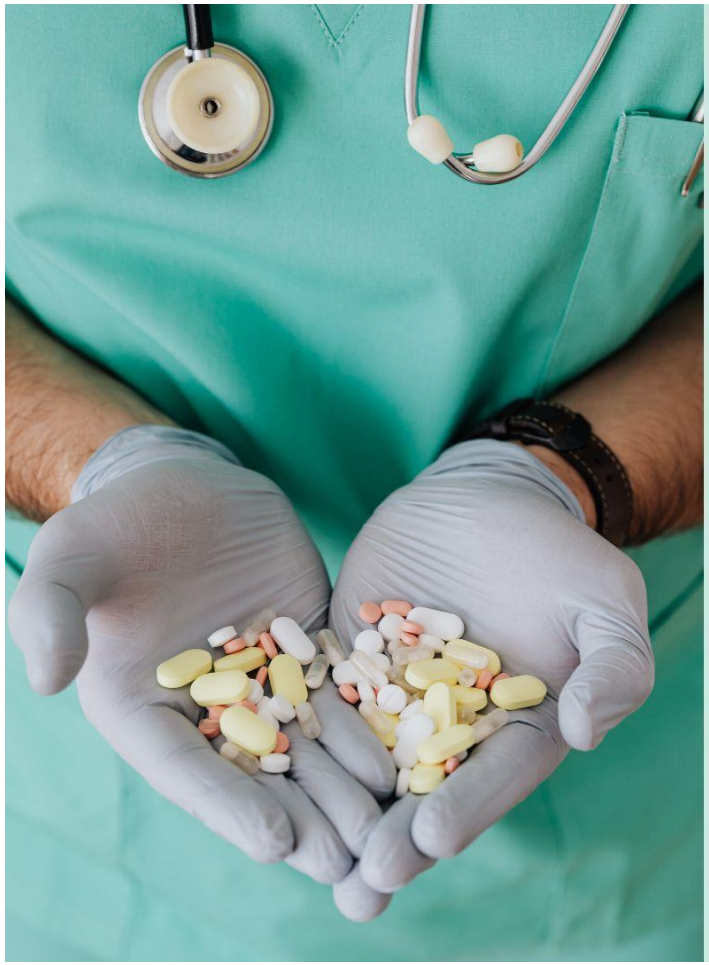


Is Canada losing its status as a priority medicine launch country?

June 2, 2022

Canadian commercial pathway for medicines is uncertain and long

Since mid-2019, of the 129 medicines approved by FDA, less than half were submitted to Health Canada

Health technology assessments

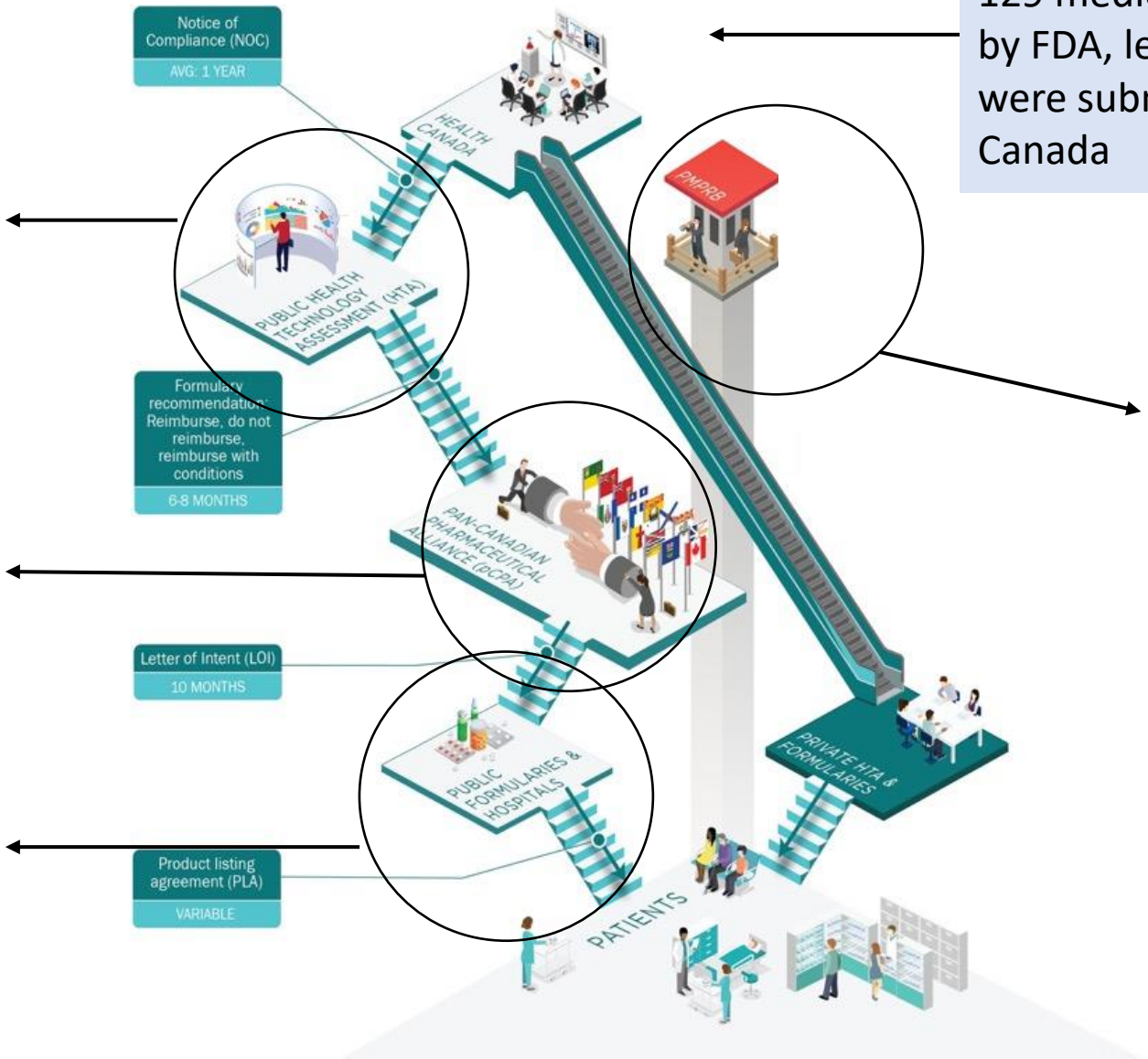
- Restrictive reviews overly focused on pricing

pCPA

- Long and uncertain process (10 months on average)
- Lack of transparency and accountability

