



August 4, 2020

Patented Medicine Prices Review Board  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario K1P 1C1

Dear PMPRB Board Members,

**Subject: Consultations on the June 2020 Draft Guidelines**

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to provide feedback on the PMPRB's revised draft guidelines.

LSO is a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector. Members of LSO include life sciences companies, entrepreneurs, members of academia, and service providers from many different areas of the life sciences ecosystem, including biopharmaceuticals, agriculture, agri-food, the bioeconomy, medical devices, animal health, environmental technologies, and more. Ultimately, our mission is to encourage commercial success throughout this diverse sector by collaborating with governments, academia, industry and other life sciences organizations in Ontario and across Canada.

LSO has actively monitored developments related to the PMPRB reforms since they were first introduced and has engaged with government officials and other stakeholders out of concern for the potential impacts of the new rules on Canada's diverse life sciences ecosystem.

As the unprecedented COVID-19 pandemic has clearly demonstrated, having a strong life sciences sector is not only good for Canadians and the economy when times are good, but also absolutely critical when they are not. Moving forward, the life sciences sector represents a tremendous opportunity to drive Canada's post-COVID economic recovery, while also contributing to global efforts to develop vaccines, antivirals, and other treatments needed to stem the tide of this crisis. Here in Ontario, the government has identified life sciences as one of three sectors for COVID-19 recovery where the province has a globally competitive advantage.

In this increasingly challenging context, we remain deeply concerned about the federal government's patented medicine price controls and their potential to undermine our sector's efforts to support Canadians and the innovation economy.

Earlier this year, to help measure the impacts of the new price controls in Canada, LSO commissioned a survey of pharmaceutical and other life sciences leaders to see how they believe the PMPRB changes will impact their operations in Canada. Respondents were

unanimous on the negative impacts, including fewer new medicine launches, investments in clinical research, and life sciences jobs in Canada. These are the leaders who make decisions based on the commercial prospects on the ground in Canada, and their warnings are in contrast to the PMPRB's continued assertions that prices do not affect decisions on launches and research investments. We have attached a copy of this report for your review as part of our submission.

As a science-based organization, LSO wanted to further examine the concerns about commercialization decisions to understand how they have been made in practice. For this, we commissioned IQVIA, a health data and analytics firm, to look at medicine launch trends in Canada and globally over the past 20 years to see if anything has changed in recent years. Unfortunately, the results largely substantiate what we heard from companies in our survey and we have attached a copy of the IQVIA report to this submission for your reference.

The report highlights a number of important considerations, including:

- Until recent years, Canada was gradually getting faster and more extensive access to new therapies relative to other countries
- In 2019, the year the drug price controls were adopted, there was a dramatic 40% drop in the number of new globally launched drugs commercialized in Canada – this despite the overall number of global launches rising during the year.
- By mid-2020, Canada benefitted from less than half of the new therapies launched globally in 2018 (16 of 37). The majority of the medicines still not commercialized in Canada are for rare diseases and cancer.

From the outset, the PMPRB's approach to drug price regulation has been rife with problems including the devaluation of intellectual property and the contravention of Treasury Board and best practice standards for regulatory oversight. Among the most problematic specific issues are the proposed use of economic factors to control drug prices. The economic factors and the resulting uncertainty has repeatedly been identified as a major cause of concern from stakeholders. The application of economic factors makes it difficult for companies to appropriately price their products, which also makes the return on investment highly uncertain. This, in turn, makes it difficult for companies to make a compelling business case to prioritize the Canadian market for new medicine launches and investments in clinical research, patient support programs, compassionate funding or even Special Access Programs.

Unfortunately, rather than reversing course on this flawed approach, in its revised draft guidelines, the PMPRB has opted for a 'duct tape' solution to salvage what is fundamentally unsalvageable. While the PMPRB has made efforts to address concerns related to the economic factors by raising its proposed thresholds, it has done little to address the underlying uncertainty related to their use. The forecasted range of regulated price reductions continue to be unreasonably severe. The PMPRB has also made the overall system more complicated and difficult to understand, which will further deter pharmaceutical companies from the Canadian market. The PMPRB should also be informed by the recent Judicial Review decision that confirms

the limits of the PMPRB's regulatory oversight to the ex-factory "list" prices of patented medicines. The decision is a signal for the PMPRB and the government to reconsider and ultimately remove the economic factors from the *Patented Medicines Regulations*, and for the PMPRB to suspend their application in the meantime. Given that the PMPRB effectively ignores other "mandatory" factors, such as the consumer price index, there is precedent that would support this way forward.

A new approach is critical at this moment for Canada, as our society faces its largest collective health crisis of the past 100 years. We strongly urge the PMPRB to facilitate and support alternative solutions to meet the government's twin objectives of affordability and access to medicines. This has to be done immediately to avoid further damage to our life sciences ecosystem.

Sincerely,

A handwritten signature in black ink, appearing to read "Jason Field".

Jason Field  
President & CEO  
Life Sciences Ontario  
C: (647) 821-3392  
[jason.field@lifesciencesontario.ca](mailto:jason.field@lifesciencesontario.ca)

Encl.






# Impact of PMPRB Pricing Changes

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## Final Research Report

February 3, 2020

Research etc.

# Background

Recently, the Canadian federal government passed regulations that change how the **Patented Medicine Prices Review Board (PMPRB)** will regulate maximum prices for patented medicines for every sale in Canada, which will come into force on July 1, 2020.

The regulatory changes include **revisions to the basket of comparator countries** (removing the US and Switzerland and adding six jurisdictions with lower-than-Canadian average list prices) and mandating the PMPRB to use **new economic factors** in its regulatory determinations (cost-per QALY thresholds and price reductions based on market size).

**Life Sciences Ontario (LSO)** commissioned a research study to better understand the **impact of these changes** on the pharmaceutical industry and life sciences organizations.

## Three Key Research Objectives

1. **Understand awareness of and reaction** to upcoming changes to price controls in Canada among key decision-makers
2. **Determine likely response** to Canadian price control reforms, including any expected changes in business decisions and investments in Canada
3. **Confirm or refute the hypothesis** that the new pricing regime will have no negative impacts on access to medicines and investments in Canada

# Methodology



## STEP 1: Quantitative research

**N=46 completes**

5-minute online survey with decision-makers

Fielded Nov 19, 2019 to January 17, 2020



## STEP 2: Qualitative research

**N=10 completes**

30-minute follow up in-depth telephone interviews (IDIs)

Fielded January 21 to January 31, 2020

## Quantitative Sample Profile

**N=36** Senior Pharmaceutical Executives (Presidents, GMs, EVPs, Director level)

- N=27 Canadian affiliate of a global company
- N=6 Parent company based outside Canada
- N=3 Parent company based in Canada

**N=10** Life Sciences Executives

- Includes clinical trials, patient support programs, IT for healthcare, non-profits

## Qualitative Deep Dive with ...

**N=6** Large Global pharma companies

**N=4** Smaller companies, including Canadian-owned and headquartered

## PMPRB changes is the “#1 topic” among senior executives right now

98%

of survey respondents said they are **familiar** with the new PMPRB changes

83%

of pharmaceutical executives said they were “**very familiar**”

“

*The single most prominent issue of our time.*

*I have been in the industry for 19 years, there has never been an issue that generated this level of concern.*

*It's a preoccupation in Canada but also in Global boardrooms.*

”

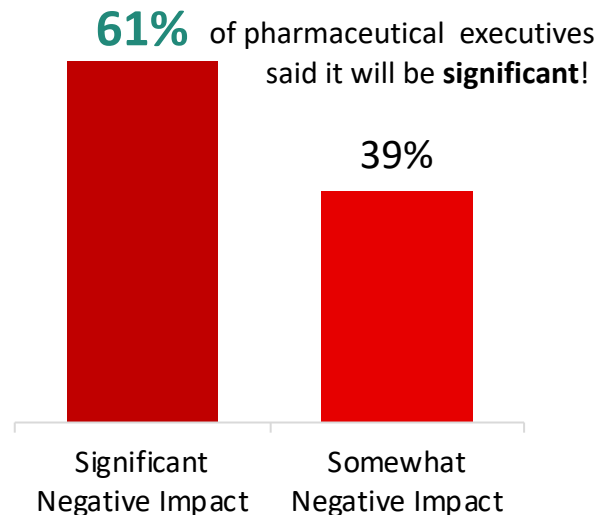
Q1. Overall, how familiar are you with the new PMPRB changes? (5-point scale: very familiar to not at all familiar) Base=46



# Findings refute the hypothesis that changes will have no negative impacts to business investments in Canada

## 100%

of pharmaceutical executives said PMPRB changes would have a **negative impact** on their overall business plans in Canada



Impacts are already felt by both larger Global and smaller Canadian companies

“

*We are a small Canadian company; we have already been impacted, putting product extensions on hold because of the uncertainty.*

*Our Global CEO visited Canada and articulated he doesn't see Canada in the same way. There are trust issues... Now we are seeing delays in decisions for Canada.*

”

Similar high results for Life Sciences executives with 80% indicating negative impact

Q2. Please indicate the level of impact that the PMPRB changes will have on your plans in Canada? (5-point scale: significant positive impact to significant negative impact) Base=46 “N/A” excluded from the analysis

# Executives explain PMPRB changes on business decisions

## WHY?

are the impacts expected to be so profound?

Lower pricing + higher uncertainty = unfavourable market conditions

“

*New guidelines want to put us in the middle of international pricing but [PMPRB] doesn't realize that you can't have that with the deeper public discounts we already provide and also apply the economic factor – this will put us at the lower end with Poland and Turkey which do not have access to new medicines.*

”

“

*It's January and in 6 short months these guidelines are supposed to come into effect. The economic factor is not known, it's hard to forecast and leaves us in an ambiguous place. When we consult with government, they don't have the answers, and it's leaving us confused.*

”

## Executives explain the need for market certainty

### WHY?

are the impacts expected to be so profound?

\$1M-

\$2.5M

investment requires  
ROI certainty

*“Our ROI is highly uncertain”*

“

*At a basic level if you want to launch a new product into the market, with regulation filing, the cost to go through Health Canada and pricing review, etc. it's \$1 million to \$2.5 million investment. That's an investment with 100% certainty of costs. Now it's hard to predict if the investments will produce revenues because of uncertainty.*

”

# Executives put Canada in context with global decision-making

## WHY?

are the impacts expected to be so profound?



