New Medicine Launches: Canada in a Global Context

June 22, 2020
Agenda

• Introduction by Dr. Jason Field, President, Life Sciences Ontario
• 8-minute executive summary
• In-depth analysis of results
• Discussion on implications
Survey on Federal Patented Medicine Price Controls

100% of pharmaceutical executives forecast a **negative impact** on their plans in Canada.

Q: 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); n=36; report published February 3, 2020

For the full Research etc. report, visit [bit.ly/MedPriceControlsSurvey](bit.ly/MedPriceControlsSurvey)
New Medicine Launches:
Canada in a Global Context

June 22, 2020

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?
To do this we used IQVIA MIDAS® the gold standard source of pharmaceutical data, used across the industry and governments.

The trusted industry gold standard in global market measurement

<table>
<thead>
<tr>
<th>Countries</th>
<th>Distribution Channels</th>
<th>Active Ingredients</th>
<th>Global Medicines</th>
<th>Packs</th>
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<tbody>
<tr>
<td>93</td>
<td>152</td>
<td>7K+</td>
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- 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*
Using MIDAS®, we looked at simple metrics to track new product launches in Canada versus other countries

Methodology

1. **Time period (20 years):** 2000 to 2019
2. **Top 25 countries** by sales*
3. **NAS:** New active substances (new active ingredients launched globally)
4. **Launch dates:** Global 1st launch date and launch date in each country

Key Metrics

1. **Time to launch**
2. **Proportion launched**
3. **Recent trends**

* Austria & Sweden excluded due to data limitations

NAS: New active substance
Canada ranked 4th to launch a new active substance just behind the US, Germany and UK; with a median 1.2 years lag from first global launch.
Canada ranked 9th based on proportion of new medicines launched globally, with 66% launched in the last 20 years, versus the US, leading at 89%
Canada is grouped with Switzerland following UK and Germany, as countries with a higher number of medicines launched and shorter median time to launch.

Proportion of New Active Substances

Country Grouping Based on Proportion and Median Time of New Active Substance Launches
(Data Period: 2000-2019, Global Launches = 516)

Some common characteristics:
• Unrestricted list prices
• Large markets
• High level of regulatory certainty

Both Canada and Switzerland are comparable:
• Unique but fairly harmonized regulatory agencies
• Robust private insurance markets
• Relatively high list prices

World’s 2nd largest market, but historically complex & unpredictable regulatory environment

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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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 these policy announcements?
Median time to launch and rank have steadily improved for new medicine launches in Canada in the last 10 years.
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)
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.
By directly comparing Canadian launches with global launches from 2 years past, the correlation, and drop in 2019, becomes far more apparent.
2018 New Active Substances Not Launched in Canada

What Is Canada Missing? Oncology, rare diseases and other innovative new medicines

21 (56.8%) out of 37 NAS launched globally in 2018 were not launched in Canada*

* 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.
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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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

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
2. Top 25 countries by 2019 sales (where data is available)
3. Launch date by country
4. New active substances (novel active ingredients launched globally)

Key Metrics

2. Place in launch sequence
3. Time to launch by country
4. Proportion of new active substances launched by country

Sub-analyses

3. Time series analyses
4. 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.

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* 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.

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

**Definition of Launch Date**

- **Launch Date** was defined as:
  - The date from which sales first begin to accumulate
  - 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.

**Musculo-Skeletal System**
Examples: Antirheumatic (Xeljanz), Antigout (Fasturtec), etc.

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

**Nervous System**
Examples: Antipsychotic (Abilify), Antimigraine (Aimovig), etc.

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

**Respiratory System**
Examples: Antiasthma (Nucala), COPD (Xolair), etc.

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

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

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

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

**Systemic Anti-infectives**
Examples: Antifungal (Posanol), Antiviral (Harvoni), 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.

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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

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
   - 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 4th to launch a new active substance just behind US, Germany and UK; with a median 1.2 years lag from first global launch.
Canada ranked 9th based on proportion of new medicines launched globally, with 66% launched in the last 20 years, versus the US, leading at 89%
Canada is grouped with Switzerland following UK and Germany, as countries with a higher number of launches and shorter median time to launch.

**Country Groupings Based on Proportion and Median Time of New Active Substances Launch**
(Data Period: 2000-2019, Global Launches = 516)

- **Group 1**
- **Group 2**

Some common characteristics:
- Unrestricted list prices
- Large markets
- High level of regulatory certainty

Both Canada and Switzerland are comparable:
- Unique but fairly harmonized regulatory agencies
- Robust private insurance markets
- Relatively high list prices

World’s 2nd largest market, but historically complex & unpredictable regulatory environment
Looking at the top best-selling new active substances, Canada still ranks 4th 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 1st 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.
Canada launched 86% of the top 50 best-selling global new active substances over the last 20 years, ranking 5th globally.

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.
Canada ranked 6th in median time to launch for new biologics, at 1.3 years from first global launch

**Biologics**

Median Time from Global Launch to Local Country Launch

*Biologic New Active Substances*  
(Data Period: 2000-2019)

*Biologic New Active Substances* from all therapeutic areas were grouped together.

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
Canada launched 62% of all new biologics over the last 20 years, ranking 9th globally.

Biologics

Proportion of New Active Substances Launch Country
Biologic New Active Substances
(Data Period: 2000-2019; Global Biologic launches = 164)

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.
Canada ranked 4th 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
Canada launched 69% of all Oncology New Active Substances over the last 20 years, ranking 9th globally

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
In Canada, systemic anti-infectives achieved the best time and proportion of launches compared to any other therapeutic class.
This report outlines relevant findings from MIDAS® global data analysis for all New Active Substances and relevant subgroups.

Analysis Outputs

MIDAS® Global Data Analysis

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
While steadily climbing for most of the study period, annual new drug launches in Canada dropped significantly in 2019.
Globally, we see a different trend, with global launches on the rise

35 new medicines were launched in US in 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.
By directly comparing Canadian launches with global launches from 2 years past, the correlation, and drop in 2019, becomes far more apparent.
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.
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.

21 (56.8%) out of 37 NAS launched globally in 2018 were not launched in Canada.

- 6 in Oncology
- 6 in Rare Disease Area
- 3 in Systemic Anti-infectives
- 4 in Blood Coagulation & Hematology
- 2 in Nervous System
- 1 in Gastrointestinal System
- 1 in Dermatologicals
- 1 in Respiratory System
- 1 in Ophthalmic System
- 1 in Enzyme Replacement

* 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.
Detailed Report

+ Project Objectives and Approach

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

**Global Launch Sequence**
- Canada ranked 4th in median time to launch (1.2 years) and 7th 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

**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

**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 (6th)
- Canada launched 70% of new **oncology** medicines with 1.1 years median time to launch (4th)

**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 3rd 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

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
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 terms of 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.
Discussion on implications
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