Provincial listings

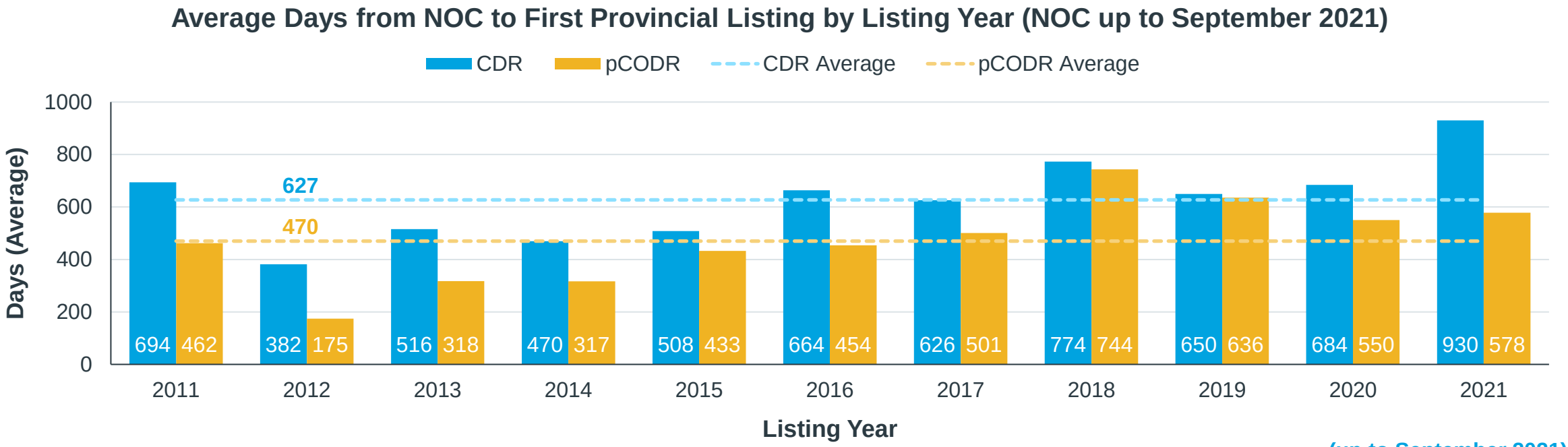
- Long and variable from one province to another



PMPRB

- Reform created significant business uncertainty over past 6 years
- Damaged Canada's position in global launch sequencing

On average, time from NOC to listing continues to trend upward, taking more than 1.5 years to first listing



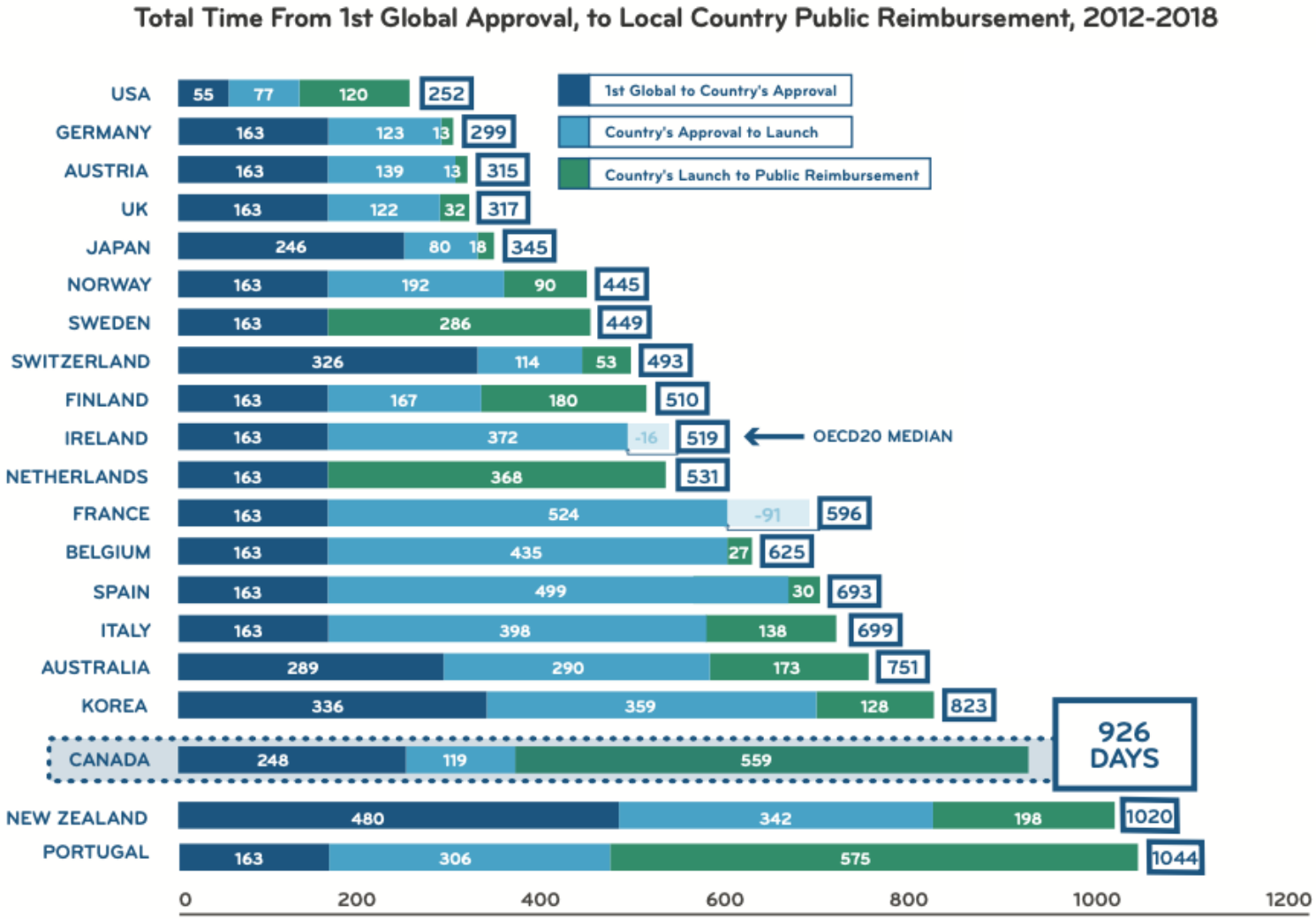
(up to September 2021)