*“Canada is a small player”*

“

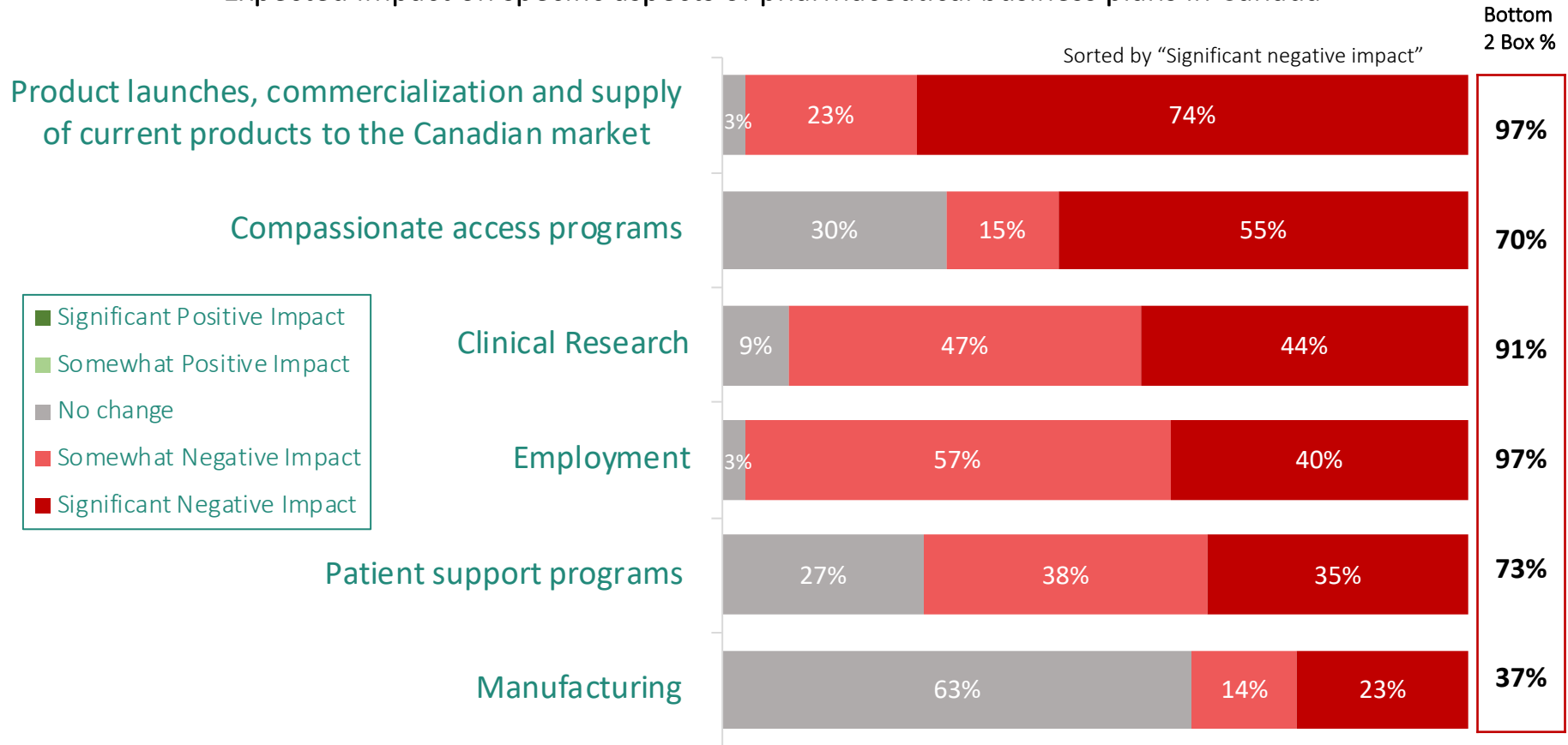
*Canada is a reference country in other markets and prices in Canada have an impact elsewhere in the world. Most of these markets are much larger than Canada and innovators will sacrifice the Canadian market to be able to retain value in the other markets.*

*Canada is 2% of the global market. The US is 50%. We are not going to risk the rest of the world for the sake of Canada.*

”

# Pharmaceutical executives expect impacts across business

## Expected Impact on specific aspects of pharmaceutical business plans in Canada



Q2. Please indicate the level of impact that the PMPRB changes will have on your plans in Canada? (5-point scale: significant positive impact to significant negative impact) Base=36 Only pharmaceutical executives asked (not Life Sciences Orgs) "N/A" excluded from the analysis

## PMPRB changes expected to have a “cascade effect”

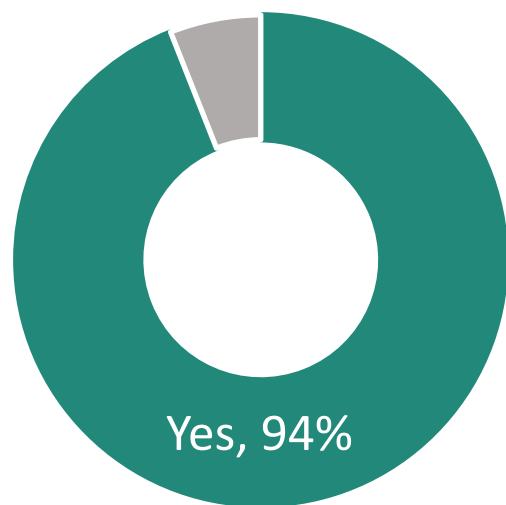


One pharmaceutical executive explained a “cascade effect” starting with delays around product launches ...

“ We intended to launch a new medicine in early 2021. Now that it’s clear our price will be dramatically reduced, we suspended our regulatory submission because the original business case and pricing assumptions have been challenged. ... It has a compounding problem, if not launched in a timely way, it will have impacts on staffing, training, hiring support, patient programs, etc. ”

# PMPRB changes will negatively impact product launches

Almost all pharmaceutical executives foresee both delays and no launch decisions



## 1-3 years

typically cited as expected delay

“Potentially 1-3 years based on the impact of Canada's price in other country's reference based pricing framework.”

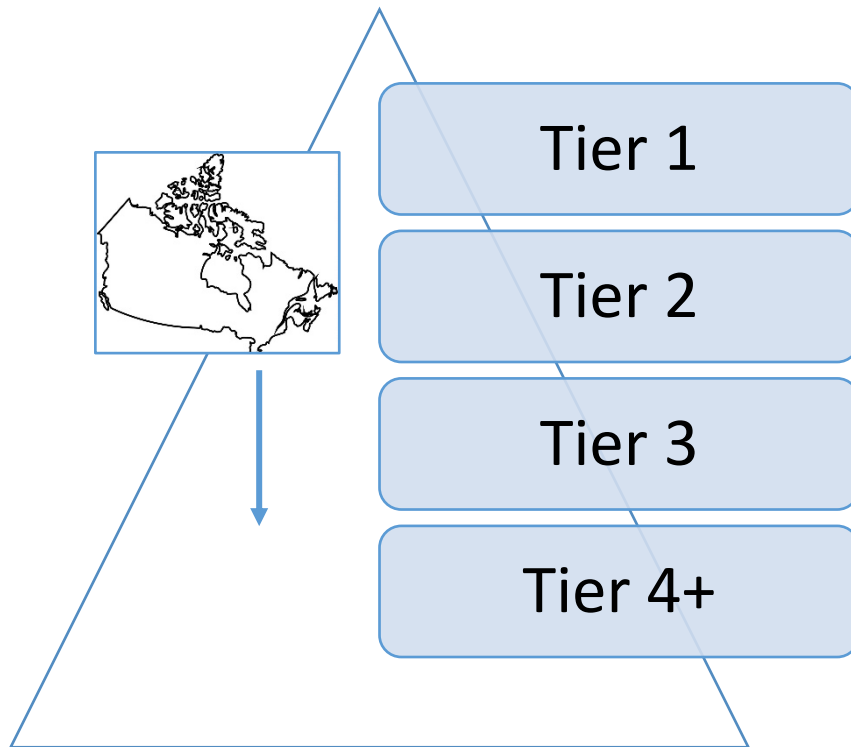
## No launch

“More decisions will be made to not launch at all vs delay because of the potential for broader harm to other larger markets.”

Q4. Do you foresee any of the following? “No launch” decisions for medicines in Canada? Delayed launches for medicines in Canada? (Yes/No), Base=36. If yes to delay, by how many months? Base=36

# Impact on Canada's position globally

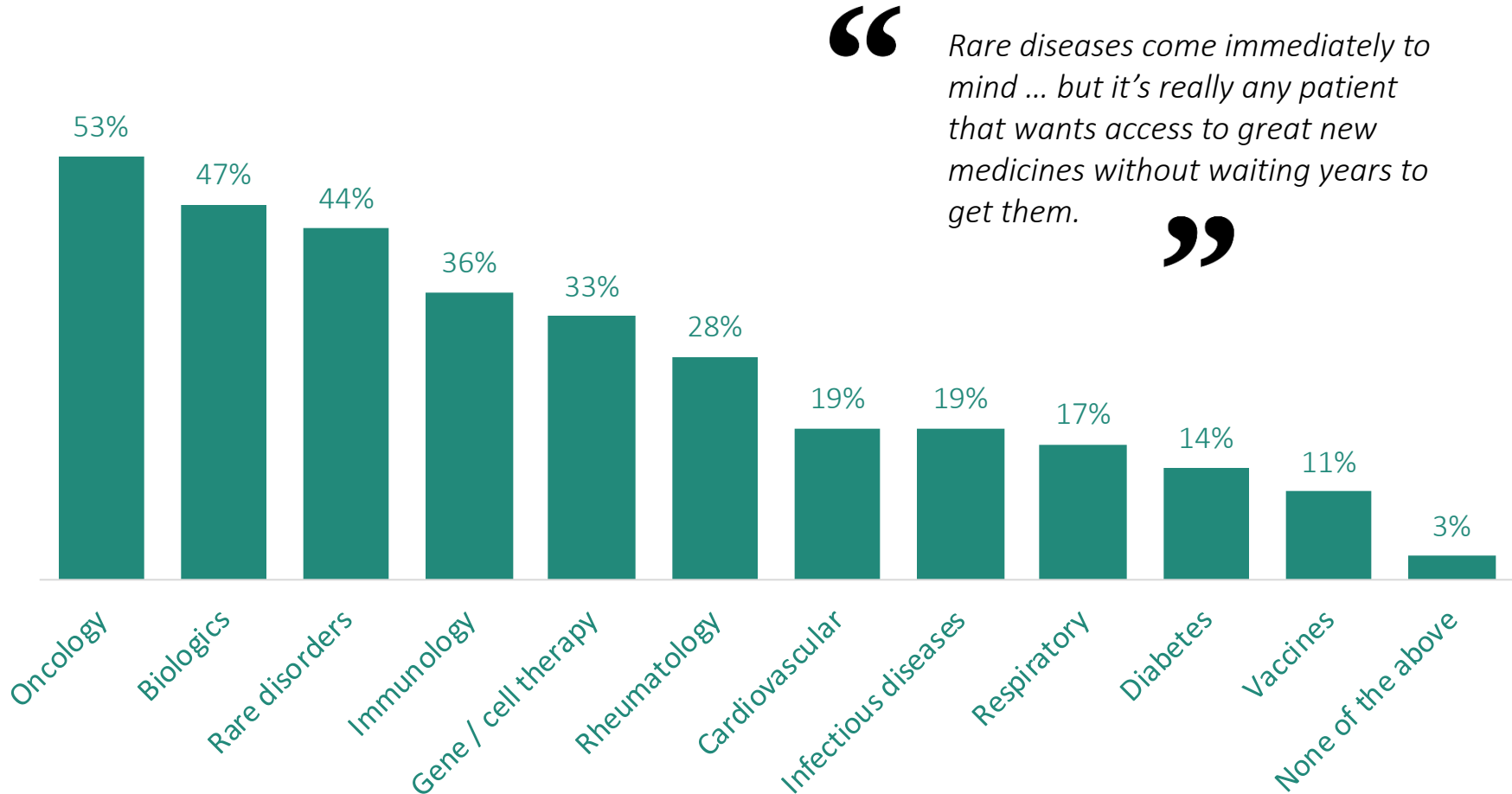
Pharmaceutical executives explain how PMPRB changes will impact Canada's global launch position



