



Innovative Medicines Canada

Data Analytics and Members'
Economic Footprint and Impact in
Canada

Analysis and Assessment of Members'
Economic Footprint and Impact in Canada to
Support Innovation and System Sustainability

October 2017



Building a better
working world

About Innovative Medicines Canada

Innovative Medicines Canada represents Canada's innovative pharmaceutical industry. Innovative Medicines Canada is the national voice of Canada's innovative pharmaceutical industry. The association advocates for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians, and supports members' commitment to being valued partners in the Canadian healthcare system.

About Ernst & Young

EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

Our Global Life Sciences and Health Sectors jointly bring together a worldwide network of 19,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. This wide-reaching network allows us to rapidly share leading practices and solutions around the globe and contribute to building a better working world for all stakeholders.

Project background

EY was commissioned by Innovative Medicines Canada in January 2017 to provide data analytics and insights. This work is intended to inform an evidence-based predictable, stable and sustainable pricing and patient access environment with the public payers, as well as the various bodies (PMPRB, pCPA, CADTH, INESSS, CAPCA etc.) that influence pharmaceutical review and funding decisions in Canada. This will ultimately improve timely and appropriate access for patients, affordability for public payers, and support R&D and innovation in the pharmaceutical sector. This report is not an analysis of the entire life-sciences sector in Canada.

Key contributors

The following individuals contributed to the content of this report:

From Innovative Medicines Canada:	From EY:
▶ Chander Sehgal	▶ Giselle Commissiong ▶ Mike Miller

A number of other individuals contributed to the planning, data collection, data analysis and development of the content of this report:

From Innovative Medicines Canada:

- ▶ Sarah Lussier-Hoskyn
- ▶ Declan Hamill
- ▶ Glenn Monteith

From EY:

- ▶ Chris Wayman
- ▶ Mehdi Assadi-Moghadam
- ▶ Varun Malhotra
- ▶ Elizabeth Pequegnat

Contents

Executive summary.....	1
Introduction.....	6
Scope and objectives.....	11
Methodology.....	13
Results	17
Discussion	28
Appendix	33
References	43

This publication contains information in summary form, current as of the date of the publication, and is intended for general guidance only. It should not be regarded as comprehensive or a substitute for professional advice. The information presented in this publication should not be construed as legal, tax, accounting, or any other professional advice or service. Ernst & Young LLP can accept no responsibility for loss occasioned to any person acting or refraining from action as a result of any material in this publication. You should consult with Ernst & Young LLP or other professional advisors familiar with your particular factual situation for advice concerning specific audit, tax or other matters before making any decision. (c) 2017 Ernst & Young LLP. All rights reserved.





Executive summary

Drug spending represents a significant component of healthcare spending in Canada, along with hospitals and physicians. As such, it is an increasing focus area for policy makers, with systemic changes, from PMPRB, to CADTH, INESSS, CAPCA, and pCPA (please see Appendix-A for Glossary) all designed to increase scrutiny on value and cost-effectiveness. With higher priced, specialty drugs making up an increasing share of products being introduced into a budget-constrained market on the one hand, and the advent of new technologies such as biosimilars and genomics enabling a search for value on the other, pressure and complexity of pricing approaches can only be expected to increase. For example, in May 2017, Health Canada proposed updating several aspects of PMPRB regulations governing patented medicines, including an update of the reference country basket set.

The objective of this project is to help Innovative Medicines Canada and its members inform future public policy responses using hard data, supported by an analytical model, and based on actual member data. Ultimately, this work should inform a “made-in-Canada” patient access and innovation framework. The project has several objectives:

- ▶ Develop a comprehensive data set based on member data
- ▶ Assess the economic footprint and impact of Innovative Medicines Canada members;
- ▶ Quantify Innovative Medicines Canada members' investments in Canada;
- ▶ Identify potential solutions, based on data and evidence, to support long-term sustainability for all stakeholders.

The analysis for this project is informed by Innovative Medicines Canada member-specific data collected by EY including revenue, R&D, other investments, operational and corporate datasets. The data has been aggregated to conduct analysis and inform key insights. A critical mass of two-thirds or more of the Innovative Medicines Canada members contributed to different parts of the datasets of this report as of August 9, 2017. Given that data was not collected from all members, the resulting gross revenue and investment figures may be considered conservative.

Economic footprint and impact

Innovative Medicines Canada members contribute to Canada's health sector ecosystem and broader economy, indirectly supporting other employment through the network effect of its supply chain and distribution activities, and through the purchasing power of its employees. Analysis was completed to determine the economic impact of Innovative Medicines Canada's members, based on the data collected from individual members.

As can be seen in Figure 1, the activities of the Innovative Medicines Canada members who submitted data as of August 9, 2017, added over \$19.2B of gross value added (GVA, a measure of the total economic footprint) to the Canadian economy in 2016. For every \$1.00 attributed directly to the participating members, another \$0.59 is generated indirectly by the activities through the supply chain, while a further \$0.44 of induced impact is supported by the employment income and associated spending across the Canadian economy.

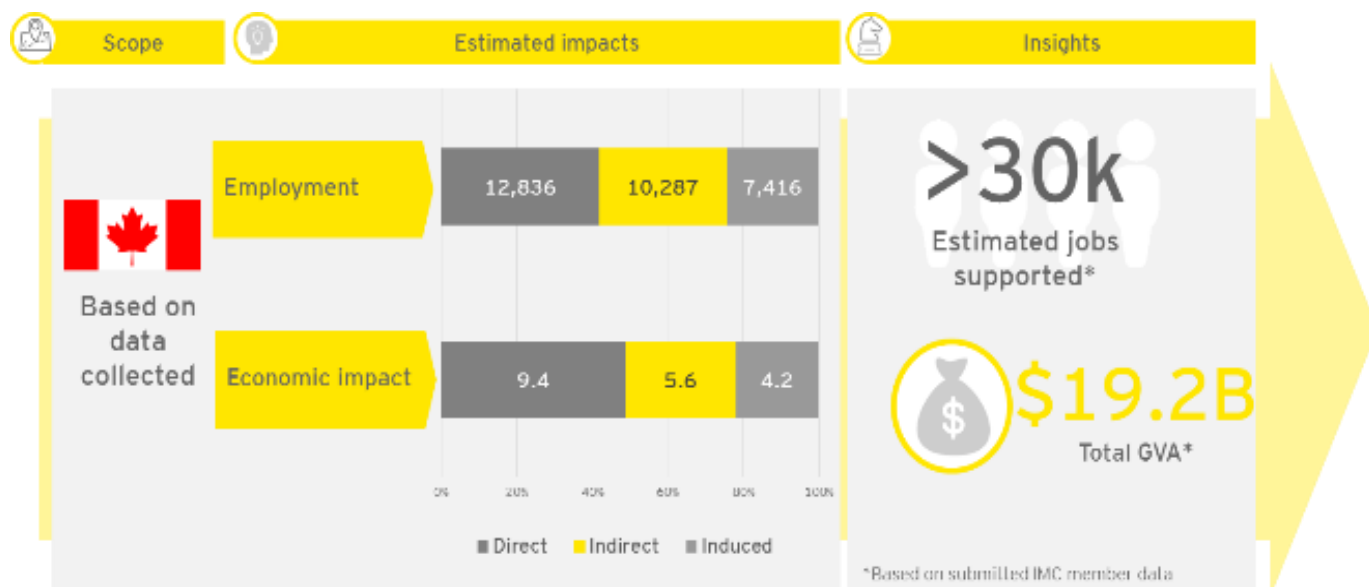


Figure 1. Economic impact of participating Innovative Medicines Canada members.

The activities of these members also support just over 30,000 jobs across the Canadian economy, as shown in Figure 1, which represents a relatively important contribution with respect to other sectors. For example, in terms of R&D, while it is not the largest R&D investor, it has a strong R&D footprint: a report

by Research Infosource compiled information on Canada's top corporate spenders for 2016 suggests that the Pharmaceutical and Biotechnology firms represented in the top 100 list have the third greatest combined total spending on R&D, only behind the Aerospace and Software/Computer Services sectors.