Listing Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
CDR	18	22	14	23	24	25	16	34	36	13	10	**235**
pCODR	2	2	10	12	10	7	14	9	21	20	9	**116**

CADTH submissions with First Listing date up to September 29, 2021 were included. Resubmissions were included in the analysis. pCPA 2nd attempts were condensed. Request for advice, drug plan submissions, and discontinued drugs were excluded. Listing dates in Quebec were not used to calculate time to listing. 17 CDR reviews with time to listing greater than 5 years and 1 CDR review with provincial listing before NOC were excluded. 2 pCODR reviews with time to listing greater than 5 years and 3 pCODR reviews with provincial listing before NOC date were excluded.

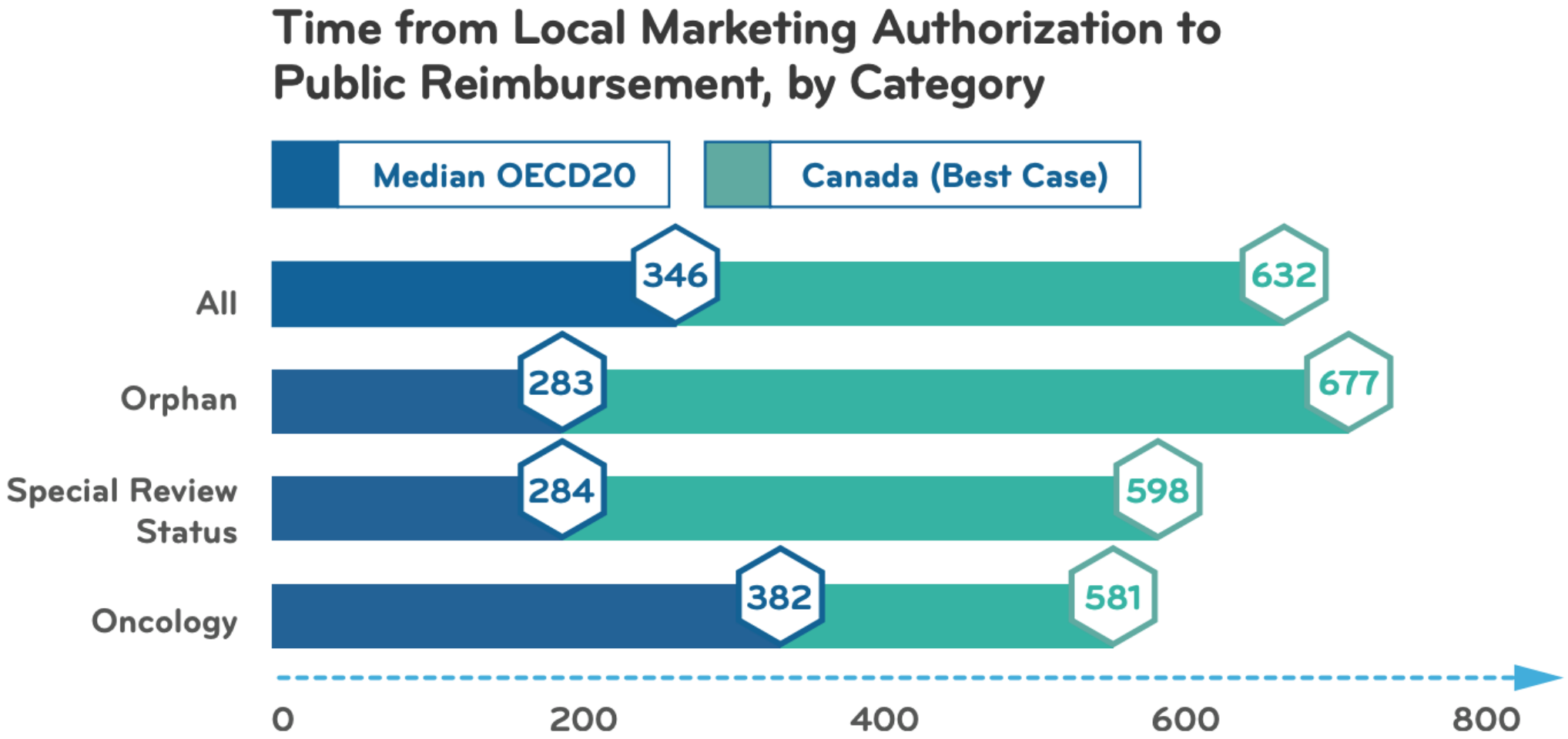
Source: IQVIA. Market Access Metrics Database. September 2021

Canada is among the slowest of the OECD20 to reimburse medicines through its public plans