“ A lot of companies have tiered launch waves. Canada was always considered a Tier 1 or 2 country, launched either with or just after US, Germany, UK, etc. ...  
Now it will be several years later since there will be access challenges before you even get to reimbursement. We will move down to Tier 3 or 4, or even worse, not launched at all. ”



## Several therapeutic areas are likely to be impacted



Q5. Which of your therapeutic areas in Canada, if any, are likely to be impacted as a result of the new PMPRB changes?  
Base=36

## Everyday Canadians should care about this issue

“

*It goes to the heart of what we are here to do which is to ensure Canadians can access our medicines. It will significantly affect our ability to launch and launch in a timely way.*

*It's a shame that at this time where we now have truly revolutionary products such as potentially curing lung cancer that 5 years ago would have been unthinkable, that it's at this time the Canadian government is making a stand – right when we are at a tipping point. They see it as a budget issue but now we have personalized medicine and they don't even want to pay for testing. It's narrow thinking and it's wrong.*

*We are an ethical company. If we have a life saving product, it will be available in some form. But if it's not acute, not life and death, more chronic then there will be delays or reduction in choices. Only the sickest of the sick will get access. They are forcing us to make decisions we do not want to make.*

”

## Life sciences executives explain impacts on hospitals & patients

“

*Many of our out of hospital support programs will be negatively impacted if prices are rolled back or reduced (infusion clinics) which mean closures and increased wait times at hospitals.*

*Changes will reduce the number of innovative products available in Canada and over time impact Canada's place in the global pharmaceutical industry. This will impact clinical trials groups, opportunities for new graduates and patients.*

*The proposed changes to pricing of specialty and rare disease drugs can translate to reduced investment in vital and value-added patient support services for patients and will ultimately reduce access to life-saving treatment for these patients. The changes will also impact patients as manufacturers will not be able to offer the same assistance and support to patients through patient support services to patients.*

”

## Micro to Macro Impacts on Canada



“  
*We are different from bigger companies: we develop products here and have manufacturing and R&D here. If we don't launch here, the future of our company is at stake.*  
”

“  
*Canada is 2%-2.5% of the world's pharmaceutical market. It will drop to 1%-1.5%, essentially cut in half because of PMPRB. Launching product in Canada is less attractive*  
”

*There will be more layoffs, less investments, and fewer smaller companies going forward*

We employ **250 high paying employees** in Quebec alone, 35% are PhDs and 60% Masters, all tax payers. PMPRB threatens them plus another **300-400 suppliers** which is 500-600 jobs in the next 3 years in Quebec alone, not to mention the impact on their families.

## Final message to the Canadian Government

If you could only communicate one thing to the Canadian government about their intended PMPRB changes, what would it be?

*Unless you change these regulations, you will be hurting Canadian patients indefinitely. This harms patients – full stop.*

*It's a tragedy of this proposal that these policy proposals will create a great deal of problems for patients and for companies but won't save money for the government.*

*Changes are needed but they need to be well-planned. This is not well-planned and there is no time for transition.*



**Government  
of Canada**

*Be careful what you ask for and the consequences you get. You worked to make PMPRB relevant. You need to understand the consequences.*


*A good solution can only be done collaboratively between regulators and those providing the medicines. This is too blunt an instrument and will hurt patients.*



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# Thank you!

Rachelle Deshaies | [rachelle@researchetc.com](mailto:rachelle@researchetc.com) | 1.416.845.8565

Research etc.

## Business realities: Additional verbatim

*We estimate a 75% reduction in price for [one] of our medicines.*

*We are small and don't have the scale of big manufacturers to compete. This is adding another challenge to a challenging industry.*

*Globally we invest 25% in revenue to R&D. If we take 25% reduction or more in revenue, we have to relook at investments – researchers, vendors, suppliers, employment across the board.*

*Through case studies, price reductions would be 40-70% and no impact on jobs or investment. It's disingenuous to believe this – how can any industry withstand that kind of reduction?*

*We will need to remove a key revenue generating product, and first line treatment option in its therapeutic class, from the Canadian market as a result of the changes. The new price we will be required to charge is below our cost of goods.*

## No/ Delayed product launch: Additional verbatim

*Some products will not be launched at all in Canada. Even upcoming indications of currently approved products may not be launched in Canada.*

*Due to these pricing changes, Canada will likely be considered later in the launch sequence of countries, if at all.*

*We already have major challenges convincing our global headquarters to invest in Canada because it takes very long to get public reimbursement, but now we also have this great uncertainty about prices. I am afraid Canada will lose its place as a preferred country to launch new products - that's bad for us and bad for patients.*

*We are planning to delay the launch of [a new medicine] from 2020 to 2021 and perhaps until 2022. If we cannot get an acceptable price, then we will not launch the product in Canada despite the significant investments made by the company in Canada. Furthermore, our early access program for this medication is not likely to start. Canada is not a favorable launch environment at this point.*

*We have delayed launch of two significant innovative products due to uncertainty around the regulatory environment and the lack of predictability and stability around establishing a fair price in Canada. With no new products coming to Canada, planned significant expansion has been halted.*

Verbatim from written survey responses from N=36 respondents as well as insights from Qualitative IDIs with N=10 pharmaceutical executives



## Clinical trials: Additional verbatim

*Will not do clinical trials for risk of having to keep patients on therapy in perpetuity without prospects of reimbursement at an acceptable price.*

*This will also affect the number of clinical trials we will be able to attract to Canada.*

*Is it ethical to expose patients to clinical studies if the company's product might not make it here?*

*These regulatory changes will negatively impact the world-class clinical trial network developed in Canada and will limit our industry's ability to invest in innovative R&D and high value jobs in the life science sector.*

*We have operations around the world and chose where to conduct clinical trials. We select accommodating environments. Canada is deemed a "bad market". It's a mess right now. Same applies to manufacturing.*

Verbatim from written survey responses from N=36 respondents as well as insights from Qualitative IDIs with N=10 pharmaceutical executives





# New Medicine Launches: Canada in a Global Context

June 22, 2020

Prepared by IQVIA Canada  
Real World Solutions Consulting Group

# Detailed Report

+ **Project Objectives and Approach**

+ **Results**

+ **Summary**

# In light of proposed drug pricing policy changes, we wish to examine where Canada stands globally in terms of access to novel pharmaceuticals

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## INTRODUCTION

- The topic of **Canada's access to medicines** has been hotly debated in the past few years, particularly in light of significant **federal proposals for policy changes on pricing pharmaceuticals**
  - This research was undertaken to set a benchmark of where Canada stood globally in terms of access to novel pharmaceuticals and to examine more recent indicators of change in the availability of new product launches
  - We took a data-driven approach and leveraged IQVIA's global launch and sales database (MIDAS®) to understand Canada's position in global launch sequencing decisions over the last 20 years
- 

## KEY QUESTIONS

- **How does Canada compare to international markets in terms of time to launch, proportion of launches and sequence in launch?**
- **Have we seen changes in Canada in the recent years following these policy announcements?**

## MIDAS® data was used to analyze launch sequencing of new active substances over the last 20 years from 2000-2019

### Data Extraction

1

- 20 years: January 1, 2000 to December 31, 2019
- Top 25 countries by 2019 sales (where data is available)
- Launch date by country
- New active substances (novel active ingredients launched globally)

### Key Metrics

2

- Place in launch sequence
- Time to launch by country
- Proportion of new active substances launched by country

### Sub-analyses

3

- Time series analyses
- Subgroups:
  - Best-selling\* medicines
  - Biologics
  - Oncology & Other TAs

\*Top 50 new active substances by 1st year sales in US during 2010-2019 are defined as best-selling 35 new medicines

# The IQVIA MIDAS® database is the gold standard source of pharmaceutical data, used across the industry and governments



MIDAS Global  
Data Analysis

*IQVIA  
National  
Audits*

*The trusted industry gold standard in global market measurement*

93	152	7K+	250K+	4M+
Countries	Distribution Channels	Active Ingredients	Global Medicines	Packs
12 years of running data available	95% precision at global level	Monthly tracking of volume and value		
Local presence and support	Independent and consistent	Full pack and product harmonization		
120 production heads in 7 countries	Complete view of competitive landscape	Full cross-country comparability		

\* MIDAS®: Multinational Integrated Data Analysis System

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## The top 25 countries were identified by global pharma market sales in 2019 and launch date is defined as date of first sales and/or manufacturer launch

Top 25 Countries by Global Pharma Market Sales in 2019	
No.1 USA	No.14 AUSTRALIA
No.2 CHINA	No.15 SAUDI ARABIA
No.3 JAPAN	No.16 POLAND
No.4 GERMANY	No.17 TURKEY
No.5 FRANCE	No.18 MEXICO
No.6 ITALY	No.19 SWITZERLAND
No.7 UK	No.20 BELGIUM
No.8 BRAZIL	No.21 AUSTRIA*
No.9 CANADA	No.22 ARGENTINA
No.10 SPAIN	No.23 SWEDEN*
No.11 INDIA	No.24 THAILAND
No.12 RUSSIA	No.25 TAIWAN
No.13 KOREA	

\* Austria, Sweden and Netherlands are not included in the analysis due to launch data quality

Data Source: IQVIA World Review Preview 2020 – Worldwide Pharma Markets

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### Definition of Launch Date

**Launch Date** was defined as:

- The date from which sales first begin to accumulate

AND/OR

- The reported date of launch by manufacturer where available

Note: Launch date is irrespective of channels (retail or hospital) or payers (public or private)



## New active substances (NAS) first launched and available globally within 2000-2019 are included

### Inclusion Criteria

- Global first launch at the molecule level in 2000-2019
- For use in human therapy
- Has been approved by officially recognized governmental bodies (e.g. FDA)
- Is commercially available in at least one of these three regions (US, Europe or Canada)
- Global first launched branded pharmaceutical



### Exclusion Criteria

- Generics and Biosimilars
- New indication of existing substance
- New combination of existing substance (aka fixed dose combos)
- New salt, hydrate, crystalline form, formulation etc. of previously approved substance
- Not an active substance (e.g. drug delivery system)
- Natural product, tissue or plant extract with no identifiable therapeutic entity
- Blood products, vaccines, or natural health products/vitamins
- Products that launched in only ONE country
- Products/countries where data not available

NAS: New active substance

# Medicines were categorized into 12 key therapeutic areas based on first global launch indication to facilitate further subgroup analyses



## Gastrointestinal System

Examples: Antidiabetics (Januvia), IBD (Entyvio), Antiemetic (Aloxi), etc.



## Blood Coagulation

Examples: Antithrombotic agents (Apixaban), Antidote to anticoagulants (Praxbind), etc.



## Cardiovascular System

Examples: Calcium antagonists (Cleviprex), Diuretics (Vaprisol), etc.



## Dermatologicals

Examples: Anti-psoriasis (Taltz), Anti-inflammatory (Dupixent), etc.



## Hormonal Preparations

Examples: Hormonal contraceptives (Ortho Evra), Antigrowth hormone (Signifor), etc.



## Systemic Anti-infectives

Examples: Antifungal (Posanol), Antiviral (Harvoni), etc.