Gross patented product revenues of Innovative Medicines Canada members

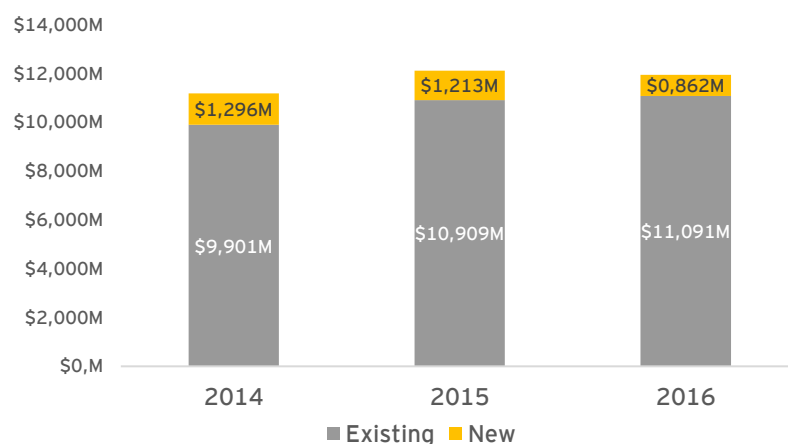


Figure 2. Total reported gross patented products revenue for participating Innovative Medicines Canada members.

Total reported gross patented products revenue as reported by the participating Innovative Medicines Canada members to PMPRB was approximately \$11.95B for 2016. The growth in gross annual patented product revenue as reported to PMPRB was marginal over the reporting period of 2014-16 (CAGR 2.2%), with a slight reduction observed in 2016 from 2015.



These revenue figures exclude public sector rebates, such as those negotiated by pCPA, but may include other benefits reported to PMPRB as per the current regulations.

Research and development

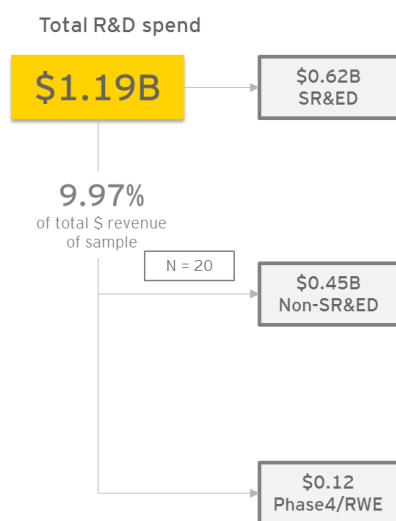


Figure 3. Total R&D spend 2016 as reported by Innovative Medicines Canada members

Participating members also reported a total of \$1,19B in R&D investments for 2016, primarily for clinical research-based activities. These investments include PMPRB Form 3 SR&ED-eligible and non-SR&ED-eligible R&D such as investments in randomized controlled trials (RCT), real world evidence, and Phase IV studies. This amounts to an estimated total 9.97% of gross patented product revenues (i.e. \$1,190M of the \$11.95B) reported in 2016. Of note, even with the decrease in gross revenues from 2015 to 2016, the total investment in R&D and innovation still increased.

members' reported level of investment also increased over the time period, from \$560M in 2014, to \$720M in 2015, to \$900M in 2016, suggesting ongoing and long term commitments by members to patients and PSPs. Just over 50% of 2016 PSP spending was allocated to non-oncology specialty drugs.

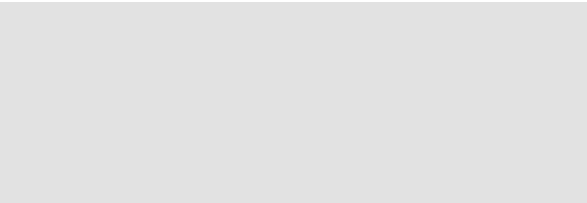
Patient support programs

Patient support programs (PSPs) have been developed by innovative pharmaceutical companies over time to help patients and health care providers navigate the gaps and challenges in accessing manufacturers' innovative therapies within a healthcare system that is not always equipped to deliver these emerging new therapies at launch. Despite this, there are no published comprehensive sources of the estimated scope and impact of PSPs in Canada. This exercise attempted to build a baseline data set from which to begin to understand this impact. Based on the member data collected, the number of patients reported by participating members to be enrolled in PSPs in Canada was approximately 673,000 in 2016. In tandem with the increase in number of patients supported over the reporting period,

Moving forward

The findings from this exercise demonstrate that there are potential benefits for Innovative Medicines Canada members, payers and policy makers, in co-developing solutions to the system sustainability challenges that will lead to longer term certainty of outcomes for patients, payers, and manufacturers. Examples of potential areas of collaboration include improving system efficiencies, collaboration between public and private sectors to make Canada a more competitive place for both basic R&D and clinical research, implementation of performance-based risk-sharing agreements supported by real-world evidence, and building and governing the necessary associated data and infrastructure.

Key to the implementation of such agreements



is the data infrastructure, administrative capacity, and governance model in which they are implemented. At present, although Canada benefits from highly centralized datasets of public administrative data which could facilitate the implementation of such agreements, the investment required to establish an effective infrastructure to manage such a system on a widespread basis over the long term, enabled by real-world evidence collected at the point of patient care, is significant. Innovative Medicines Canada member participation and

investment in such infrastructure could help move system transformation forward.

This exercise is ultimately one step in a long-term journey. While a critical mass of data has been captured and analysed, it is important that the exercise not stop at this early stage. It is essential that efforts be made to maintain and build on the current dataset, to establish a longitudinal and robust set of information that can be analysed over time.

Introduction





Introduction

Policy environment for prescription medicines in the Canadian healthcare system

Overview

The policy environment for drug pricing and reimbursement in Canada has evolved significantly in the past 15 years. As healthcare has consumed increasing shares of overall public budgets across the country, driven by demographic and other demand factors, policy makers have placed their focus on new approaches to manage the long-term sustainability challenge. Opportunities are being identified to shift patients out of more expensive acute hospital settings, into community based care. Innovative models of care are being developed to determine how more multidisciplinary provider approaches can improve patient care while reducing overall cost structures. For drugs, the discussion has largely been around price. The system has gone from one where pricing was left to be negotiated between manufacturers and individual provincial jurisdictions, with little to no provincial coordination, to the present system in which the pan-Canadian Pharmaceutical Alliance (pCPA) is driving negotiation of pricing terms on behalf of the provinces. While this has resulted in a more streamlined process, it has actually amplified the very real challenges of establishing a common vision of the value of pharmaceuticals between payers and manufacturers.

In this environment, the challenge of

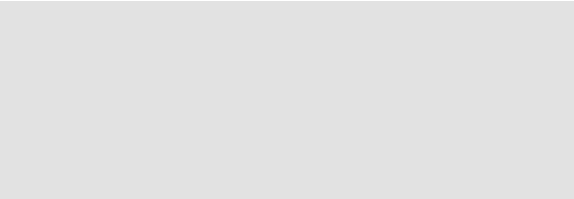
demonstrating the value of innovative medicines in Canada has never been greater. In addition to providing “pills”, value may be contributed in other ways, through additional front-line supports such as investments in R&D and clinical trials; medical education, patient education, specialized tools, patient support programs, and financial assistance; community investments; as well as the effort invested in working collaboratively with payers in the conversation around achieving system sustainability, through mechanisms such as rebates to public payers.

Key considerations for a comprehensive pricing policy and patient access framework

Public health care spending takes up an increasing share of government budgets and is becoming more challenging for governments to finance. In Canada, according to the Canadian Institute for Health Information (CIHI), total health expenditure in 2016 was expected to reach \$228.1 billion. Earlier CIHI data from 2013 showed that health care expenditures represent the largest budget line for provinces, in general representing between 30% and 40% of provincial budgets although there are some outliers.¹

Drug spending represents approximately 16% of **all** public health care spending according to CIHI. In addition to public spending on drugs, individuals and private payers also contribute to pharmaceutical expenditures. Hospitals (29.5%), drugs (16.0%) and physician services

¹ Canadian Institute for Health Information, National Health Expenditure Trends 1975 to 2016



(15.3%) continue to account for the largest shares of health dollars (more than 60% of total health spending). Although spending continues to grow in all three categories, the pace has slowed in recent years.