Source: IMC's Explaining Public Reimbursement Delays for New Medicines for Canadian Patients (Jun. 30, 2020)
http://innovativemedicines.ca/wp-content/uploads/2020/07/CADTH-TTL-8.5x11-EN-Final.pdf

Reimbursement process is much slower than other developed countries



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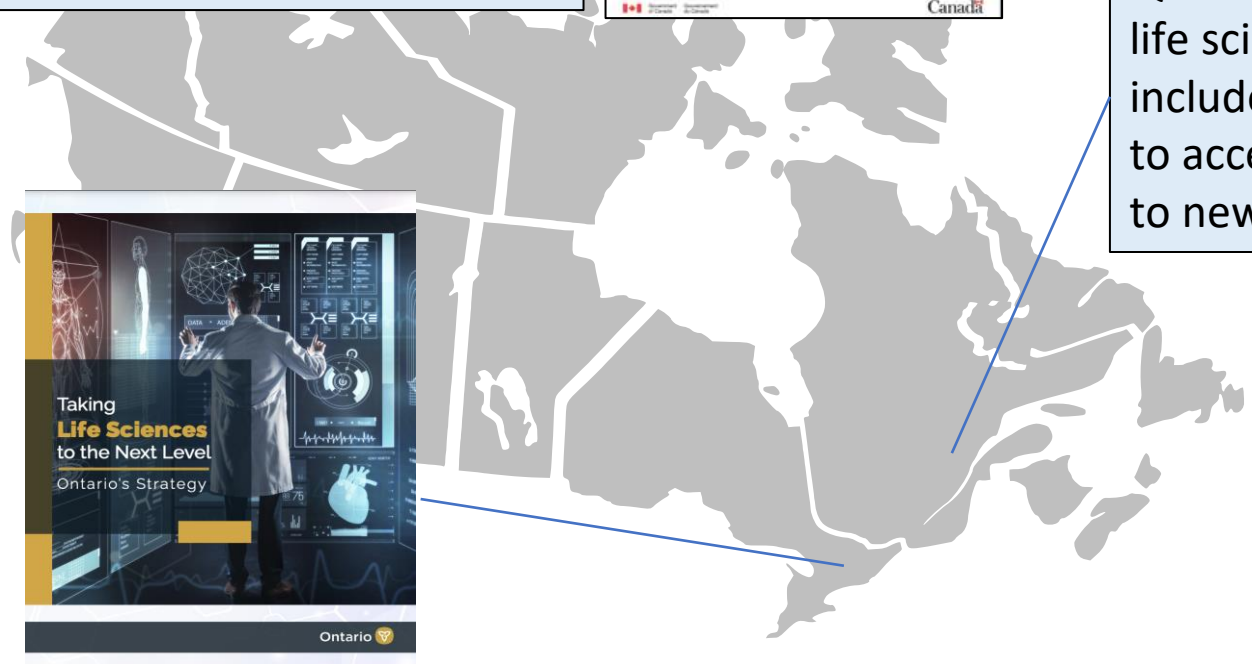
http://innovativemedicines.ca/wp-content/uploads/2020/07/CADTH-TTL-8.5x11-EN-Final.pdf

Recent life sciences strategies are the roadmaps to AIM HIGHER to accelerate and improve access to health innovations

2021 **federal biomanufacturing and life sciences strategy** strives to build Canada's life sciences sector in response to the COVID-19 crisis, including through "world-class regulation" (Fifth pillar of strategy)



The **Ontario** government launched a new life sciences strategy aimed at driving economic growth, reducing red tape, and supporting strategic domestic firms and accelerating access to health innovation

Quebec's renewed life science strategy's includes commitment to accelerate access to new medicines

New Medicine Launches: Canada in a Global Context

June 2, 2022

Prepared by IQVIA Canada
Real World Solutions Consulting Group

In light of proposed federal pricing reforms, we want to generate evidence on how Canada compares globally in access to new medicines

How does Canada compare to international markets in terms of time to launch, proportion of launches and sequence in launch **for new medicines?**

Have we seen changes in Canada since the federal policy announcements?

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In light of proposed policy changes on pricing and national pharmacare, we examined where Canada stands globally in terms of access to novel pharmaceuticals

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 and national pharmacare**
- 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 2002-2021

Data Period 1

- 20 years: January 1, 2002 to December 31,2021
- Top 25 countries by 2021 sales (where data is available)
- Launch date by country
- New active substances (novel active ingredients launched globally)