## Musculo-Skeletal System

Examples: Antirheumatic (Xeljanz), Antigout (Fasturtec), etc.



## Nervous System

Examples: Antipsychotic (Abilify), Antimigraine (Aimovig), etc.



## Respiratory System

Examples: Antiasthma (Nucala), COPD (Xolair), etc.



## Ophthalmic System

Examples: Wet AMD (Lucentis), Antiglaucoma (Vyzulta), etc.



## Oncology

Examples: Checkpoint inhibitor (Keytruda), Anti-VEGF (Avastin), etc.



## Other Immunosuppressants

Examples: Anti-TNF (Cimzia), Selective Immunosuppressant (Benlysta), etc.



### Note:

- Products with multiple indications were classified based on indication for the first global indication based on ATC classification
- Drug classes like antiparasitic, diagnostic agents, non-hormonal gynecological drugs etc. were combined under "Other" therapeutic class

NAS: New active substance

# Detailed Report

+ Project Objectives and Approach

+ Results

+ Summary

# This report outlines relevant findings from MIDAS® global data analysis for all new medicines and relevant subgroups

## Analysis Outputs



### Canada's Position in Global Launch Sequence

- Proportion and Time to Launch
  - All New Active Substances Launched Globally
  - Best-Selling New Active Substances Launched\*
  - Biologic New Active Substances Launched
  - Oncology New Active Substances Launched
- Other Key Therapeutic Areas
- Observed Country Grouping



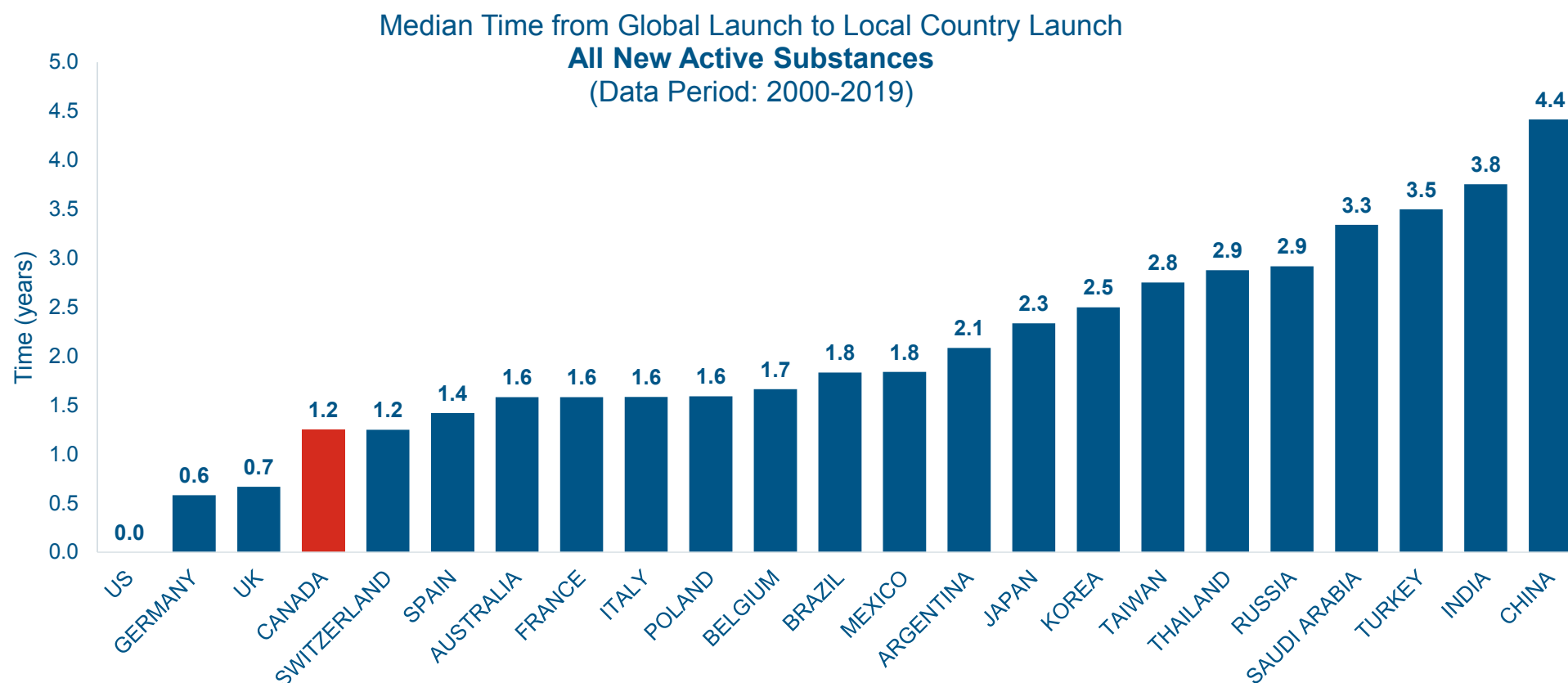
### Launch Sequence Over Time

- Canada's Launch Sequence Over Time
- Canada's Launches vs Global Launches over time

\*Top 50 New Active Substances by 1st year sales in US during 2010-2019 are defined as best-selling drugs

NAS: New active substance

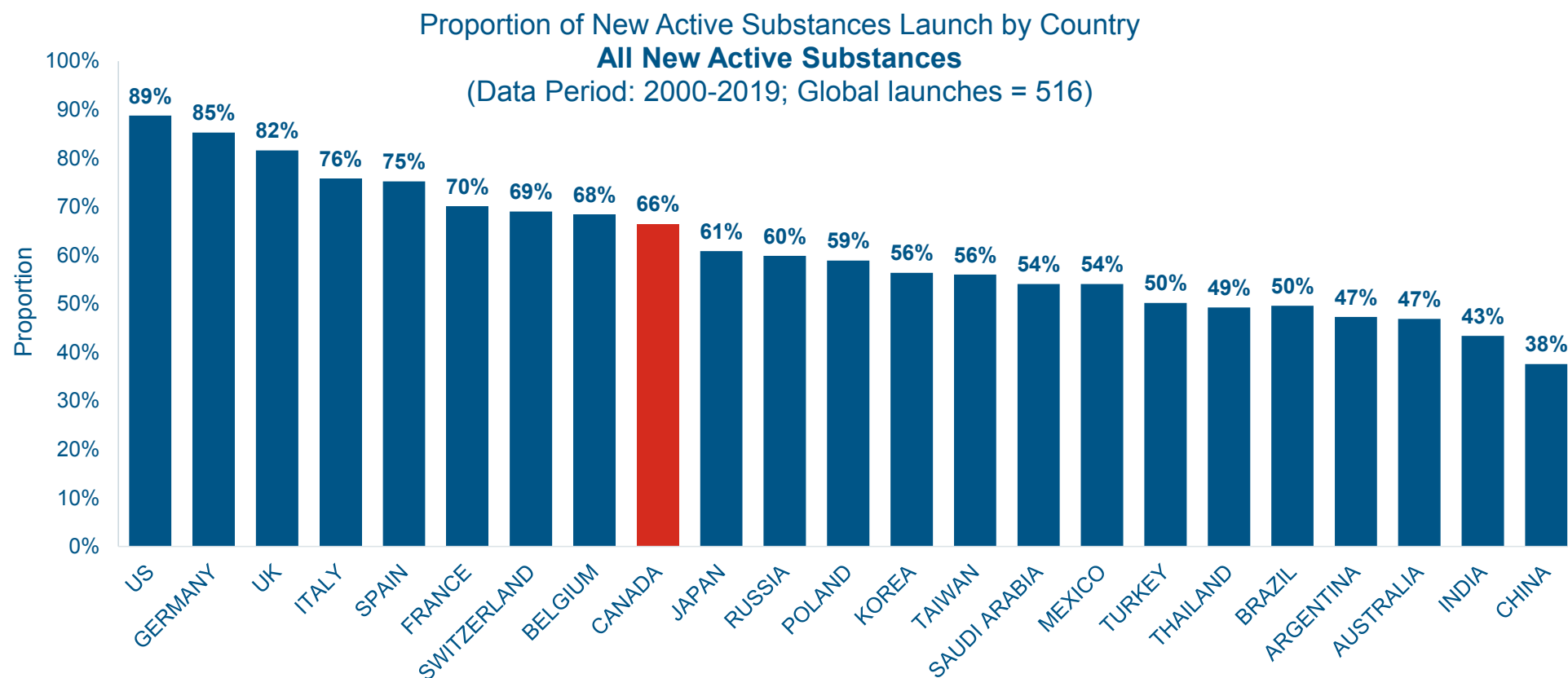
## Canada ranked 4<sup>th</sup> to launch a new active substance just behind US, Germany and UK; with a median 1.2 years lag from first global launch



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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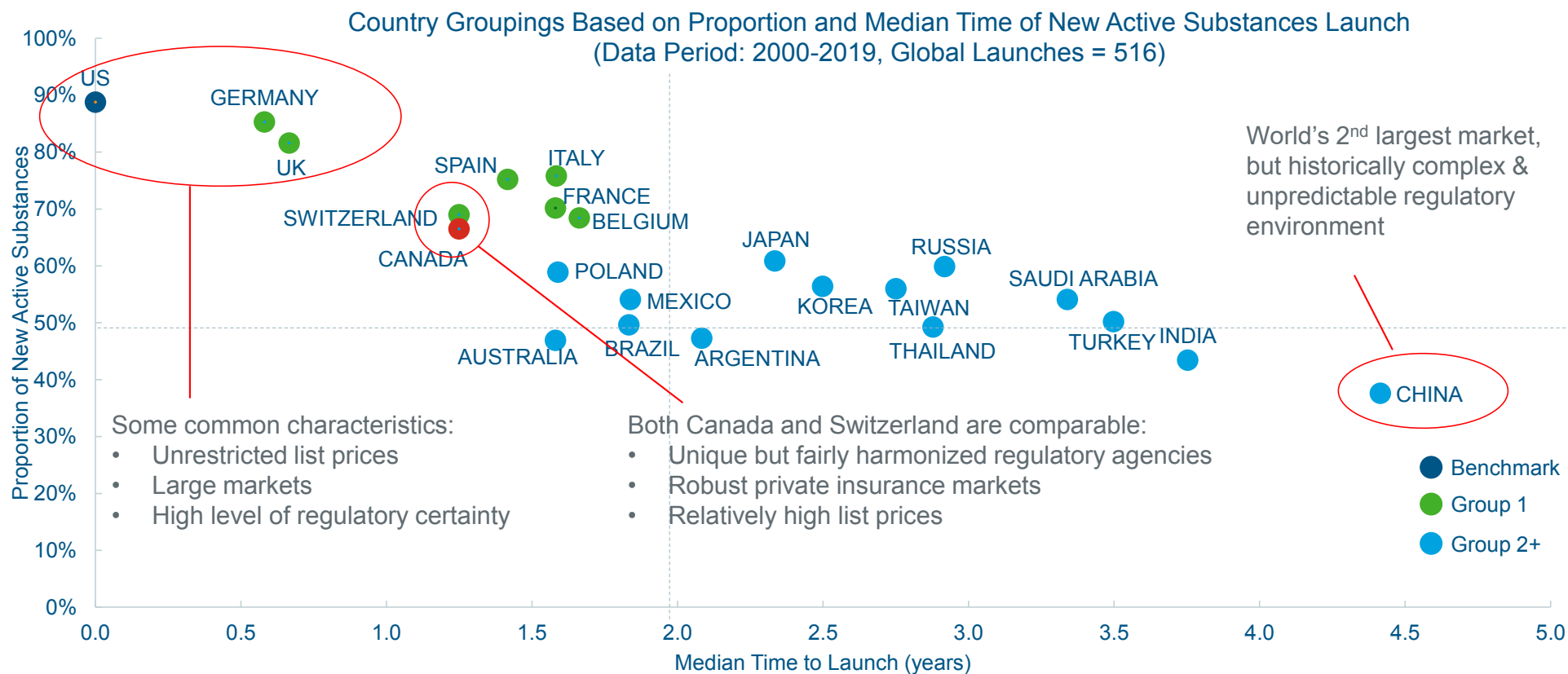
**Canada ranked 9<sup>th</sup> based on proportion of new medicines launched globally, with 66% launched in the last 20 years, versus the US, leading at 89%**



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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## Canada is grouped with Switzerland following UK and Germany, as countries with a higher number of launches and shorter median time to launch



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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Looking at the top best-selling new active substances, Canada still ranks 4<sup>th</sup> with median time to launch shorter at 0.7 years from first global launch

## TOP 50

Median Time from Global Launch to Local Country Launch  
**Top 50 Best-Selling New Active Substances\***  
 (Data Period: 2010-2019)

\*Top 50 by 1<sup>st</sup> year sales in US during 2010-2019 are defined as best-selling drugs



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance.

