November 6, 2020

Standing Committee on Health (HESA)
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: HESA study on the reforms of the Patented Medicine Prices Review Board (PMPRB)

Dear Honourable Members,

Life Sciences Ontario (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.

From the outset of the PMPRB reform process, LSO has actively monitored relevant developments and 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, which will make it more challenging for our sector to commercialize new medicines and vaccines and invest in health research in Canada. To put it simply, this undermines our sector's efforts to support the health and wellbeing of Canadians and our 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 (i.e.,

commercialization of new medicines), 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 whether and to what extent the PMPRB reforms have impacted companies' commercialization plans in Canada. 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 had 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 concerning developments, 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 federal government's approach to drug price regulation has been rife with problems. It is also telling that the federal government has decided to exempt COVID vaccines and therapeutics from the new pricing regime, demonstrating that the federal government knows the new regulations are a regulatory barrier, despite their dozens of claims over the past three years to the contrary.

By far the most problematic and contentious aspect of the reforms has been the proposed use of economic factors to control drug prices. The proposed system for applying the economic factors has introduced a labyrinth of complex formulas and processes that must be followed by companies, with no real certainty about how they will be applied in practice. Without certainty around pricing or the potential return on investment, it is very 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.

While the PMPRB's final guidelines, released on October 23, 2020, have temporarily paused the systematic application of the economic factors to determine maximum price ceilings in light of an ongoing legal challenge, the PMPRB plans to use them on a case-by-case basis in the event of a complaint. It can also reinstate their full application at a later time depending on the outcome of the legal case. All of this continues to perpetuate uncertainty and impact commercial decisions for companies.

In the context of the present HESA study, LSO's one and only recommendation is to remove the economic factors from the *Patented Medicines Regulations*.

This will remove the cloud of uncertainty over the pricing system and has to be done immediately to avoid further damage to our life sciences ecosystem.

Sincerely,

Jason Field
President & CEO
Life Sciences Ontario
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Encl.

Annex 1 – Survey of life sciences leaders' views on PMPRB reform

Impact of PMPRB Pricing Changes

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

Research etc.

Methodology

STEP 1: Quantitative research

N=46 completes

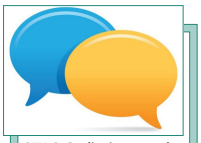
5-minute online survey with decision-makers

Fielded Nov 19, 2019 to January 17, 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



STEP 2: Qualitative research

N=10 completes

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

Fielded January 21 to January 31, 2020

Qualitative Deep Dive with …

N=6 Large Global pharma companies
N=4 Smaller companies, including Canadian-owned and headquartered

Research etc.

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.*

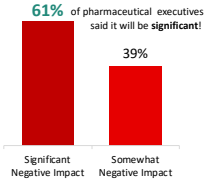
Q1. Overall, how familiar are you with the new PMPRB changes? (5-point scale: very familiar to not at all familiar) Base=46

Research etc.

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

Research etc.

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.*

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

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.

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

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.

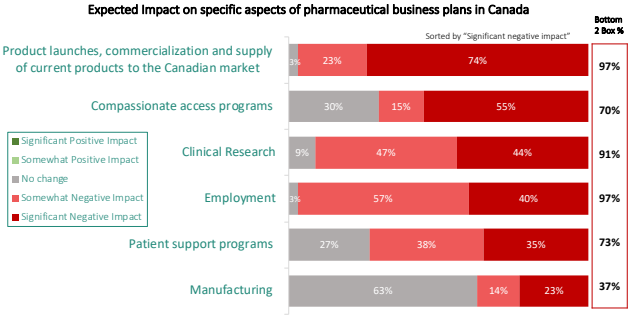
Canada is 2% of the global market. The US is 50%. We are not going to risk the rest of the world for the sake of Canada.

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

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

Research etc.

PMPRB changes expected to have a "cascade effect"

One pharmaceutical executive explained a "cascade effect" starting with delays around product launches …

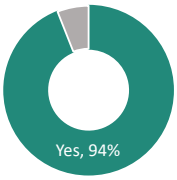
We intended to launch a new medicine in early 2021. Now that it's clear our price will be dramatically reduced, we suspended our regulatory submission because the original business case and pricing assumptions have been challenged. … It has a compounding problem, if not launched in a timely way, it will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

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research 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

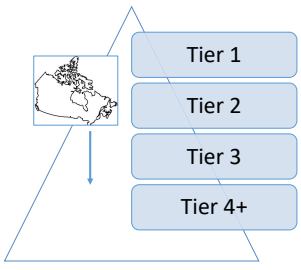
More decisions will be made to not launch at all vs delay because of the potential for broader harm to other larger markets.

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

Research etc.

Impact on Canada's position globally

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



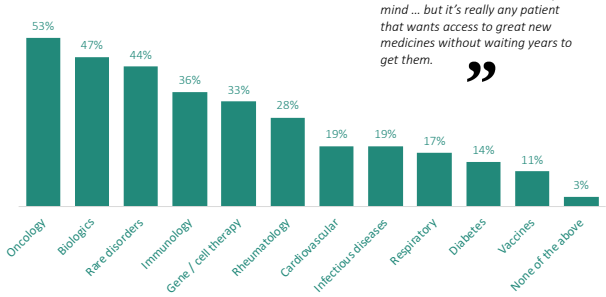
A lot of companies have tiered launch waves. Canada was always considered a Tier 1 or 2 country, launched either with or just after US, Germany, UK, etc. …

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.

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

Several therapeutic areas are likely to be impacted



> *Rare diseases come immediately to mind … but it's really any patient that wants access to great new medicines without waiting years to get them.*

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

Research etc.