Key Metrics 2

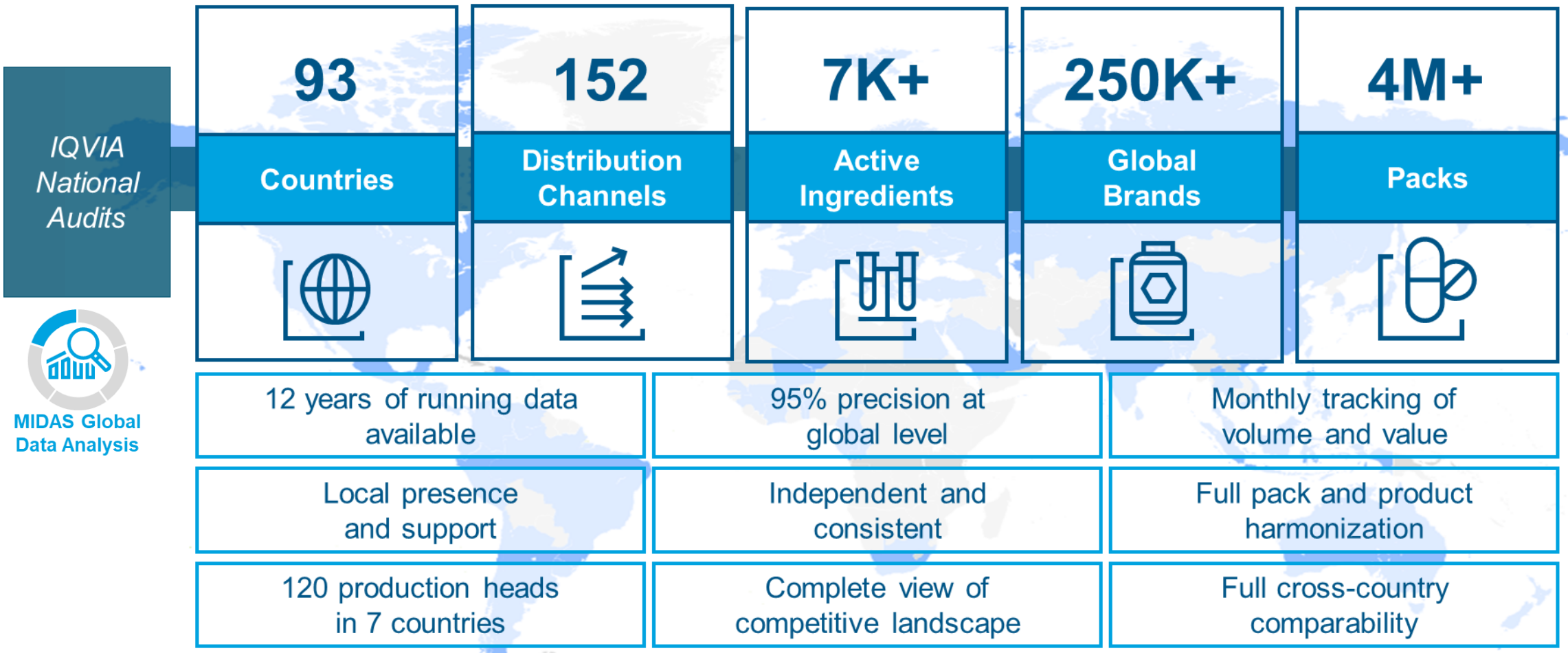
- Country's place in launch sequence
- Average time to launch by country
- Proportion of new active substances launched by country

Time Trends 3

- Launches by country over time vs global launches over time

IQVIA MIDAS database is a robust source of worldwide pharmaceutical sales data

The trusted industry gold standard in global market measurement



* MIDAS: Multinational Integrated Data Analysis System

Note: Reporting delays by manufacturers may cause observational error in the analysis.

The top 25 countries were identified by global pharma market sales in 2021 and launch date is defined as date of first sales and/or manufacturer launch

Top 25 Countries by Global Pharma Market Sales in 2021	
No.1 USA	No.14 RUSSIA
No.2 CHINA	No.15 POLAND
No.3 JAPAN	No.16 SAUDI ARABIA
No.4 GERMANY	No.17 MEXICO
No.5 FRANCE	No.18 TURKEY
No.6 UK	No.19 SWITZERLAND
No.7 ITALY	No.20 BELGIUM
No.8 SPAIN	No.21 AUSTRIA*
No.9 CANADA	No.22 ARGENTINA
No.10 BRAZIL	No.23 SWEDEN*
No.11 INDIA	No.24 TAIWAN
No.12 KOREA	No.25 THAILAND
No.13 AUSTRALIA	

Definition of Launch Date

Launch Date was defined as:

- The date from which sales first begin to accumulate

AND/OR

- The date of launch by manufacturer where available

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

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

Data Source: IQVIA World Review Preview 2022 – Worldwide Pharma Markets

New active substances (NAS) first launched and available globally within 2002-2021 were included

Inclusion Criteria

- Global first launch at the molecule level in 2002-2021
- 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) and available in more than 1 country
- 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 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

Identified NAS 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
- Drug classes like antiparasitic, diagnostic agents, non-hormonal gynecological drugs etc. were combined under “Other” therapeutic class

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This report outlines relevant findings from MIDAS global data analysis for all NAS and relevant subgroups

Analysis Outputs

MIDAS Global Data Analysis

1

Canada’s Position in Global Launch Sequence

- Observed Country Grouping
- Proportion and Time to Launch
  - All New Active Substances Launched Globally
- Key Therapeutic Areas in Canada

2

Launch Sequence Over Time

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

This report outlines relevant findings from MIDAS global data analysis for all NAS and relevant subgroups

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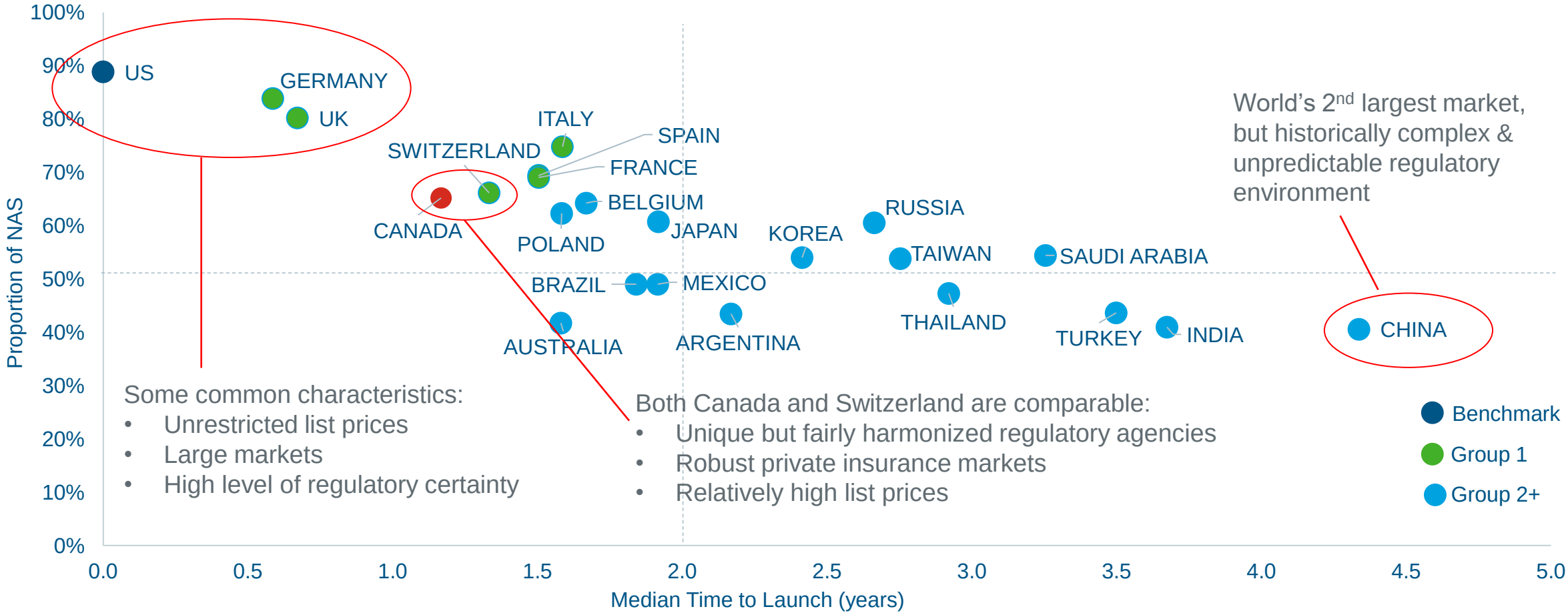
Launch Sequence Over Time