Reflecting global trends, the mix of drug therapies that Canadians are accessing is evolving to higher-priced, specialty drugs. CIHI data shows that, from 2008 to 2013, for example, that 4 of 10 drug classes contributing to the bulk of public drug spending were biologic agents.² A review of manufacturer pipelines suggests that there are many more such therapies on the horizon to come to market in the coming years. All of these factors, among others, point to an increasing challenge for patients to access the drugs that they need and for public payers to contain the costs of drugs. Thus, on several fronts, there is impetus to assess broader approaches to achieving universal drug coverage for citizens in Canada. Below are several key considerations for Innovative Medicines Canada in developing a comprehensive pricing framework with payers.

1

Budget Sustainability

The approach for developing a comprehensive pricing policy and market access framework will need to balance the desire to reduce the burden on taxpayers and create a more consistent environment of drug pricing while maintaining quality and accessibility to new and existing drugs. Like most developed countries, Canada has adopted a good number of policies aiming to control pharmaceutical spending, including price caps,

drug reimbursement limits (formularies), cost-effectiveness analyses and bulk purchasing.

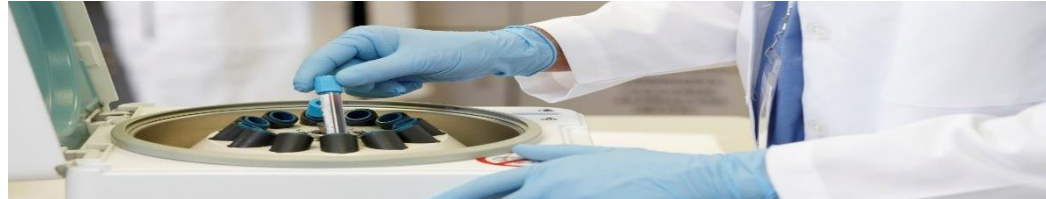
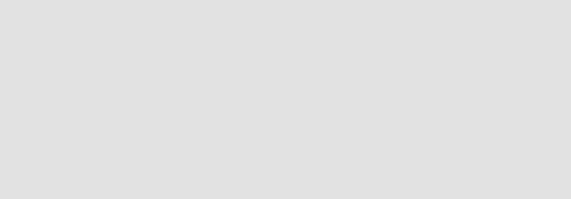
Therefore it is timely to seek a different approach to increasing the availability of prescription drugs through new approaches to value, cost, and pricing, including new contracting models based on patient outcomes and risk-sharing or pay for performance, for example. While these models have held some appeal, the challenge of defining and agreeing on end points, how risk is shared, how performance is rewarded, etc. is more difficult to address at a conceptual level. The idea of developing a comprehensive analytical model to analyze various scenarios could be a key starting point in gaining this agreement.

2

Creating value within the health system

The desire to increase reasonable and equitable access to drug treatment options and improving consistency of access across Canada while rewarding innovation are important goals for a comprehensive patient access framework. While other jurisdictions may be implementing new approaches, there are also differences in health system design and governance, including the role of public payers, providers, and HTA bodies, which may inform important considerations given Canada's complex operating environment. For example, the role of patient support programs in Canada is very different than that in other jurisdictions: Canadian patient support programs often address gaps in the healthcare system to help enable patient access. Experience in other jurisdictions will highlight the importance of

² Canadian Institute for Health Information, *Prescribed Drug Spending in Canada, 2013: A Focus on Public Drug Programs*, (May 2015).



defining, in a Canadian context, the roles and responsibilities of manufacturer and payer, and the value delivered by each party. Proactively agreeing on what services and value the public system can provide, and what the role of the manufacturers should be, is key to striking the balance between patient accessibility and health system affordability.

3 Creating value beyond the Health System

The potential economic value generated to the overall economy by drug manufacturers and their products and activities extends beyond the healthcare system. Identifying the value generated by employment, community and infrastructure investments, contributions to research and innovation, and other factors beyond direct health system impacts is an important element of developing a comprehensive pricing and market access framework. It will be important to ensure that any long-term solutions take economic impacts into account.

4 Optimizing Canadian decision processes

The existing landscape of governance and administration of drug funding decision processes in Canada has multiple layers, including PMPRB, pCPA, CADTH, INESSS, CAPCA, and also requires engagement of patient groups to be effective. These multiple review steps contribute to a relative lack of timeliness in getting drugs to patients, post-NOC. There is opportunity to look across NOC, HTA, price negotiations, and other key

processes to understand and quantify inefficiencies, and build these into the model, in terms of potential resource savings, improved patient outcomes and other key benefits. The UK Accelerated Access Review³, which provides an example of strategies to enhance patient access through collaboration between governments and innovative pharmaceutical companies, is an attempt to cut through some of these inefficiencies under the appropriate conditions. However, these types of innovative approaches also require collaboration to implement, underlying the importance of bringing system stakeholders together to develop common ground.

³ Accelerated Access Review: Final Report, Review of innovative medicines and medical technologies, Wellcome Trust, 2016



5 Experience in other jurisdictions

The issues described are not unique to Canada. Other jurisdictions have faced and begun addressing the same types of issues. The UK experimented with a Cancer Drug Fund to provide access to innovative medicines. However, the drugs funded were generally ones that had been rejected by the HTA agency, NICE, which created misalignment across the system. More recently, the NHS and manufacturers have agreed on a budget cap scheme, which caps the overall expenditure on drugs, in the form of rebates. More broadly, across other jurisdictions, experience with approaches such as dose capping (UK), conditional treatment continuation (UK), risk

sharing with real-world evidence (France) are all being implemented with a view to optimizing the value for manufacturers, payers and patients. These experiences demonstrate the willingness of manufacturers and payers to have a discussion on new approaches to funding, based on a new framework, which can move the discussion away from price and toward value and can help inform a data-driven discussion with payers in pursuit of a comprehensive pricing and market access framework. Figure 4 below provides a snapshot, based on EY research, of some experiences from other jurisdictions which have experimented with other approaches, and some of the learnings that could be taken into the Canadian context.

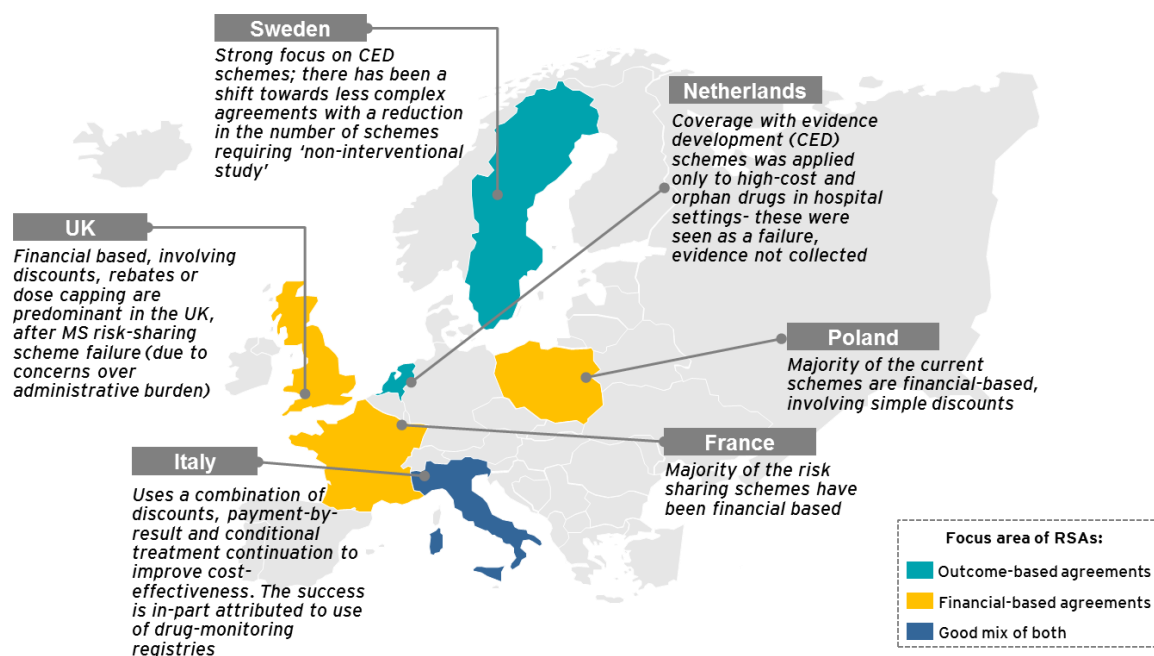


Figure 4. Examples of contracting approaches in EU jurisdictions.

