or regulatory measures on RDP.

Encourage system of communication between COFEPRIS, IMPI and industry and implementation of patent linkage.

- Interviews with experts revealed poor communication between COFEPRIS, industry and IMPI have led to delays in clinical trial approval, poor enforcement of patent linkage and sparse communication with industry.
- Lessons from Singapore and Denmark highlight how organisations and platforms which aim to improve communication between innovation stakeholders can facilitate technology transfer. In addition, Taiwan and South Korea implemented local laws to enforce patent linkage and improve communication between the national health and patent authorities.
- In Mexico, the expanded Patent Linkage system, as per the new IP Law, enhances the communication between COFEPRIS and IMPI and will signal to industry that patents are being protected. However secondary implementing regulations are still required to ensure legal certainty and to adopt measures introduced by the USMCA allowing the participation of the involved parties in the Patent Linkage system to provide arguments supporting their interests, through a non adversarial proceeding.

FINDINGS (3/3)

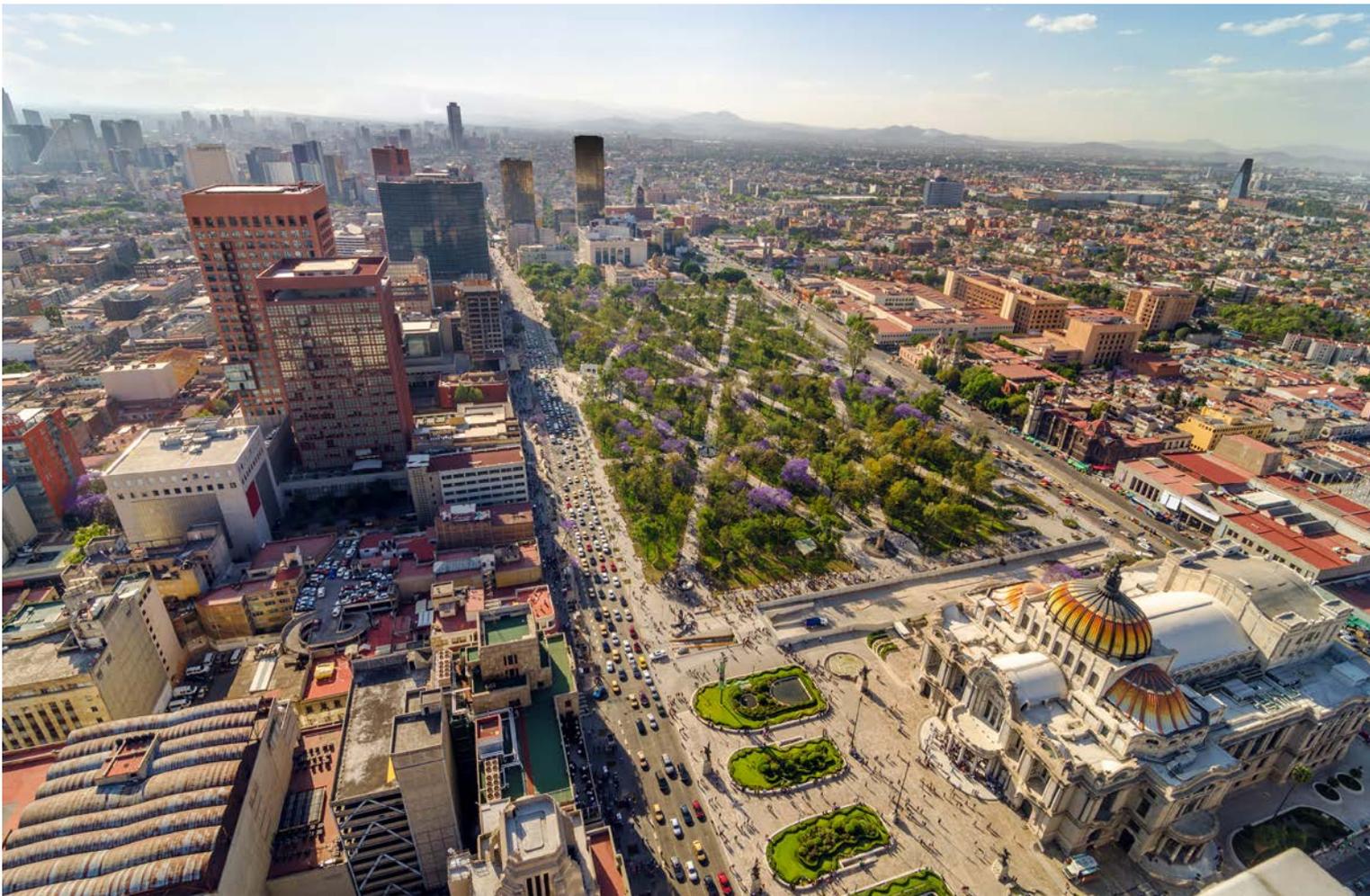
2. Implications for Mexico's innovation and economic policy.

Creation of an environment that provides legal certainty for collaboration and tech transfer.

- Mexico's population have a strong skill-set however academics lack the opportunity to partner with industry and the incentive (e.g. licensing, royalties) to commercialise patents. However, some universities are starting to recognize the value of innovation e.g. the University of Monterrey. Denmark was once in a similar position. The Danish government made a concerted effort to foster collaboration between industry and academia, and an environment of legal certainty around innovation through incentives, grants and knowledge sharing platforms to support pharma innovation.
- In the same vein, the Mexican Federal government could encourage the amendment of university regulations to foster private-public partnerships, allocate public funds on the basis of the commercial potential of the research and amend the Science and Technology Law to align stakeholders' research objectives and signal government's commitment to innovation.

Government prioritization of innovation.

- The Mexican Federal government's austerity measures from last recession have already reduced federal funding for innovation and future reliance on cost-cutting measures may exacerbate this trend as a result of the COVID-19 pandemic. However some States remain committed to innovation, such as the State of Jalisco, which has been investing in increasing capacity for pharmaceutical innovation and production.
- South Korea and Japan exemplify how long term, concerted prioritisation of innovation can lead to economic growth and high levels of patient access. Singapore facilitated the coordination of public innovation bodies and industry to overcome barriers such as small population size and relatively few comparative advantages, to drive innovation.
- The Mexican Federal government should support the establishment of State-level Ministries of Innovation and more local Technology and Technology Transfer Offices at universities. By strengthening government innovation institutions, the Federal government will also motivate academia and signal to industry it's prioritization of innovation.



Aerial view of Mexico City, Mexico, shutterstock.com/it/g/JessKraft.



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October 2021

A rectangular box with a white border and a solid magenta background. The word 'BARCODE' is centered within the box in white, uppercase, sans-serif font.

BARCODE