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

Over the last 20 years, Canada ranked behind UK and Germany on median time to launch and behind six countries regarding number of launches

20-year Analysis

Country Grouping Based on Proportion and Median Time of NAS Launch
(Data Period: 2002-2021, Global NAS Launches = 520)

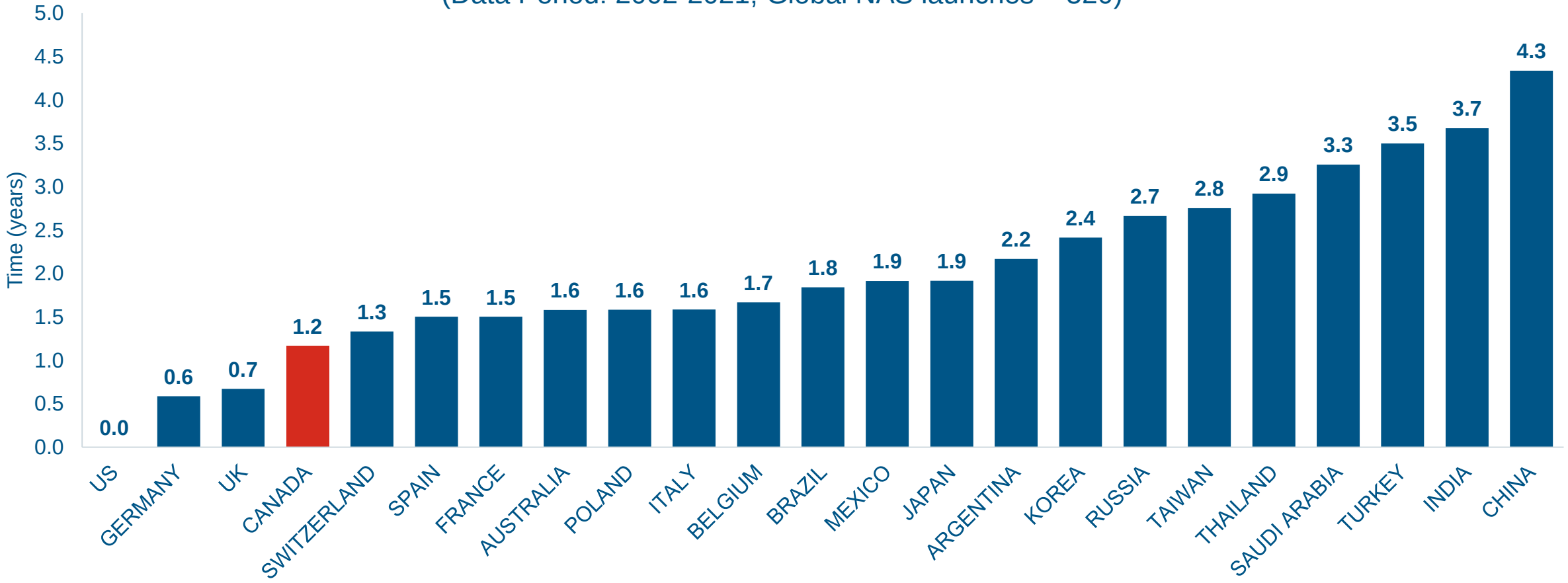


IQVIA MIDAS Database, all new launches within Jan 1, 2002 – Dec 31, 2021 (Data extracted on Mar 21, 2022). Top 25 countries based on 2021 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

Canada ranked 4th to launch a new active substance over the last 20 years with a median 1.2 years lag from first global launch

20-year Analysis

Median Time from Global Launch to Local Country Launch
All NAS
(Data Period: 2002-2021; Global NAS launches = 520)