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.*

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

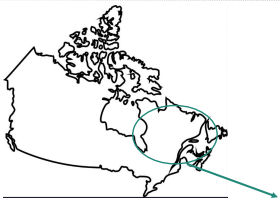
Life sciences executives explain impacts on hospitals & patients

> *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.*

Verbatim from written survey responses from N=10 life sciences respondents

Research etc.

Micro to Macro Impacts on Canada



> *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 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.*

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.

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

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.

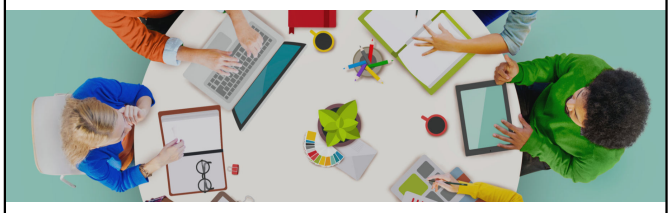
Government of Canada

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.

Insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.



Thank you!

Rachelle Deshaies | 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.

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

Research etc.

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

Research etc.

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.

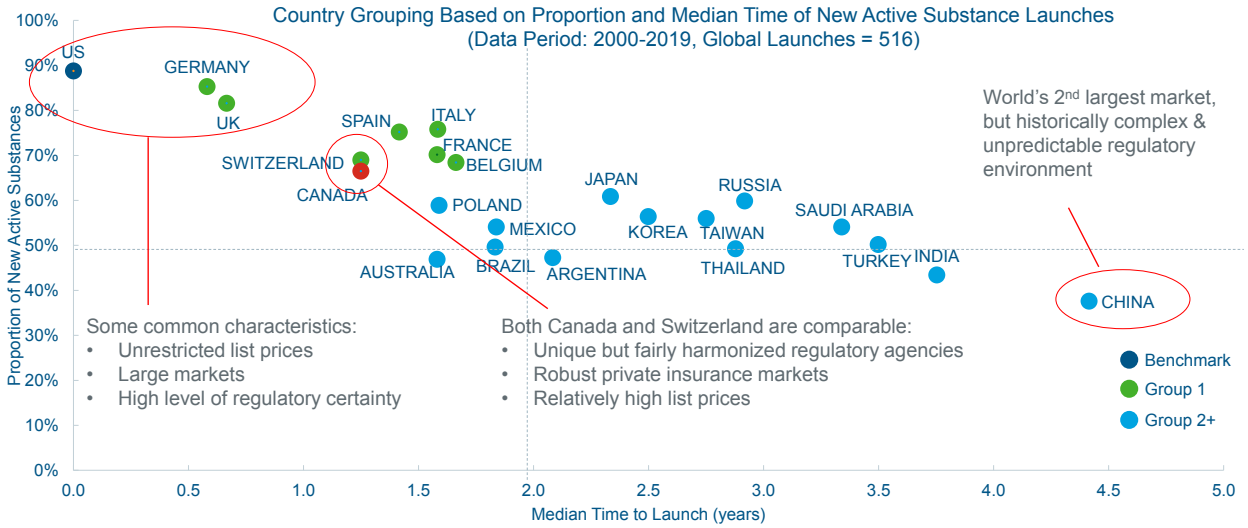
Verbatim from written survey responses from N=36 respondents as well as insights from Qualitative IDIs with N=10 pharmaceutical executives

Research etc.

Annex 2 – IQVIA New Medicine Launch data: Canada in a Global Context

Country Grouping

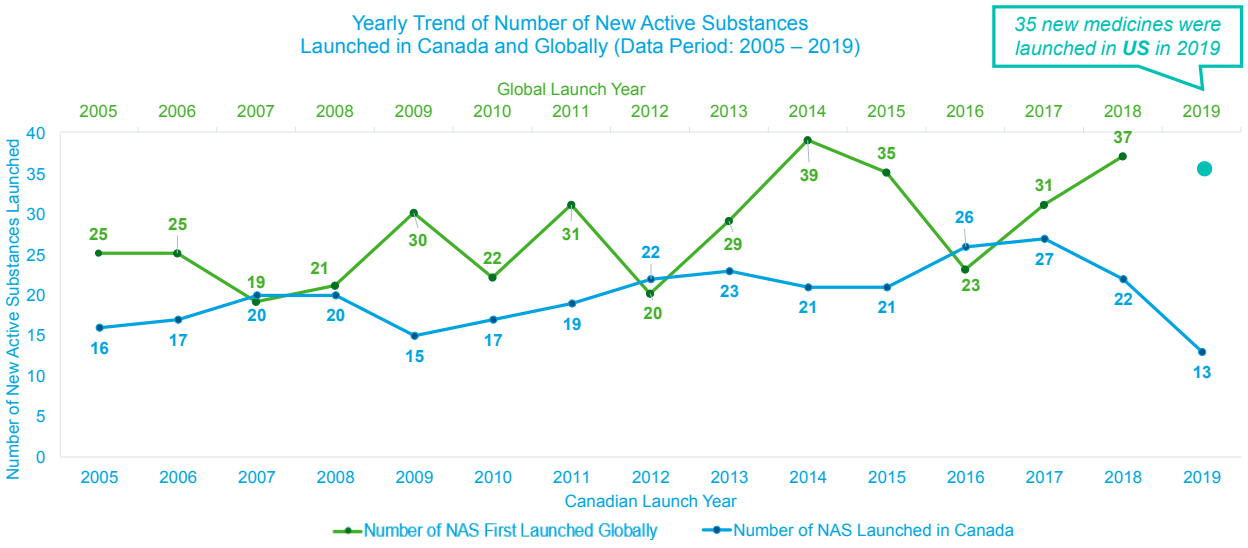
Canada is grouped with Switzerland following UK and Germany, as countries with a higher number of medicines launched and shorter median time to launch



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

Canada's Trend Over Time

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



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

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*

- **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