Scope and objectives





Scope and objectives

Drug spending is an increasing focus area for policy makers, with systemic changes, from PMPRB, to CADTH and INESSS, CAPCA and pCPA - all designed to increase scrutiny on value and cost-effectiveness. With higher priced, specialty drugs making up an increasing share of products being introduced into a budget-constrained market on the one hand, and the advent of new technologies such as biosimilars and genomics enabling a search for value on the other, pressure and complexity of pricing approaches can only be expected to increase.

The level of effort, time and resource requirements to navigate this landscape have resulted in corresponding increasing timelines from NOC (Notice of Compliance - i.e. market authorization or approval by Health Canada) to public coverage, ultimately impacting patients' ability to access new therapies in a timely manner. The sustainability of the current state from a drug budget expenditure perspective is of significant concern for payers as specialty drugs make up an increasing share of drugs being introduced into the Canadian market. In addition, the focus on funding sustainability is a concern for manufacturers from an economic perspective.

These challenges present an opportunity for a fresh approach that recognizes and leverages a broad set of tools, beyond price and cost, to deliver value for all stakeholders.

The objective of this project was to help Innovative Medicines Canada and its members inform future public policy solutions using hard data, supported by analytical models based on actual member data. Ultimately, the goal of

this and future exercises is to inform a “made-in-Canada” negotiated pricing framework to be used for all future pricing negotiations with payers.

Project Scope and Objectives:

- ▶ Identify data-driven solutions to support long-term sustainability for all stakeholders;
- ▶ Develop a comprehensive data set based on member data;
- ▶ Assess the economic footprint and impact of Innovative Medicines Canada members; and
- ▶ Quantify Innovative Medicines Canada members' investments in Canada

The goal is to constructively change the conversation and help establish a more sustainable framework that mutually benefits payers, providers, industry, and patients. A key part of changing the conversation is to establish and agree on the issues at hand, based on hard data and facts.

This initiative would enable more transparent and data-driven decision-making process around the trade-offs that policy makers and manufacturers can jointly make among price, innovation, social impact, and resource effort.

To enable this level of transparent process and discussion, this project used historical member data to understand potential trade-offs between different parameters. This undertaking, while complex, is a required step in creating alignment between payers and manufacturers on pricing and value trade-offs.

Methodology





Methodology

This section outlines the key methodologies used to collect and analyse data associated with this project. It includes a detailed overview of the methods used to collect and aggregate individual Innovative Medicines Canada member data, as well as an outline of the analytical approaches to capture insights from the collected data.

Data Collection Approach

Data description

The analyses in the current report are based in part on data solicited from the members of Innovative Medicines Canada. The data solicited from the member firms included sensitive information concerning:

- ▶ Gross patented product revenue generated from the sale of prescription medicines in Canada as reported to PMPRB
- ▶ Volumes of medicines sold in Canada as reported to PMPRB
- ▶ The geographic distribution of sales
- ▶ The distribution of sales across different buyers and payers
- ▶ The volume of investment in research and development (R&D) carried out in Canada in terms of dollars spent and R&D activities (e.g. clinical trials)
- ▶ The volume and distribution of investment and spending in non-research activities including patient support, provider education, charitable giving, and other operations.

Collection of this data took two forms, the first being the use of standard reporting forms all pharmaceutical companies in Canada are required to provide to the Canadian patented pharmaceutical pricing regulator, the PMPRB, on a regular basis, and the second being a series of customized questionnaires prepared by EY and provided to each member firm.

PMPRB Forms

Member firms were asked to provide the following forms which they provide annually or semi-annually to the Patented Medicine Prices Review Board (PMPRB):

- ▶ Form 2 - Information on the Identity and Prices of the Medicine
 - Block 4 - Sales of the Medicine by the Patentee in Final Dosage Form in Canada
 - Block 5 - Publicly Available Ex-Factory Prices for Canada and Other Countries
- ▶ Form 3 - Revenues and Research and Development Expenditures

The use of PMPRB data confers a number of advantages to the data pool used for the analysis in this report including timeliness, consistency, and transparency. Submissions covered the years 2014, 2015, and 2016.

EY questionnaires

In addition to standardized data provided to the PMPRB, the member firms were asked to respond to



several questionnaires that were prepared by EY, requesting key data for the analyses in this report. The questionnaires covered the following data areas:

R&D and Clinical Trials - The EY questionnaire concerning R&D and Clinical Trials complemented PMPRB Form 3 through a more granular view of R&D-related investments.

Patient Support Programs (PSP) - Data was solicited from member firms concerning their investment in Patient Support Programs including spending, patient type, and numbers of patients supported.

Corporate Information - Data was solicited from member firms to examine the economic role played both in the healthcare domain and in the broader Canadian economy including investment in provider education, community programs, and related initiatives. With regard to the broader economy, member firms were solicited to provide data on capital investments, salaries and benefits, and taxes.

A data collection process was developed which balanced the needs for assuring the confidentiality of the data being solicited.

Data collection results

A critical mass of Innovative Medicines Canada member data (i.e. two-thirds or more of members contributed to one or more parts of the datasets collected as of August 9, 2017) has been collected through this exercise, with most major firms (i.e. those with significant revenues and portfolios in Canada) participating.

Overview of analysis approach

Total investments


Member survey data is analysed to describe investments across:

- ▶ R&D;
- ▶ Patient support programs; and
- ▶ Community and charitable expenditures.

Economic footprint and Gross Value Added (GVA) analysis

The pharmaceutical industry's productive activity generally, and that of Innovative Medicines Canada members specifically, contributes directly to Canada's economic activity which can be shown through the Gross Value Added which it produces. Members' activities support jobs across Canada. Direct effects of participating Innovative Medicines Canada members have been calculated using the revenue, expenditure, and workforce data provided by members.

Economic activities are related to one another within the wider economy through a dense network of supplier-customer relations, and thus produce effects that cross corporate and sector borders. Each unit of output produced in a specific sector of the economy requires the production of additional units of goods and services in other parts of the economy to fulfil its input requirements. Production of an additional unit of any good or service also requires the application of additional amounts of labour. Therefore, any increase in the demand for goods and services in the economy will trigger yet more demand for other goods and services, to fulfil the input needs described above. The amount of labour as well as the quantity and type of goods and services necessary to produce an additional unit of output



is industry specific and depends on the technology used. The Input-Output model developed by Wassily Leontief describes such relationships and allows quantifying such additional demand for labour, goods and services through the computation of industry-specific multipliers. Using the Input-Output model as its main building block, the Economic Footprint methodology allows quantifying a productive activity's total contribution to the wider economy.

Within this framework, three distinct effects can be identified and measured:

- ▶ A Direct Effect arising from the initial increase in economic activity, the GVA it generates and the additional jobs it creates;
- ▶ An Indirect Effect arising from the additional demand of goods and services along an industry's supply chain; and
- ▶ An Induced Effect arising as an effect of households spending a share of the additional income generated through the provision of labour on the consumption of goods and services.

Indirect and induced economic impacts described in the economic impact analysis have been derived from direct economic impacts using multipliers for the life sciences sector in Canada. Output multipliers are obtained from Input Output tables, through a mathematical process known as Leontief Inverse. By applying industry GVA / Output ratios and apparent labour productivity measures to the Output multipliers thus obtained, industry level GVA multipliers and employment multipliers can be produced. These multipliers are described in the results section. GVA / Output ratios and apparent labour productivity measures are based on statistical data published by Statistics Canada.