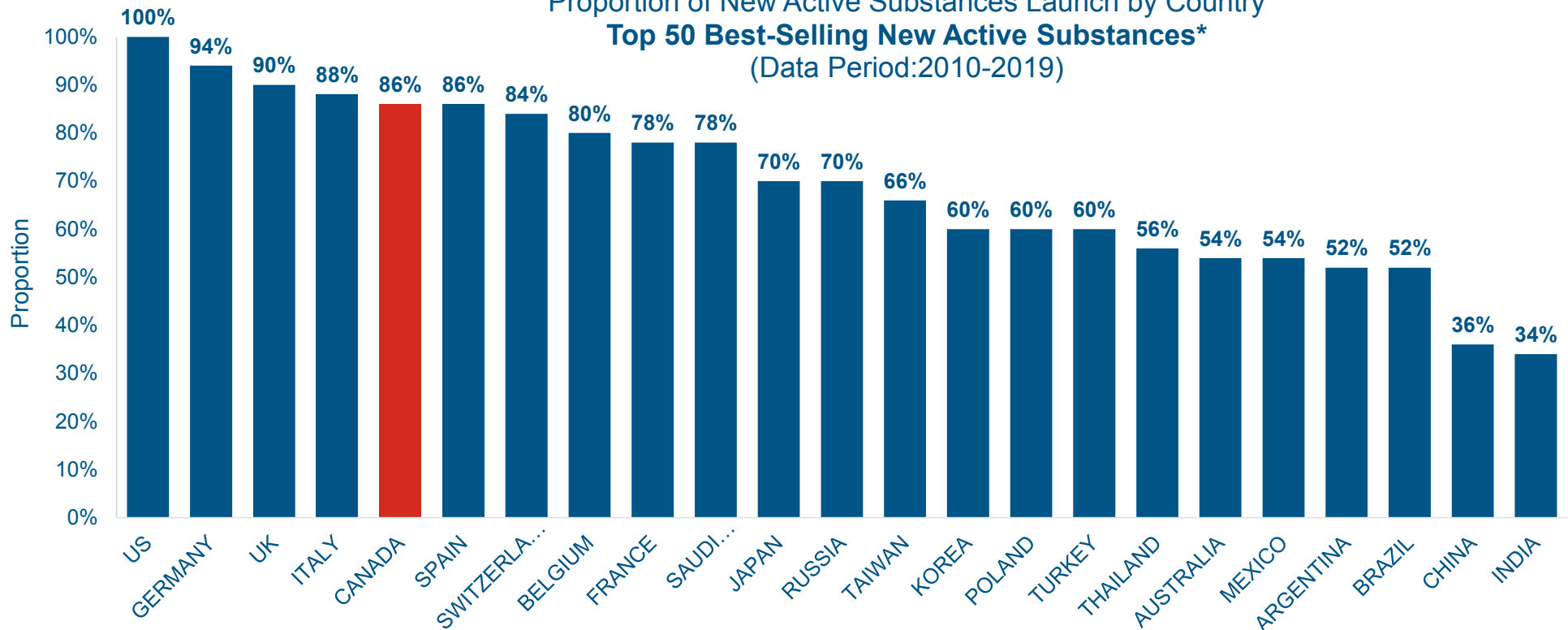
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## Canada launched 86% of the top 50 best-selling global new active substances over the last 20 years, ranking 5<sup>th</sup> globally

### TOP 50

Proportion of New Active Substances Launch by Country  
Top 50 Best-Selling New Active Substances\*  
(Data Period:2010-2019)

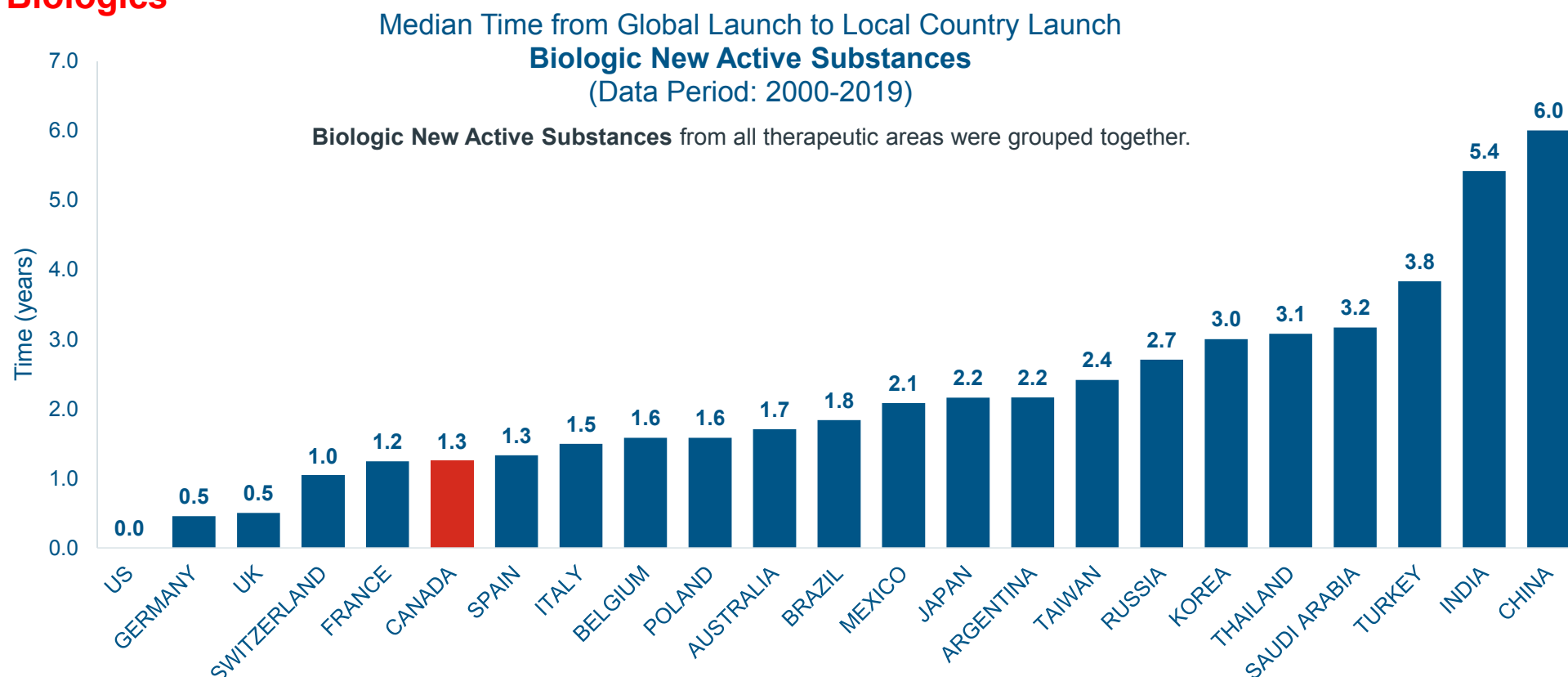


IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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# Canada ranked 6<sup>th</sup> in median time to launch for new biologics, at 1.3 years from first global launch

## Biologics

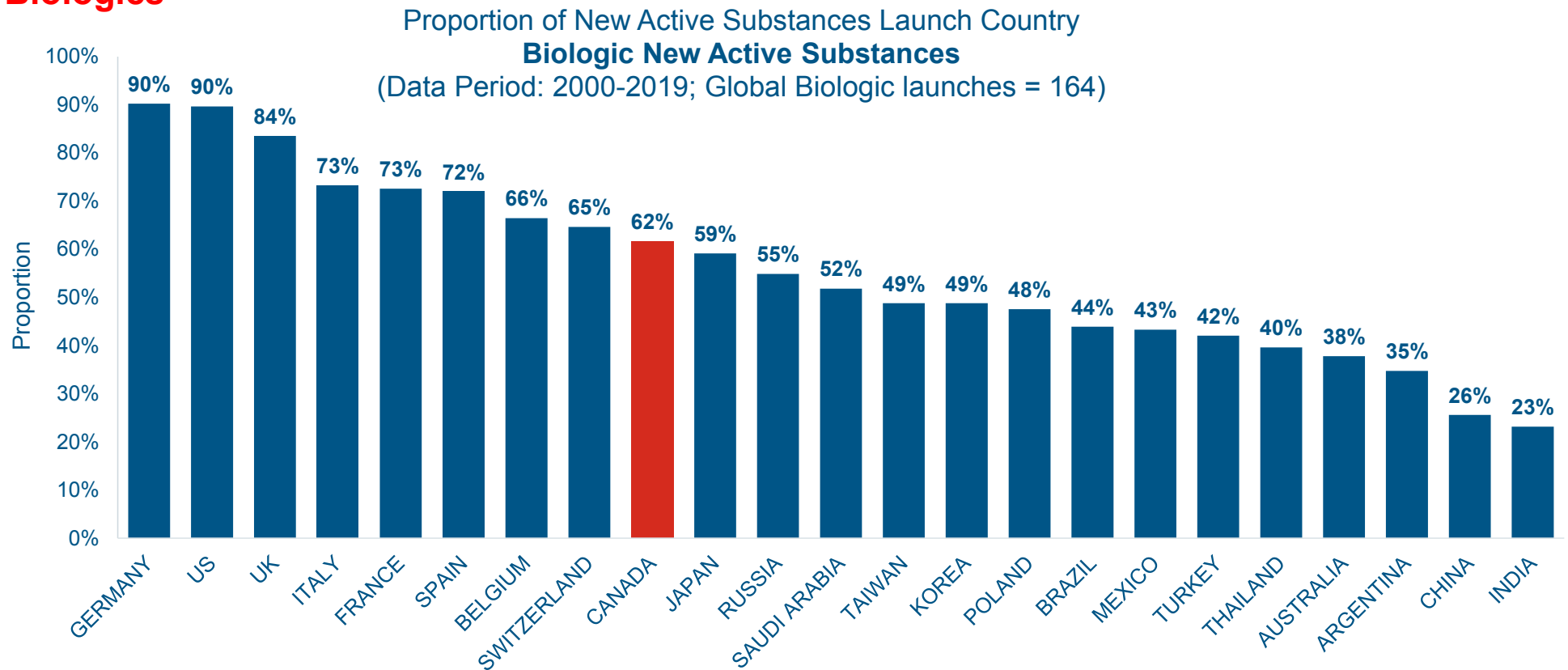


IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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# Canada launched 62% of all new biologics over the last 20 years, ranking 9<sup>th</sup> globally