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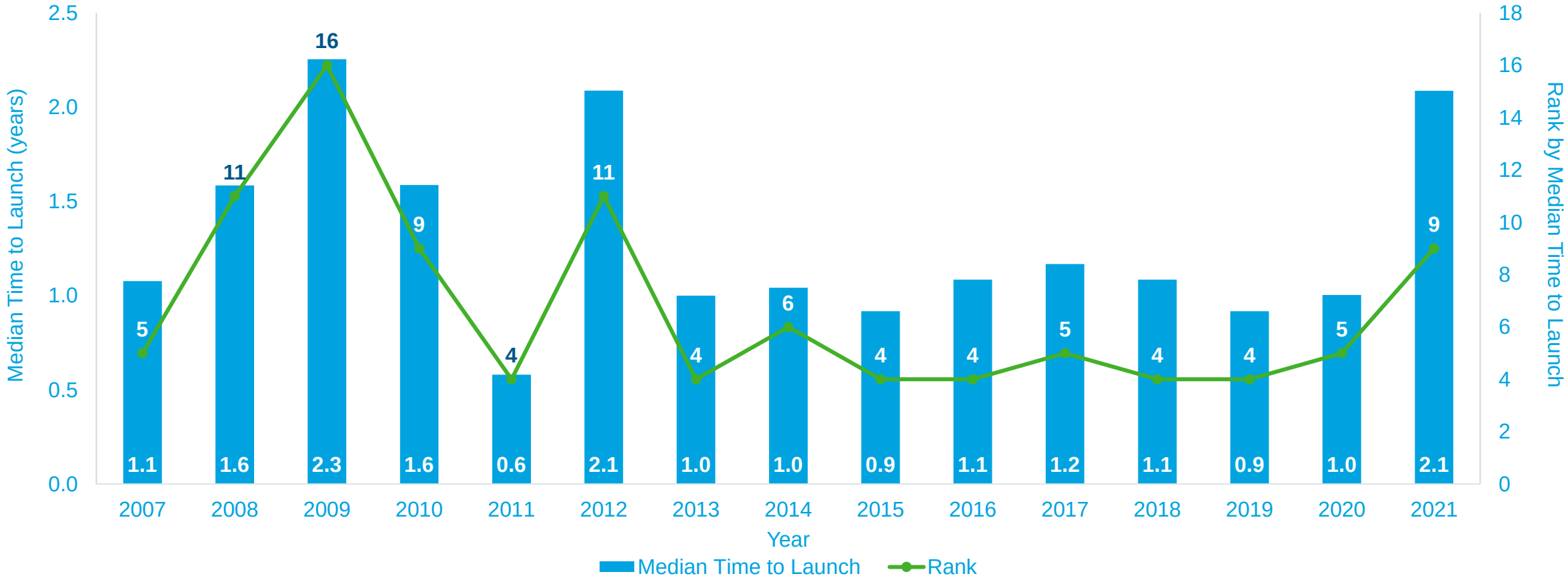
Launch Sequence Over Time

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

In 2021, Canada experienced the longest time to launch since 2012, with 2.1 years median time to launch and ranked at 9th compared to other countries

Year-over-year Analysis

Yearly Trend of Median Time to Launch and Median Launch Position in Canada (Data Period 2007 – 2021)



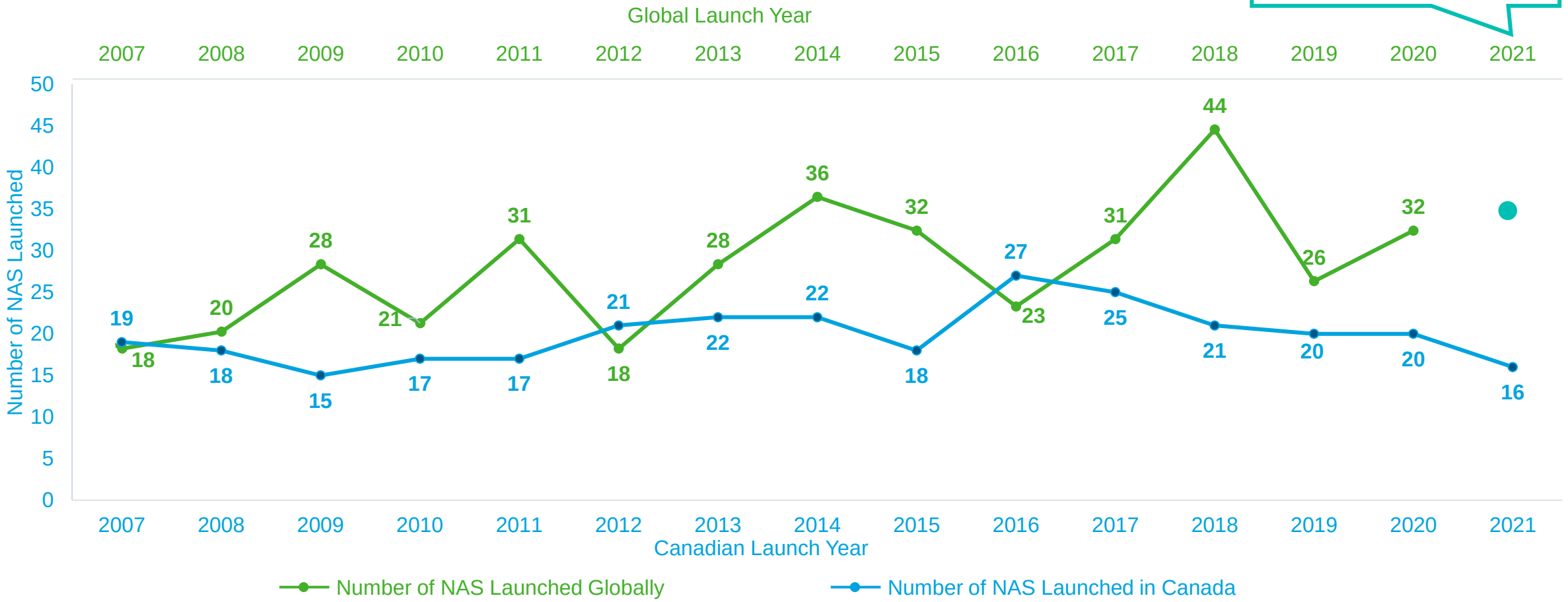
IQVIA MIDAS Database, all new launches within Jan 1, 2002 – Dec 31, 2021 (Data extracted on Mar 21, 2022). Top 25 countries based on 2021 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