Analytical limitations and caveats

Total investments

Not all members responded to the questionnaires concerning investments such as R&D, patient support programs, total costs, and other key investment measures. As such, where these results are presented, they are presented only for the subset of participating members who submitted such data.

A close-up photograph of a person, likely a scientist or researcher, wearing safety glasses with a purple frame and a white lab coat over a blue shirt. The person is looking down at a stack of papers or a clipboard. The background is a blurred laboratory setting with various equipment and containers. A yellow rectangular box is overlaid on the left side of the image, containing the word "Results" in a bold, black, sans-serif font.

Results



Results

Innovative Medicines Canada members' data

In this section, we present the analysis of the data submitted by Innovative Medicines Canada members covering 2014, 2015 and 2016. This dataset consisted of completed questionnaire responses for "corporate information", "clinical trials and innovation" and patient support programs (PSPs)". These were combined with copies of PMPRB-submitted pricing and investment summaries, i.e. PMPRB Block 4, Block 5 and Form 3 data respectively. Since not all Innovative Medicines Canada members who submitted data provided all datasets, the analysis of some parameters may reflect a subset of participating Innovative Medicines Canada members. Where this is the case, we have noted the number of Innovative Medicines Canada members represented by the analysis.

Economic footprint and impact

Innovative Medicines Canada members play an important role in Canada's health sector ecosystem by contributing to Canada's

economy through direct employment of a highly skilled workforce, indirectly supporting other employment through the network effect of its supply chain and distribution activities, and through the purchasing power of its members' employees. These direct, indirect, and induced effects have been previously defined in the Methodology section above.

Using the data collected, an analysis was undertaken to determine the economic impact of Innovative Medicines Canada's members, based on the data collected from individual members. As can be seen in Figure 5, the activities of the Innovative Medicines Canada members who submitted data add over \$19.2B of total (direct, indirect, and induced) gross value added (GVA) to the Canadian economy. For every \$1.00 attributed directly to the participating members, another \$0.59 is generated indirectly by the activities through the supply chain, while a further \$0.44 of induced impact is supported by the employment income and associated spending across the Canadian economy.

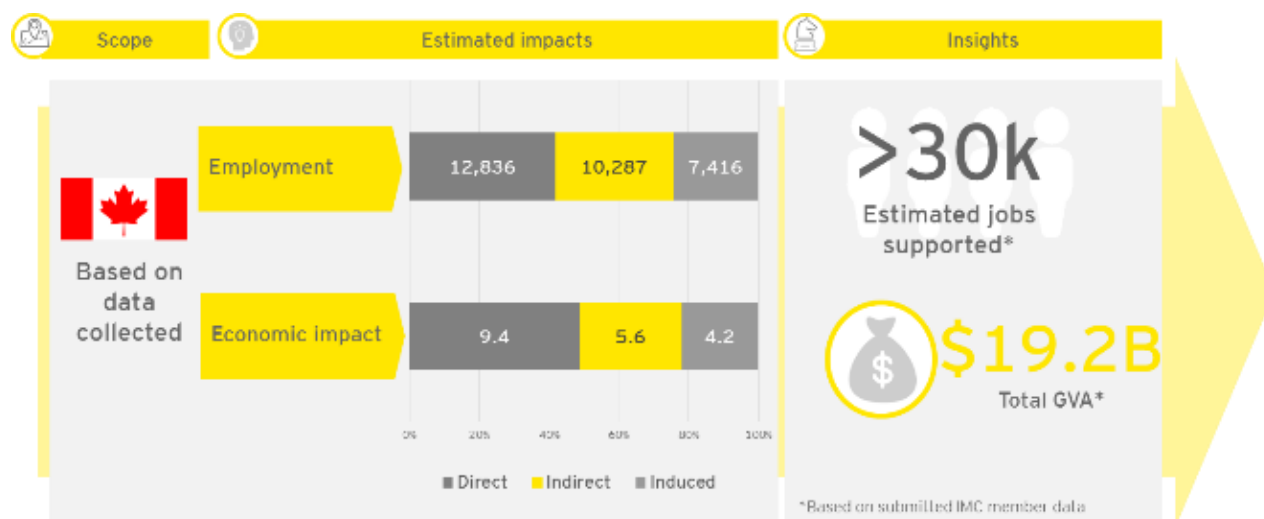


Figure 5. Economic impact of participating Innovative Medicines Canada members.



The activities of these members also support just over 30,000 jobs across the Canadian economy, as Figure 5 shows.

Based on the information analyzed, the majority of these impacts are concentrated in Ontario and Quebec, where the Canadian headquarters of most Innovative Medicines Canada members are based.

Comparing with other analyses

Since these results represent the contributions of only a portion of Innovative Medicines Canada members, and do not account for the innovative pharmaceutical sector as a whole, a desktop scan was conducted to understand how these results align with past analyses conducted by other groups. The purpose of this scan was to identify similar economic footprint analyses conducted by other organizations, as well as to assess the relative significance of the Life Sciences / Pharmaceutical sector. The analysis relies on published economic studies as its basis: it is important to emphasize that EY did not conduct these prior studies and relied on the information presented in the highlighted reports to conduct our analysis. As such, insights should be considered qualitatively directional rather than quantitatively factual.

There is no singular description of what constitutes the “Life Sciences” sector, which broadly ranges from health care delivery and support activities, to manufacturing of drugs and devices, to research and development activities across these areas. Moreover, Statistics Canada does not track a specific “Life Sciences” industry group. Therefore, for the purposes of this analysis, definitions from published economic analyses were adopted.

A 2015 report by Life Sciences BC⁴ presented an “expanded” definition for life sciences, which included items such as Health and Personal Care Stores, Hospitals, R&D Life Sciences, R&D Laboratories, R&D Biotech Research, Ambulatory Health Care Services, Other Scientific and Technical Consulting Services. The report further defined “core” life sciences which included Drugs and Pharmaceuticals, Medical Devices and Equipment, and Research, Testing and Medical Labs. Innovative Medicines Canada members are assumed to be part of the “Core” Life Sciences sector, in particular the Drugs and Pharmaceuticals sub-sector, which may also include non-members.

While each analysis has its own methodological basis and limitations, the order of magnitude of members’ impact appears to be consistent. Our review of published information for 2014 from the Life Sciences BC report, Life Sciences Ontario, as well as Statistics Canada, suggests an approximate \$26.0B total impact for the Life Sciences / Pharmaceutical sector, broken down into \$12.2B, \$7.4B, and \$6.4B of direct, indirect, and induced effects respectively. The estimate for employment however, produced a net effect of over 100,000 jobs, which may likely be accounted for due to the differences in industry scope and sample sizes. In addition there are methodological differences between the original studies, and our current analysis which takes a bottom-up approach by utilizing data from Individual Innovative Medicines Canada members.

Overall, the current total direct, indirect, and induced \$19.2B and 30,000 jobs impacts from members participating in this exercise may be considered conservative relative to the full member and industry footprints.

⁴ Life Sciences in BC: Economic Impact now and in the Future (2015)

Comparing with other jurisdictions

A scan was also conducted to understand the global context. In particular, three studies of note were reviewed: one of the UK Life Sciences sector, one for a subset of EU-based companies, and a government-sponsored analysis of the Australian pharmaceutical sector. Again, it should be noted that each study has its own methodological basis and as such the following analysis and comparisons are directional. In addition, while the assessments were conducted in local currencies, they have been converted to Canadian dollars for the purposes of this comparison, using the average exchange rate for the year in question, so purchasing parity power effects are not accounted for.

Results of this analysis are provided in Figure 6, which represents a comparison of published analyses of economic footprints of other jurisdictions with which Canada is frequently compared, namely the UK and the EU. While each analysis represents a different scope and definition of “life-sciences”, some very broad insights may be drawn. It should be noted that the analysis conducted by EY for Canada includes only Innovative Medicine Canada members which is a subset of the Canadian biopharmaceutical sector.