## Biologics



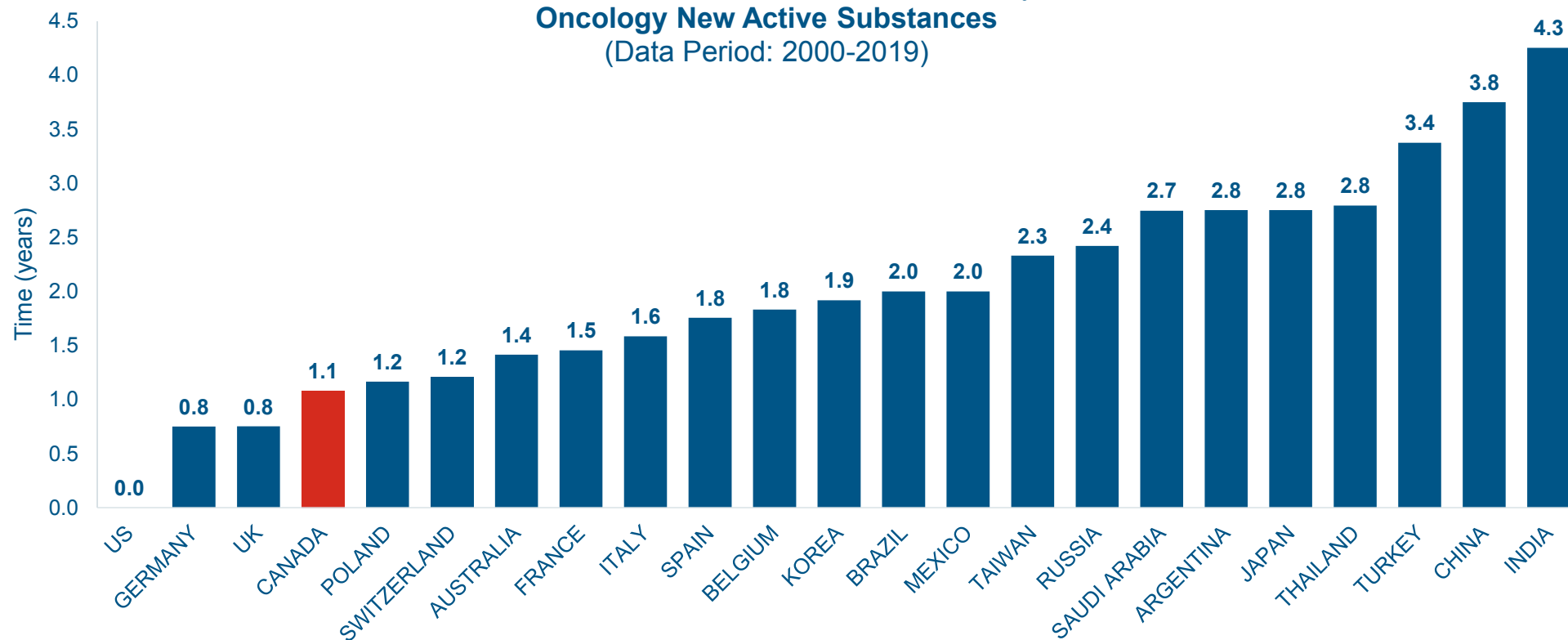
IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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# Canada ranked 4<sup>th</sup> in median time to launch for new Oncology medicines, at 1.1 years from first global launch

## Oncology

Median Time from Global Launch to Local Country Launch  
**Oncology New Active Substances**  
 (Data Period: 2000-2019)

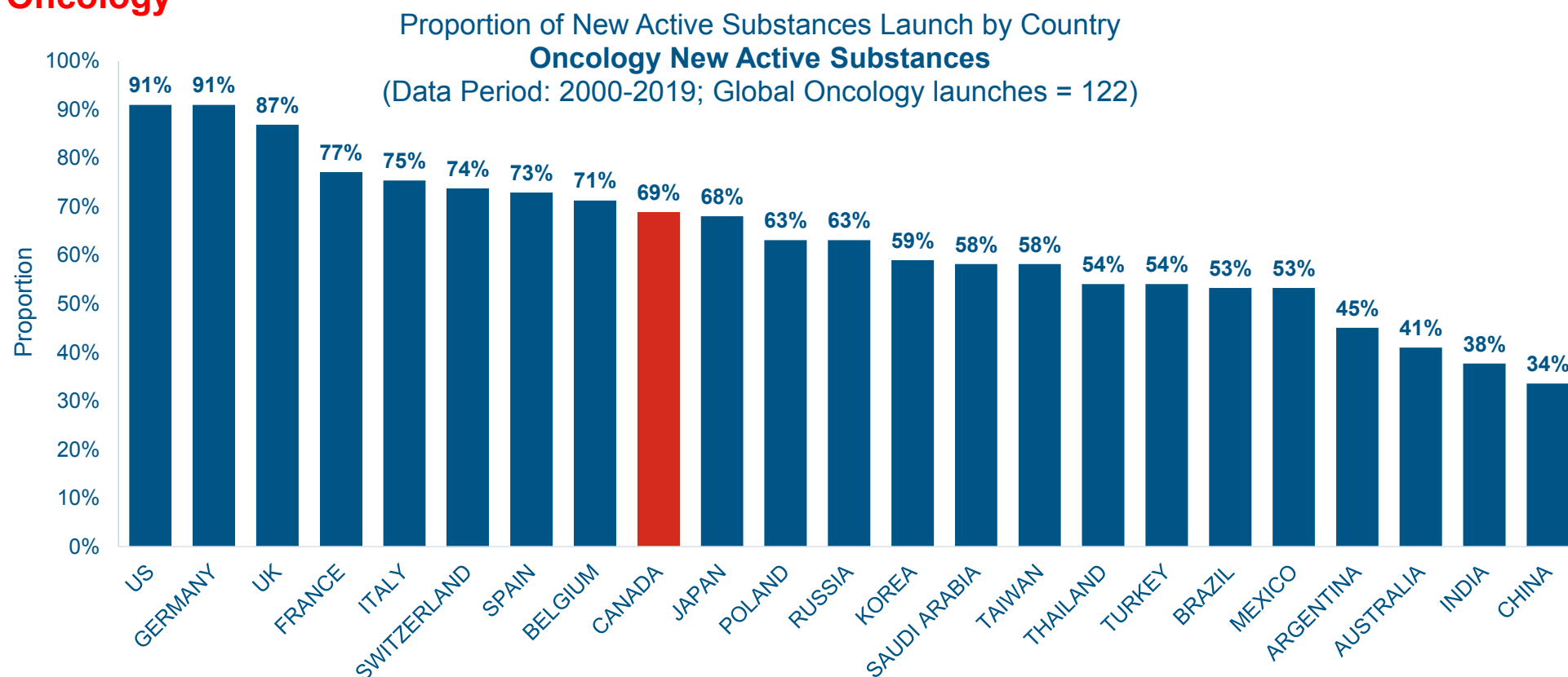


IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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# Canada launched 69% of all Oncology New Active Substances over the last 20 years, ranking 9<sup>th</sup> globally

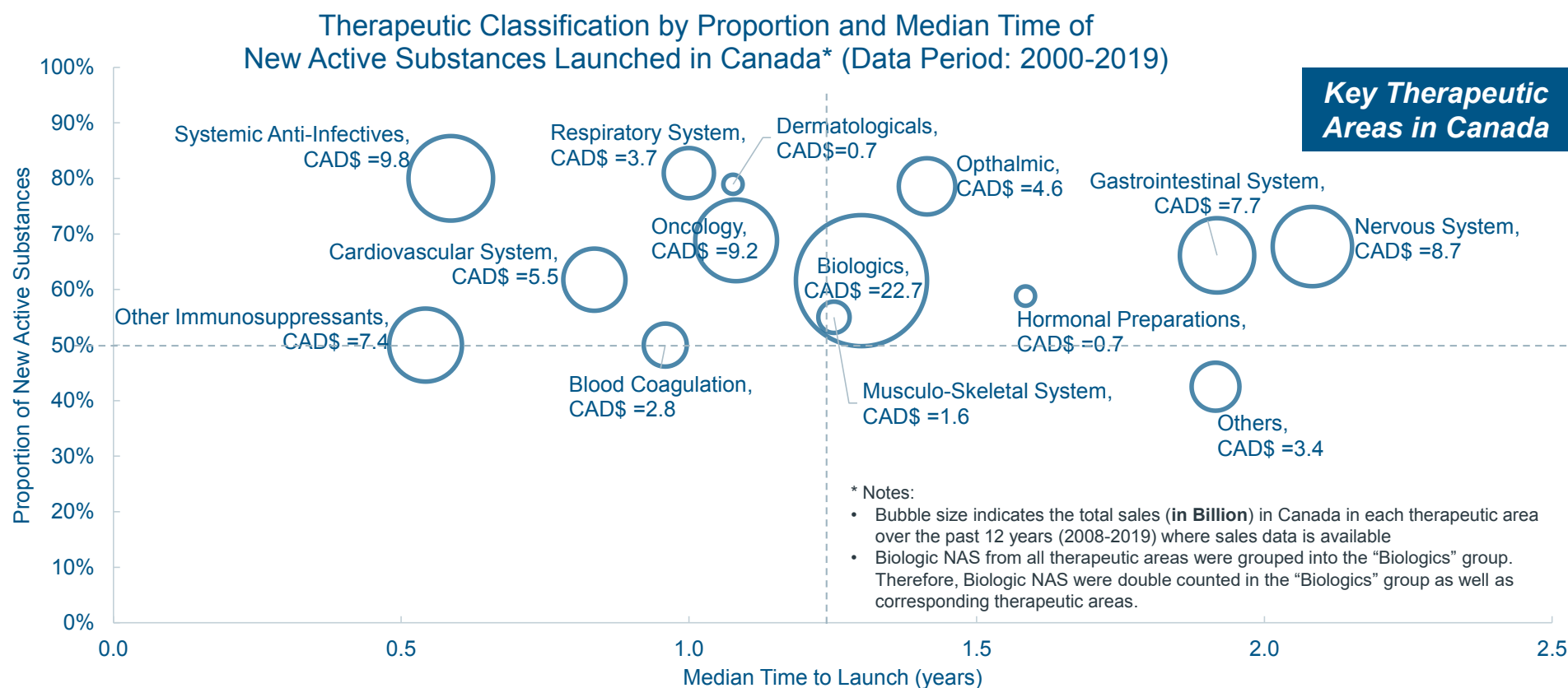
## Oncology



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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# In Canada, systemic anti-infectives achieved the best time and proportion of launches compared to any other therapeutic class