Number of annual NAS launches in Canada has declined every year since 2016 and lags behind the global NAS launches

Year-over-year Analysis

Yearly Trend of Number of NAS Launched in Canada and Globally (Data Period: 2007 – 2021)

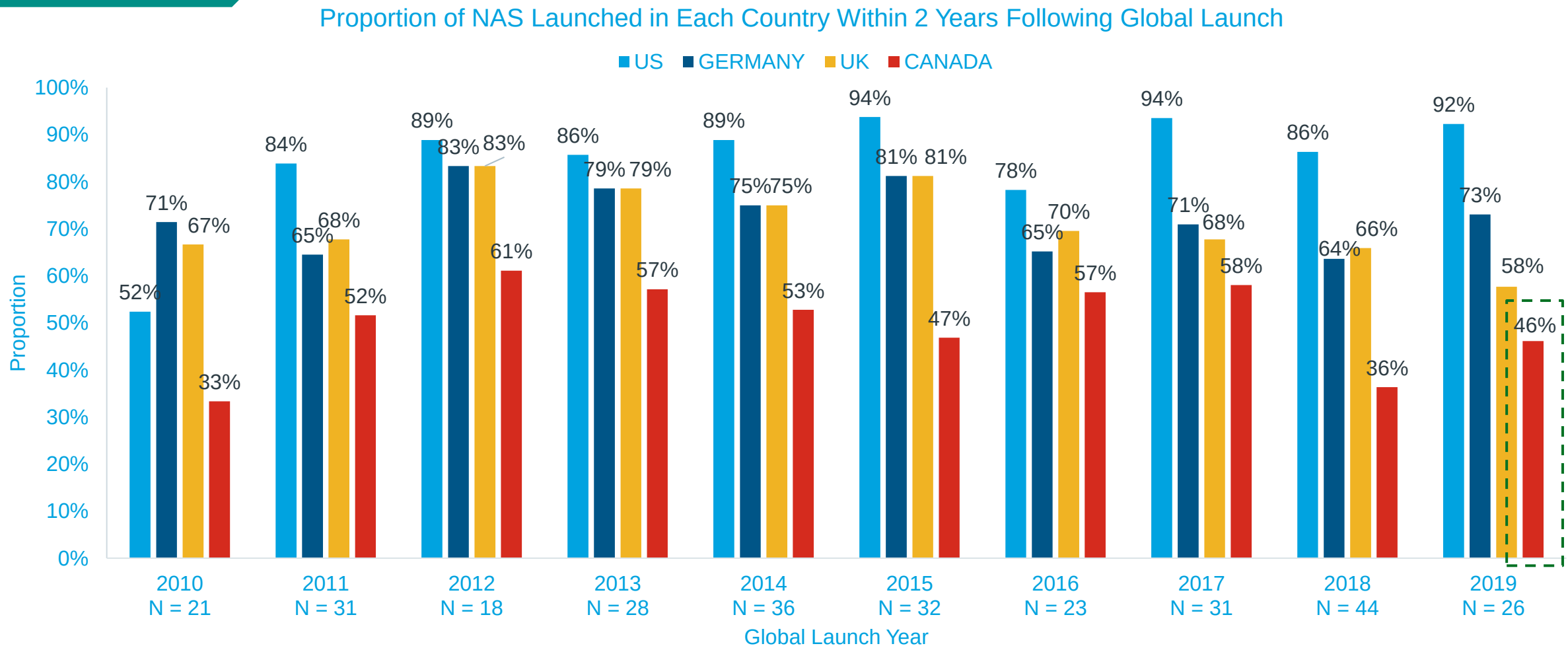
*35 new drugs were launched in **US** in 2021*



IQVIA MIDAS Database, all new launches within Jan 1, 2002 – Dec 31, 2021 (Data extracted on Mar 21, 2022). Top 25 countries based on 2021 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

Comparing with top 3 countries, there are fewer NAS launched in Canada within 2 years following the global launch

Year-over-year Analysis



IQVIA MIDAS Database, all new launches within Jan 1, 2002 – Dec 31, 2021 (Data extracted on Mar 21, 2022). Top 25 countries based on 2021 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

Among 26 NAS launched globally in 2019, 54% of them were not launched in Canada within 2 years

14 (54%)
out of 26 NAS launched globally in 2019 were not launched in Canada* within 2 years

- **5** in Oncology
- **8** in Rare Disease Area*
- **2** in Nervous System
- **1** in Other Immunosuppressants
- **1** in Systemic Anti-infectives
- **1** in Respiratory System
- **1** in Cardiovascular System
- **2** in Hematological Agents

* NAS from all therapeutic areas were grouped into the "Rare Disease Area" group according to FDA Orphan Drug Designations and Approvals Database. 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, 2002 – Dec 31, 2021 (Data extracted on Mar 21, 2022). Top 25 countries based on 2021 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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Canada has slipped from its traditional position as a top-priority country for launch, as recent years have seen increasing time to launch and declining NAS launches

Over the last 20 years

- Canada ranked behind UK and Germany on median time to launch and behind six countries regarding number of launches (UK, Germany, Switzerland, France, Italy and Spain)
- Canada ranked 4th with a median time to launch of 1.2 years among the top 23 countries between 2002 to 2021
- The US remained the benchmark, recording the most launches, and typically being the first to launch over the past 20 years

Recent trends

- The median time to launch in Canada increased from 1.0 in 2020 to 2.1 years in 2021, placing Canada 9th in launch sequence in 2021
- Number of annual NAS launches in Canada has declined every year since 2016 and lags behind the global NAS launches
- Over the past 5 years (2017-2021), Canada had an average of 20 NAS launched annually compared to an average of 34 NAS launched annually at global level

IQVIA MIDAS Database, all new launches within Jan 1, 2002 – Dec 31, 2021 (Data extracted on Mar 21, 2022). Top 25 countries based on 2021 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

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