The UK analysis⁵, which considered a “core” life sciences industry definition, estimated an

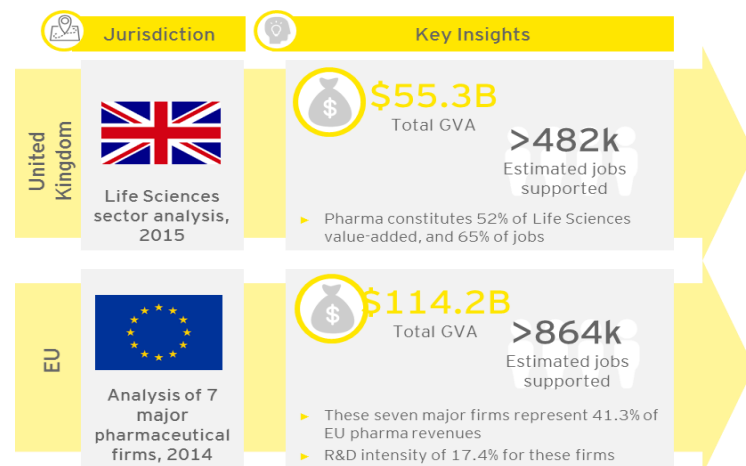


Figure 6. Summary of analysis of economic impacts from other jurisdictions, compared with current analysis.

equivalent of \$26.4B in direct impact for the industry, of which approximately 52% was assessed to be due to the pharmaceutical subsector. In contrast, the EU study⁶, which only assessed seven large pharmaceutical companies, found an estimated equivalent of \$50.7B direct impact for just this subset of companies. This result may speak to the importance of the sector within the EU economy. It is noted that for both the UK and EU, the estimated indirect and induced employment effects are proportionally greater than for Canada, which may be linked to the fact that there is comparatively greater activity along the value chain (e.g. R&D, manufacturing and supply chain) relative to Canada, as well as the presence of international headquarters.

⁵ ABPI: The economic contribution of the UK Life Sciences industry

⁶ EFPIA: The Economic Footprint of Selected Pharmaceutical Companies in Europe

Comparison with other sectors in Canada

With respect to other industry sectors in Canada, the Canadian Life Sciences sector is an important R&D contributor. While it is not the largest R&D investor, it still has a strong R&D footprint. A report by Research Infosource compiled information on Canada's top corporate spenders for 2016⁷ suggests that the 23 Pharmaceutical and Biotechnology firms represented in the top 100 list have the third-greatest combined total spending, behind five (5) Aerospace and seventeen (17) Software/Computer Services.

With respect to R&D intensity, defined as R&D spending as a proportion of revenues, the Pharmaceutical and Biotechnology firms in the top 50 have an estimated 6.9% R&D intensity based on the data reported, which appears consistent with information collected as part of this project, and slightly lower than that of the Software/Computer Services firms in the top 50 which have a combined R&D intensity of 8.4%. It should be noted that this report looked at the Life Sciences sector as a whole and may include firms who are not IMC members.

From an economic footprint perspective, our analysis above suggested that the footprint of the "core" life sciences sector was in the range of \$26B for 2014. This may be considered comparable to that of the aerospace sector at \$29.5B in 2014⁸, based on published information from the Aerospace Industries Association of Canada (AIAC). While there is no cause and effect data published, one

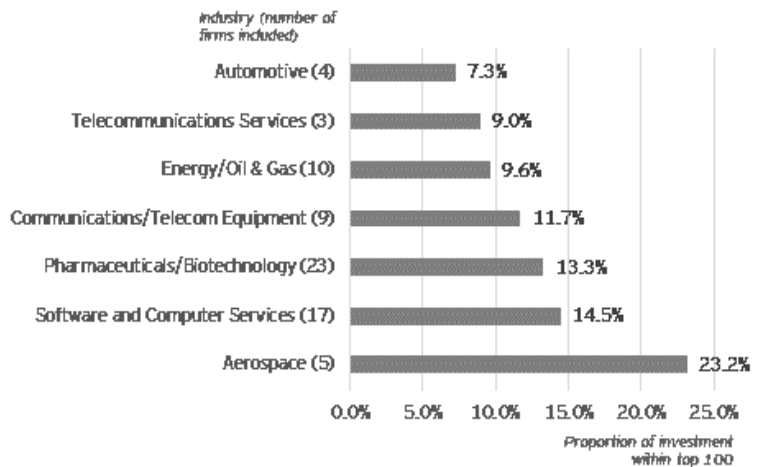


Figure 7. Estimated R&D investment by industry sector.

hypothesis is that the presence of Canadian-headquartered aerospace firms makes a key difference in terms of R&D focus and intensity.

Innovative Medicines Canada member portfolio size and growth

- Total number of patent protected medicines (DINs) by year for Innovative Medicines Canada members. Figure 8 provides the total number of unique DINs reported by members from 2014-16, broken down between existing DINs, namely those that had been marketed in previous years, and new DINs, referring to those which were sold for the first time in the given year. In 2016, Innovative Medicines Canada members had 970 total DINs listed in Canada. This number has remained largely constant over the reporting period. The percentage of new DINs

⁷ Research Infosource, 2016 Canada's Top 100 Corporate R&D Spenders Report

⁸ ISED and AIAC, State of Canada's Aerospace Industry, 2017 Report



entering the Canadian market in 2016, at 12.1%, was the lowest over the three-year period, although as a result of the new DINs

entering the market in 2014 and 2015 the number of existing medicines was higher than other reported years.

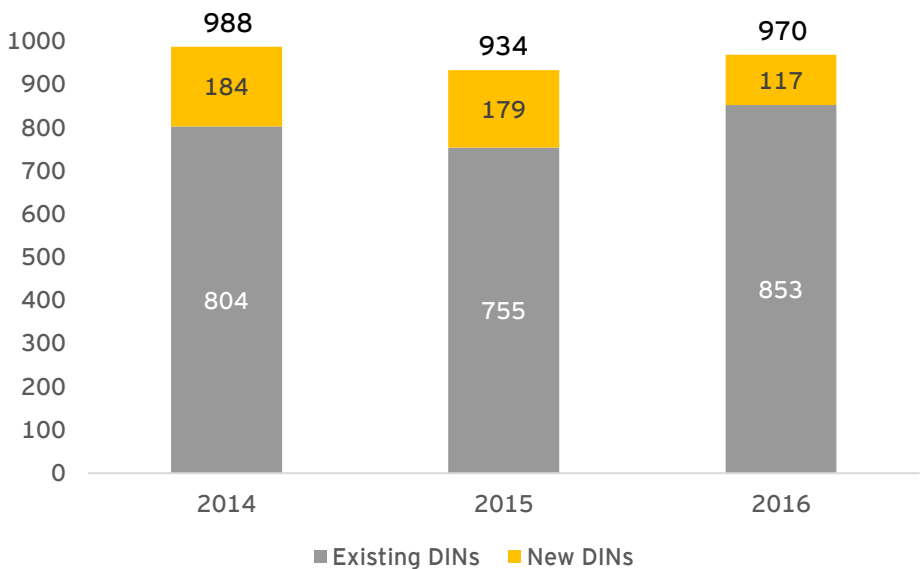


Figure 8. Breakdown of DINs between existing and new drugs for participating Innovative Medicines Canada members.