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# This report outlines relevant findings from MIDAS® global data analysis for all New Active Substances and relevant subgroups

## Analysis Outputs



1

### Canada's Position in Global Launch Sequence

- Proportion and Time to Launch
  - All New Active Substances Launched Globally
  - Best-Selling New Active Substances Launched\*
  - Biologic New Active Substances Launched
  - Oncology New Active Substances Launched
- Other Key Therapeutic Areas
- Observed Country Grouping

2

### Launch Sequence Over Time

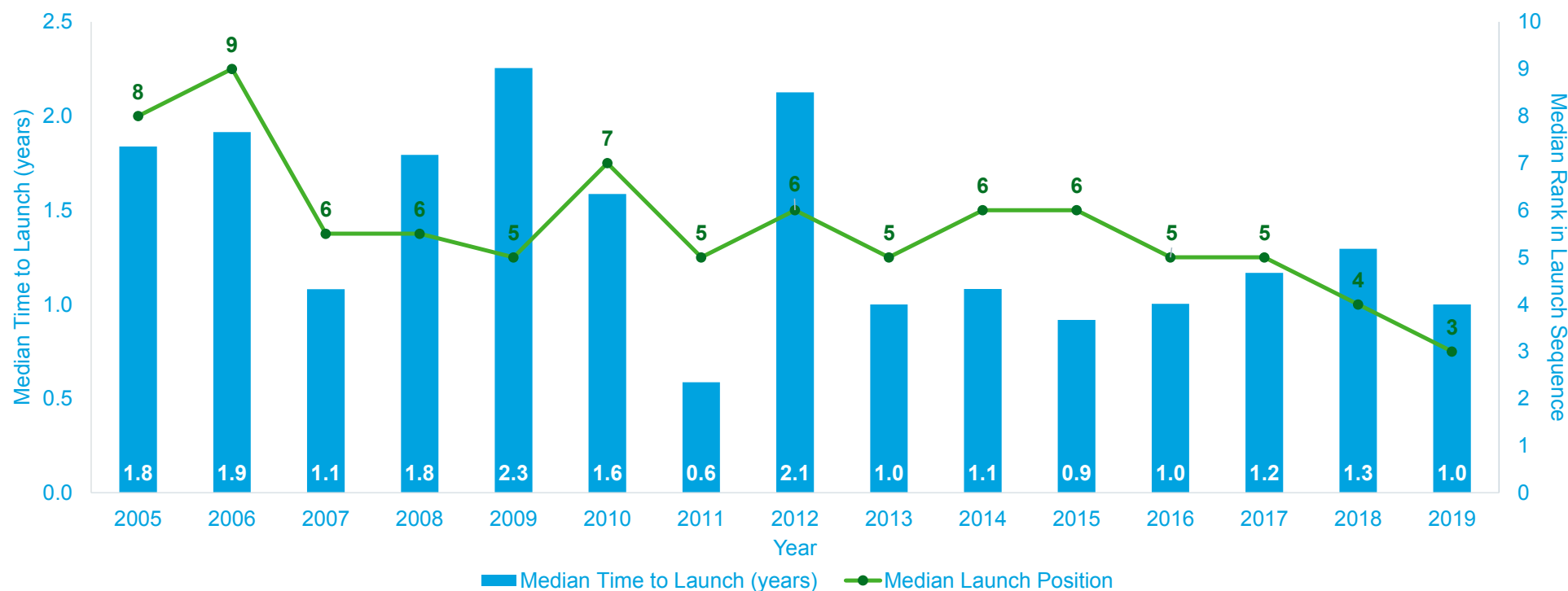
- Canada's Launch Sequence Over Time
- Global Launch Sequence Over Time

\*Top 50 by 1st year sales in US during 2010-2019 are defined as best-selling drugs

NAS: New active substance

## Median time to launch and rank have steadily improved for new medicine launches in Canada in the last 10 years

Yearly Trend of Median Time to Launch and Median Launch Position in Canada  
(Data Period 2005 – 2019)



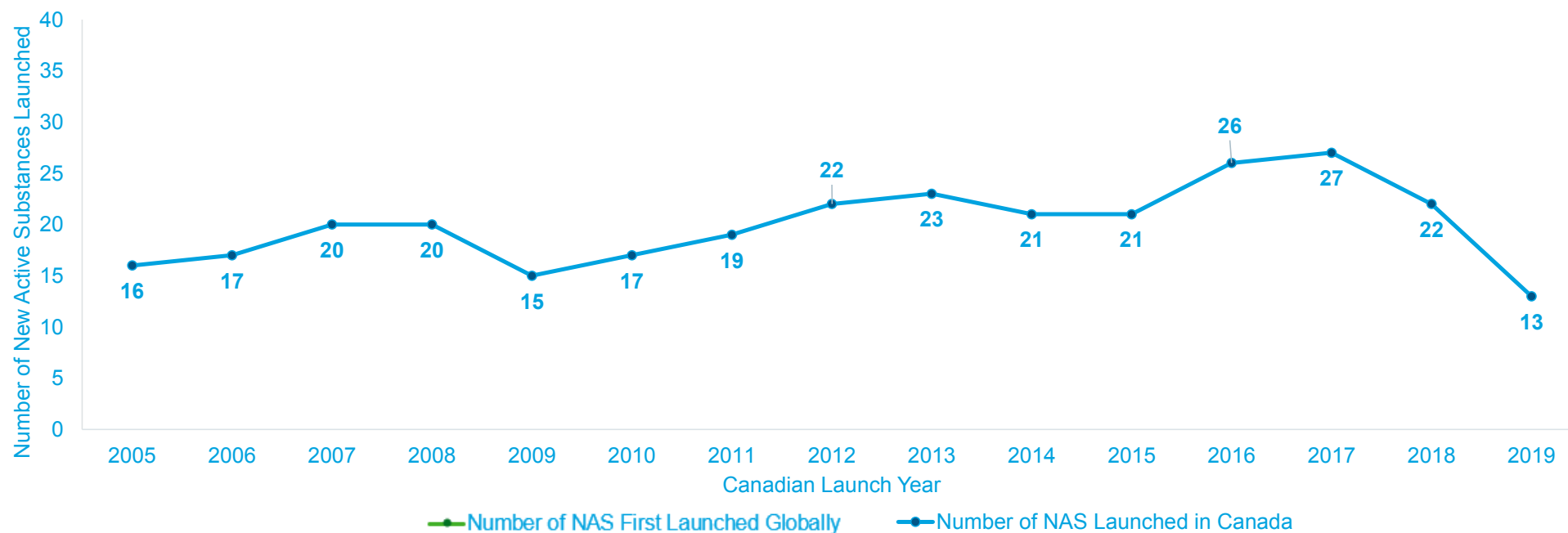
IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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## While steadily climbing for most of the study period, annual new drug launches in Canada dropped significantly in 2019

Yearly Trend of Number of New Active Substances  
Launched in Canada and Globally (Data Period: 2005 – 2019)

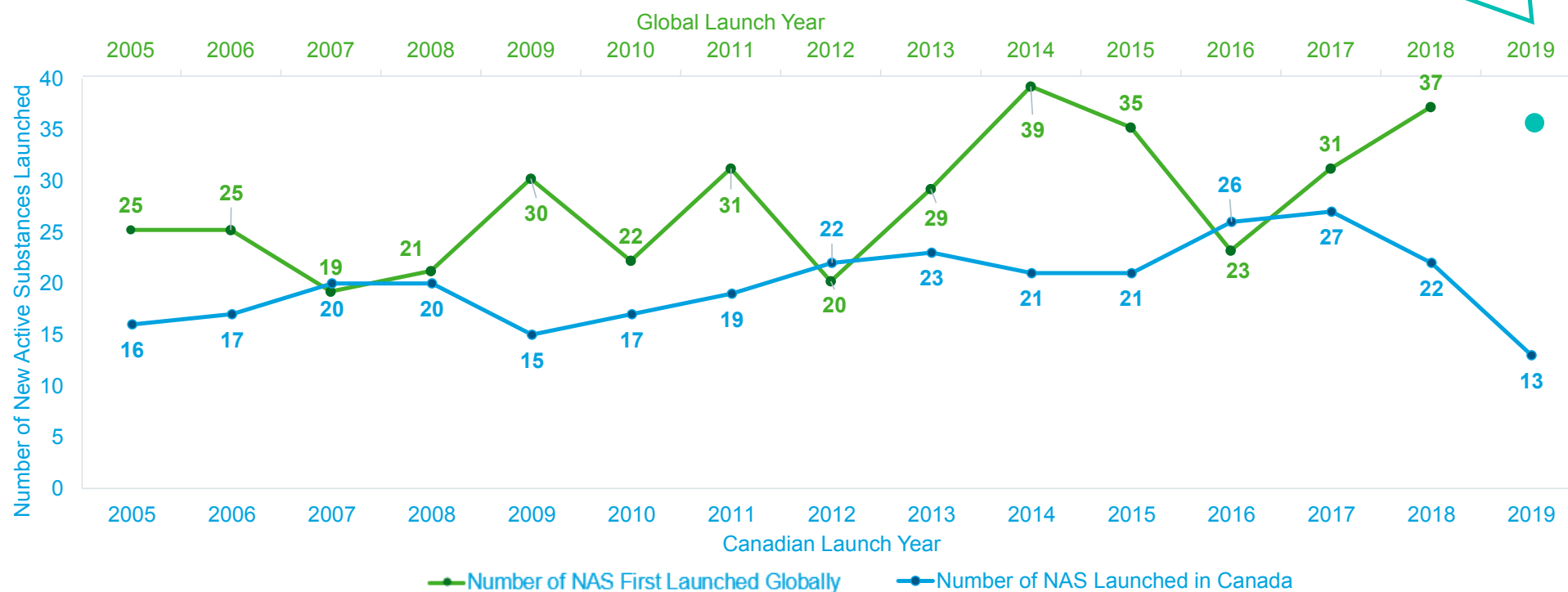


IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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## Globally, we see a different trend, with global launches on the rise

Yearly Trend of Number of New Active Substances  
Launched in Canada and Globally (Data Period: 2005 – 2019)