► **Total 2016 Gross patented products Revenue.** Figure 9 below provides the total gross reported patented product

revenues from new and existing DINs over the reporting period, which

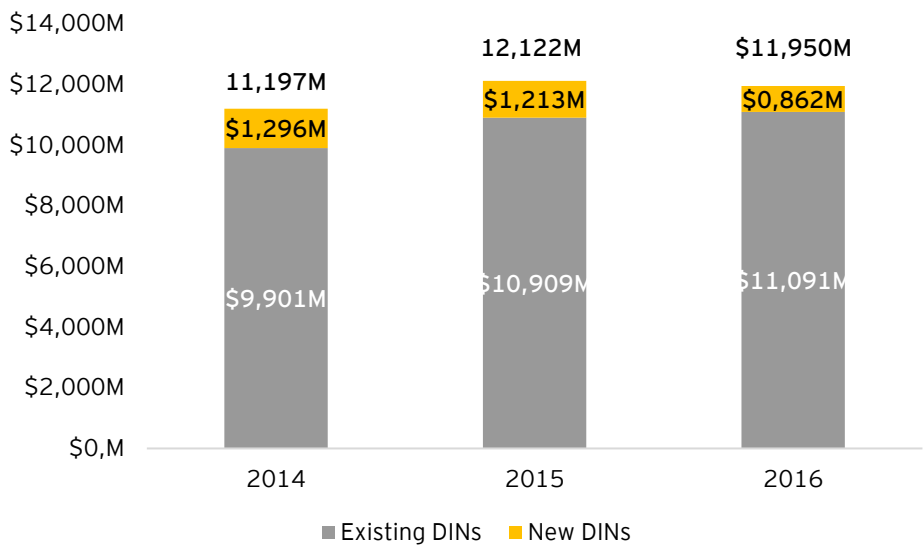


Figure 9. Breakdown of reported member revenue between existing and new drugs for participating Innovative Medicines Canada members.



correspond to payers' expenditures on members' patented products over that time period. These revenue figures exclude public sector rebates, such as those negotiated by pCPA, but may include other benefits reported to PMPRB as per the current regulations. The total reported gross revenue from Innovative Medicines Canada members' patent protected medicines based on PMPRB Block 5 submissions was approximately \$11.950B for 2016. The growth in gross annual revenue was marginal over the period 2014-16 (CAGR 2.2%), with a slight reduction observed in 2016. It should also be noted that the amount of revenue coming from new DINs declined in 2016, resulting in a net decline in overall revenues as well. Members derive over 90% of their revenue from four provinces: Ontario, Quebec, Alberta, and British Columbia, reflecting the distribution of Canada's population and budgetary resources.

Individual Innovative Medicines Canada members also provided the split of individual member revenues between public (including public drug plan and hospital payers) and private funding (private insurers but not cash) sources. For the 19 Innovative Medicines Canada members that submitted this data, the average proportion of public funding sources as a percentage of total revenues was 64%, implying that 36% of revenues were derived from private sources for 2016. Although in aggregate there was little variance in the reported public/private split over the reporting period, there were observed variations in this split across the participating members, which may be driven by differences in portfolios and disease area focus, as well as to the degree to which their portfolios address areas of focus of public payers. Figure 10 below shows the split of public/private revenue for 2014, 2015 and 2016 for the 19 Innovative Medicines Canada members that submitted data.

► **Split of gross patented product revenue by source of funding.**

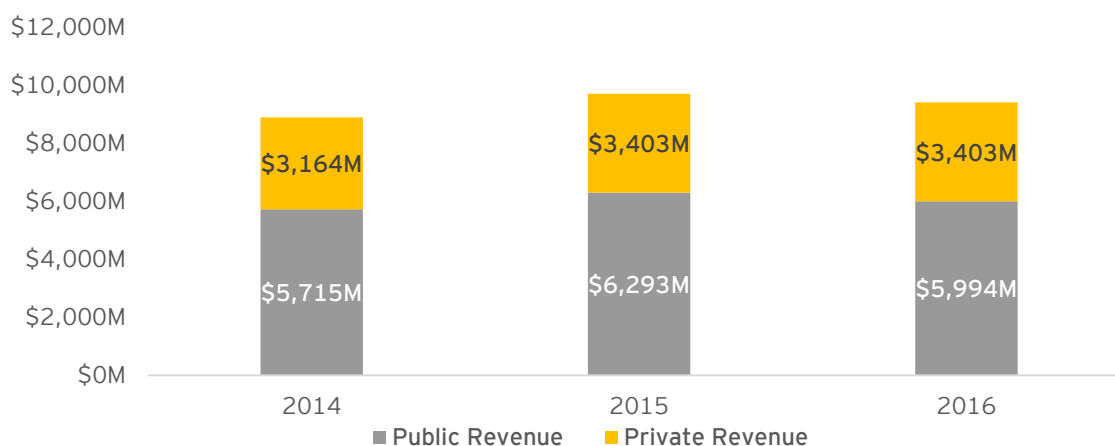


Figure 10. Estimated public/private split of member revenues (note: breakdown is based only on Innovative Medicines Canada members reporting public/private split).



Total member Investments

Historically, members have reported their investments in research and development (R&D) to the PMPRB as a means of assessing the effectiveness of Canada's patent protection regime. The patent protection regime is intended to promote re-investment of member revenues in R&D. The PMPRB collects, annually, data on members' investments in Canadian R&D. The reported figures are based on Revenue Canada definitions according to the SR&ED program. However, as R&D has evolved in Canada, certain R&D investments may no longer fit the strict definition. As such, in addition to revenue data, members were

asked to provide information on their investments in both SR&ED-eligible and non-SR&ED-eligible R&D investments. Information was also collected from members on investments in patient support programs (PSPs), and general corporate operations.

- ▶ **R&D and innovation expenditures as a percentage of revenue.** Members reported a total of \$1.19B in R&D investments for 2016. These investments include PMPRB Form 3 SR&ED-eligible and non-SR&ED-eligible R&D, as well as investments in randomized controlled trials (RCT), real world evidence, and Phase IV studies. SR&ED-eligible R&D investments reported by participating members were \$0.62B in 2016, representing 5.1% of revenues. Non-SR&ED-eligible expenditures represented a further \$0.45B or 3.8% of revenues. The inclusion of other investments in innovation, such as donations to charities for research, grants, university chair endowments, round out members' total contributions to R&D and innovation, amounting to an estimated total 9.97% of revenues in 2016. Of note, even with the decrease in gross revenues from 2015 to 2016, the total investment in R&D and innovation still increased, underlying the long-term nature of members' commitments.

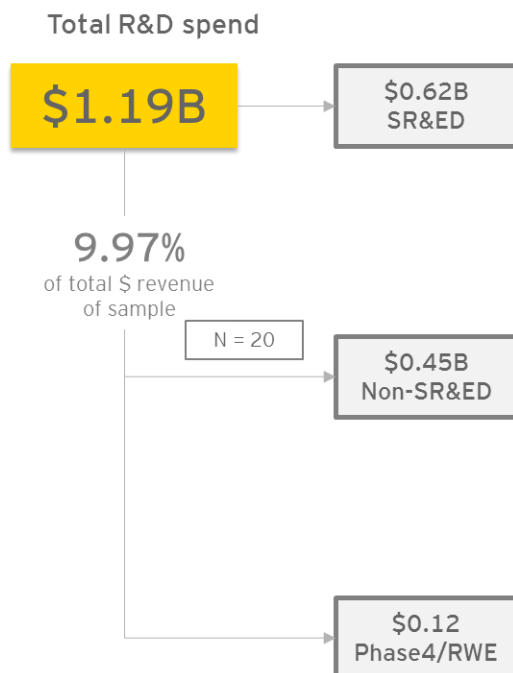


Figure 11. Total participating member R&D spend, 2016



► **SR&ED-eligible R&D investments.**

Figure 12 represents the total SR&ED-eligible R&D investment reported to the PMPRB by participating Innovative Medicines Canada members for 2016, broken down by purpose. Although the total amount of R&D investment has increased slightly from 2014-16, the

amount spent by members on Phase 3 clinical trials in Canada has decreased over time, from \$198m in 2014, to \$176m in 2016. This finding is important since the presence of phase 3 trials may be associated with increased patient access to promising new therapies at an early stage.