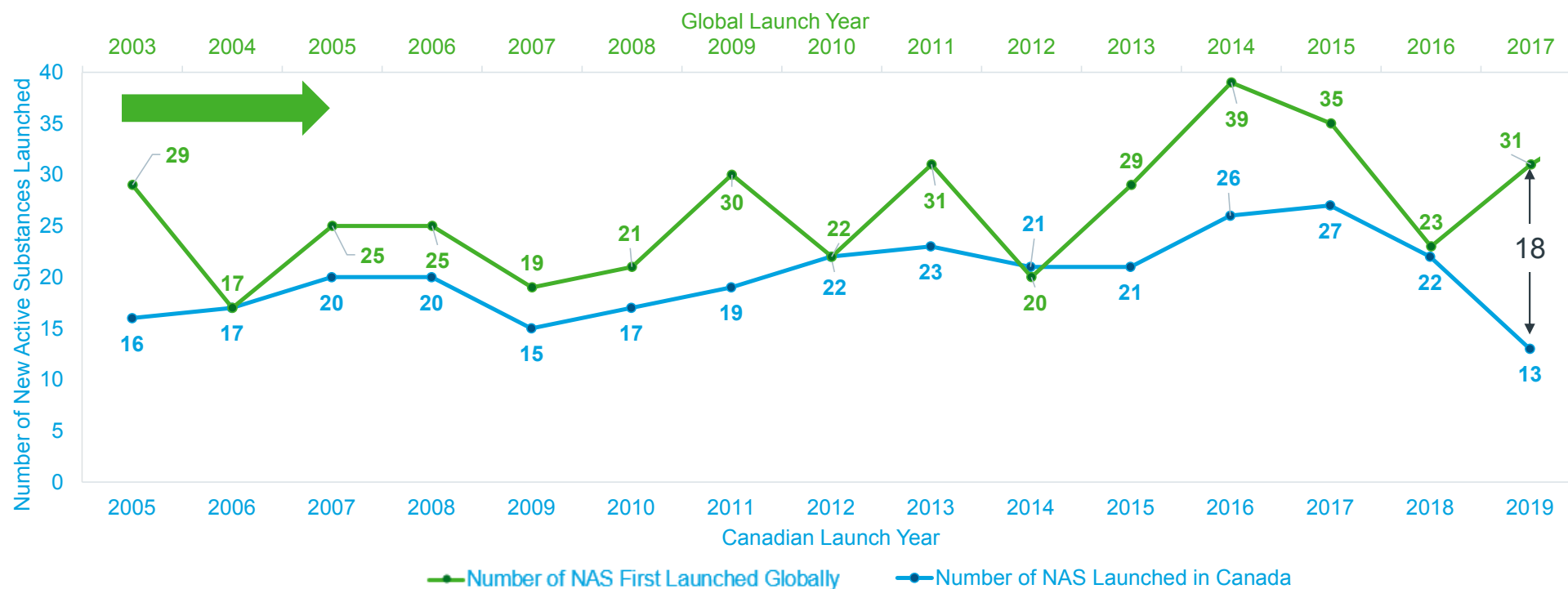


IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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**By directly comparing Canadian launches with global launches from 2 years past, the correlation, and drop in 2019, becomes far more apparent**

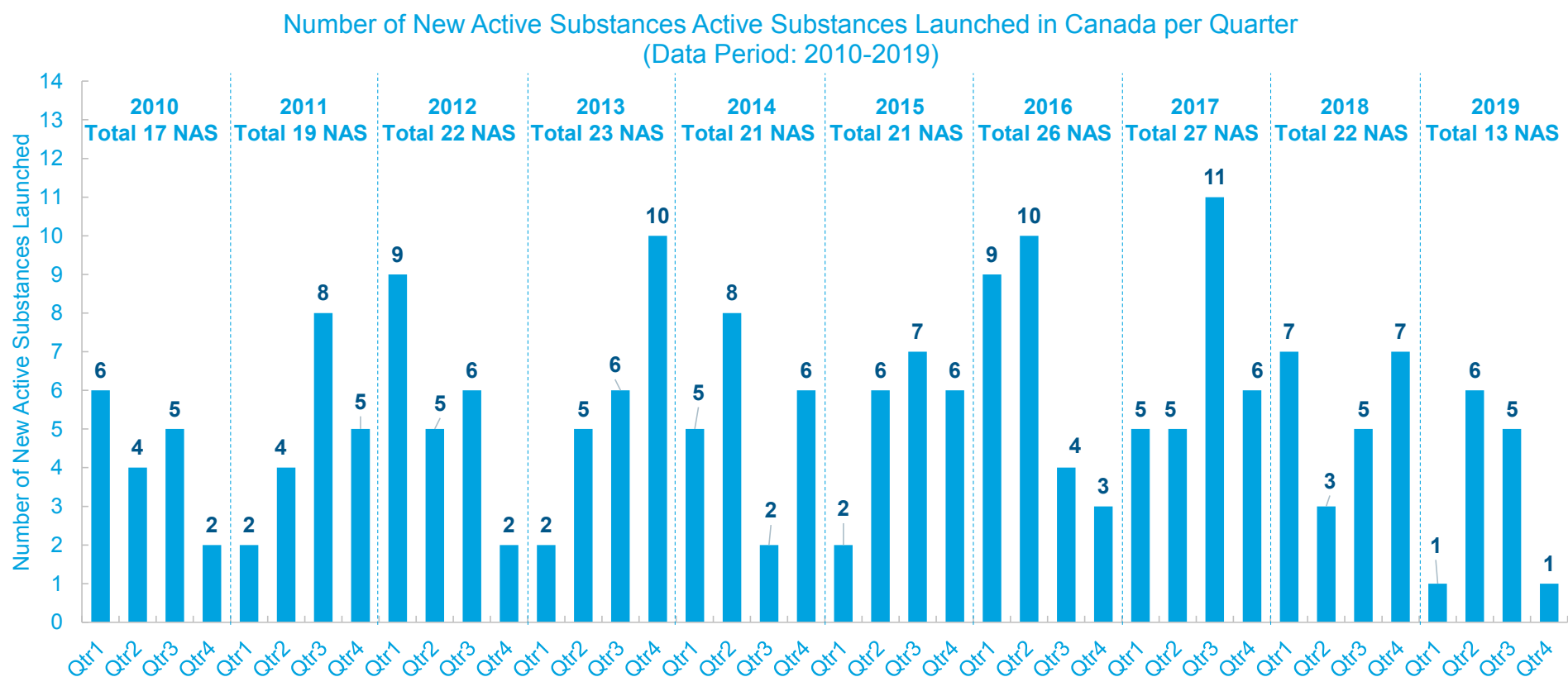
Yearly Trend of Number of New Active Substances Launched in Canada and Globally  
(Data Period: 2005 – 2019)



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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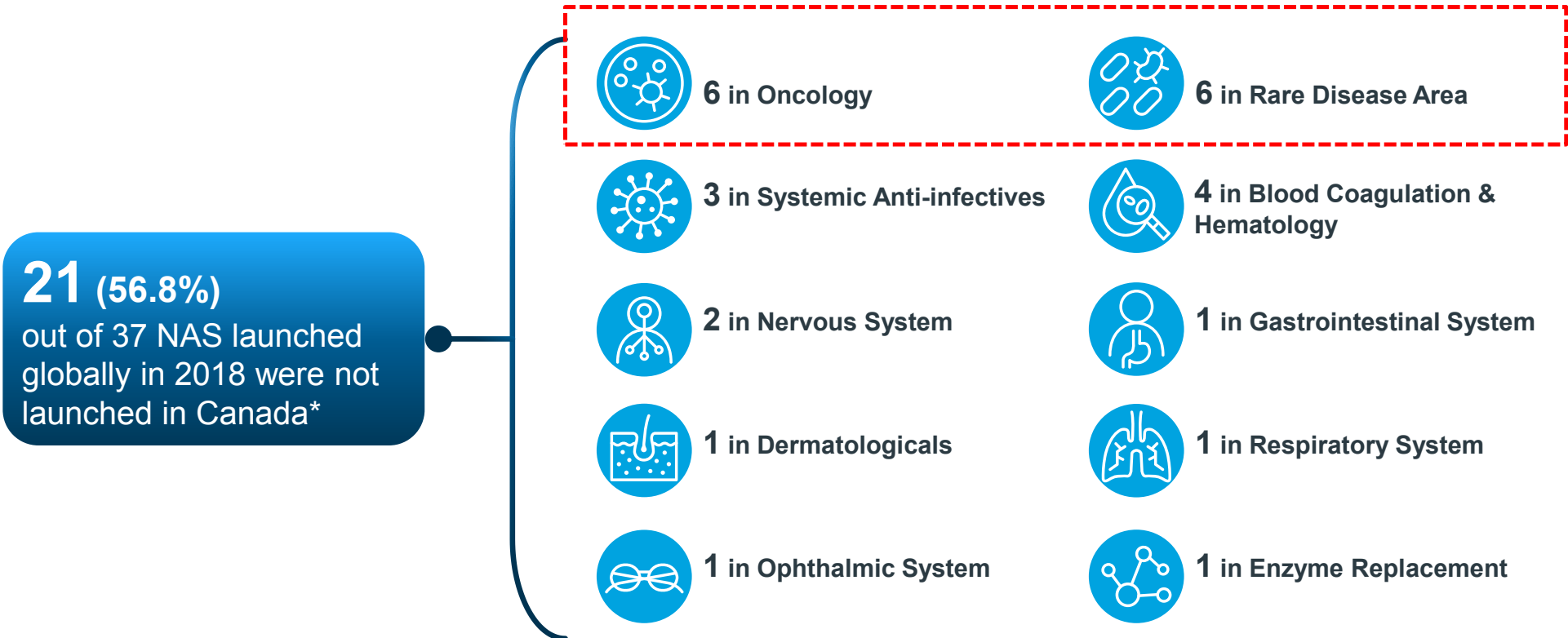
**Looking in more detail, 2019 saw two single-launch quarters, the first time we saw a single-launch quarter in the past 10 years**



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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## Among 37 new medicines launched globally in 2018, over half of them were not launched in Canada, the majority of those were in oncology and rare diseases



\* NAS from all therapeutic areas were grouped into the “Rare Disease Area” group according to FDA news release. Therefore, NAS in rare disease area were double counted in the “Rare Disease Area” group as well as corresponding therapeutic areas.

1 NAS was grouped into “Others” and not listed here.

IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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# Detailed Report

+ Project Objectives and Approach

+ Results

+ Summary

# Canada is a top tier launch destination, ranking 4<sup>th</sup> in median time to launch, receiving 67% of all global launches, although 2019 saw a sharp decline

## Global Launch Sequence

- Canada ranked 4<sup>th</sup> in median time to launch (1.2 years) and 7<sup>th</sup> in average time to launch (2.2 years) amongst the top 23 countries between 2000 to 2019
- The US remained the benchmark, recording the most launches, and typically being the first to launch over the past 20 years
- In the EU, Germany was typically the first to launch, closely followed by the UK



## Therapeutic Areas

- Canada ranked highest in **systemic anti-infectives**, **respiratory** and **oncology**
- Canada launched 62% of new **biologic** with 1.3 years median time to launch (6<sup>th</sup>)
- Canada launched 70% of new **oncology** medicines with 1.1 years median time to launch (4<sup>th</sup>)



## MIDAS® Data Analysis

## Launch Grouping

- Canada was grouped amongst Switzerland, France, Belgium, Italy, and Spain as countries with relative importance for global launch from 2000 to 2019, following US, Germany, and UK
- Canada was most often the first country to launch new medicines after launches in the US & Europe



## Launch Sequence Over Time

- In the past 10 years, the median time to launch in Canada dropped from 2.3 to 1.0 years, placing Canada 3<sup>rd</sup> in launch sequence by 2019
- More recently, Canada saw a sharp decline in the number of NAS launched dropping from 22 in 2018 to 13 in 2019; with only 1 NAS launched in Q4 2019 despite global launches rising



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## Main Takeaways

### 1 Canada is a top tier market

Canada has been a top destination for new medicine launches over the past 20 years in time to launch and proportion of launches

### 2 Canada's position has improved

That status has steadily improved over time, with Canada getting new therapies quicker every year, and higher in the sequence

### 3 2019 showed signs of change

Early evidence points to a significant change in 2019 with a major drop in new launches, directly opposite of global trends



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