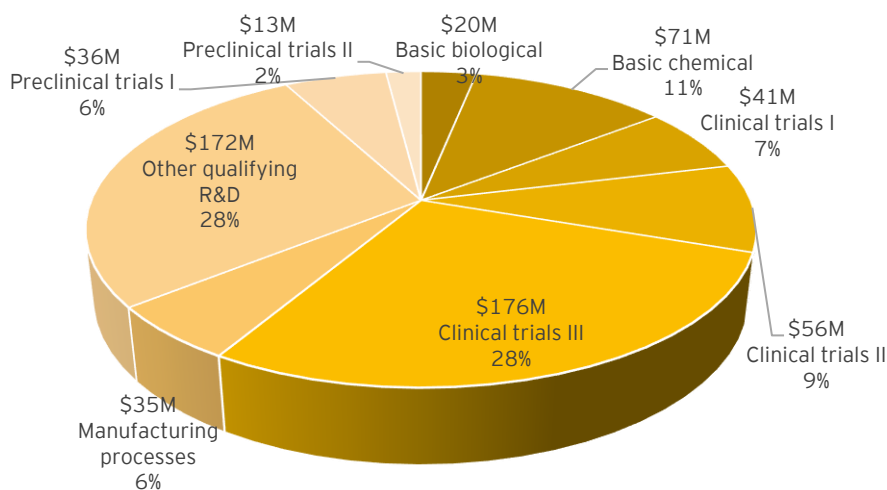


Figure 12. R&D investments, 2016, as reported to PMPRB.



Patentees are also generally directly responsible for conducting the majority of the R&D, with investigators and other

organizations representing significantly smaller proportions, as shown in Figure 13. This finding suggests that there may be additional opportunities for collaboration in increasing the R&D footprint of Innovative Medicines Canada members.

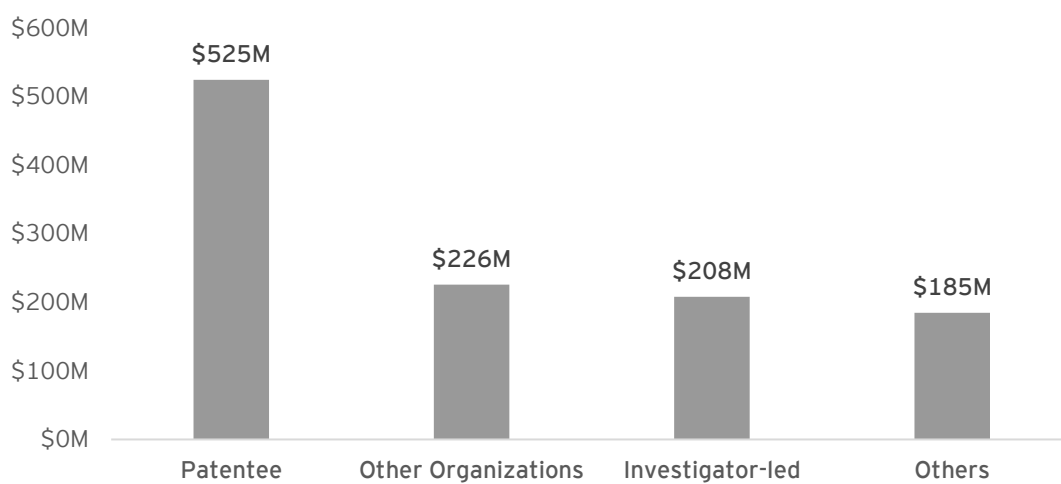


Figure 13. R&D by party conducting it in 2016.

► **Patient support programs.** Patient support programs (PSPs) have been developed by innovative pharmaceutical companies over time to help patients and health care providers navigate the gaps and challenges in accessing manufacturers' innovative therapies within a healthcare system that is not always equipped to deliver these emerging new therapies. Despite this, there are no published comprehensive sources of the estimated scope and impact of PSPs in Canada. This exercise attempted to build a baseline data set from which to begin to understand this impact. Typical PSPs encompass a range of support services, from reimbursement and compassionate financial assistance, to counseling, reimbursement navigation assistance, and drug treatment, and other

types of health care provision associated with manufacturers' medicines in non-hospital settings. While not all participating Innovative Medicines Canada members submitted data related to PSPs, the aggregated data begins to provide a

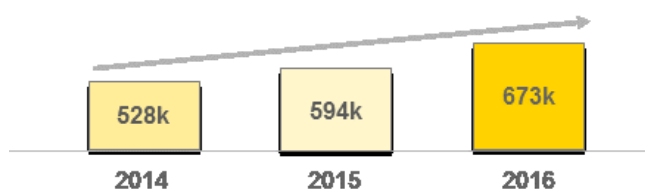


Figure 14. Number of patients enrolled in PSPs reported by participating members

window into the reach of PSPs across patient communities.

- ▶ Based on the data collected, the number of patients enrolled in PSPs increased significantly over the reporting period, from 528,000 in 2014, to 594,000 in 2015 and 673,000 in 2016, as shown in Figure 14, with just over 68% of these patients enrolled in primary care PSPs, as shown in Figure 15.
- ▶ When the allocation of PSP investment is considered, the overall picture looks somewhat different. Total spending in PSPs reached approximately \$900M in 2016, with just over 50% of this spending allocated to non-oncology specialty drugs, as shown in Figure 16. In tandem with the increase in number of patients supported over the reporting period, members' level of investment also increased over the time period, from \$560M in 2014 and \$720M in 2015. This increase in investment occurred even as members' revenues remained relatively flat over the period,

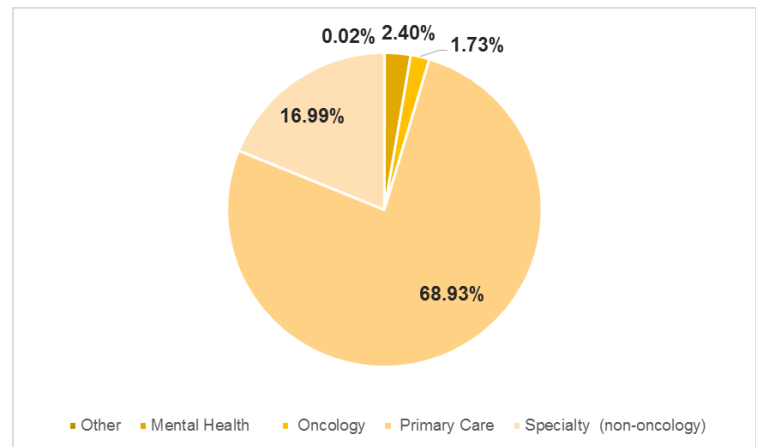


Figure 15. Enrolment of patients in participating members' PSPs, 2016

again suggesting long term commitments by members to patients and PSPs. It may be noted that the proportion of assistance allocated to financial assistance, including both reimbursement financial assistance and compassionate assistance, represented the majority of PSP spending in all three years.

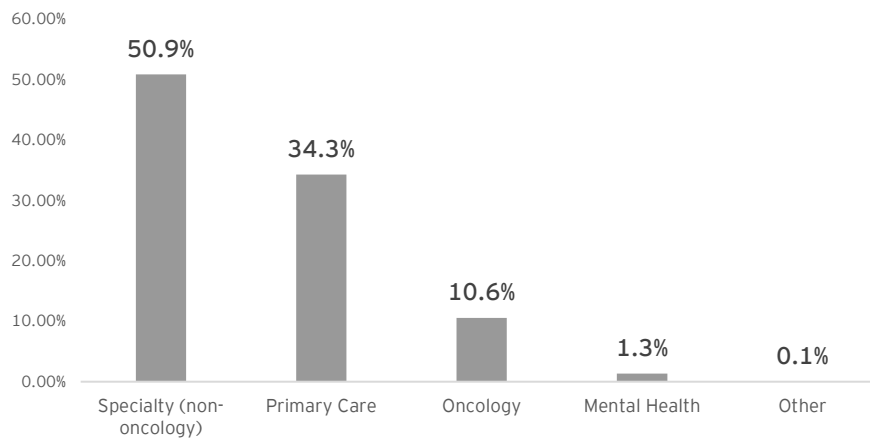


Figure 16. Breakdown of Innovative Medicines Canada member investments in PSPs.

Discussion





Discussion

Moving the dialogue in Canada from price to value

The analysis is based on data provided by Innovative Medicines Canada members, who are in turn a subset of Canadian pharmaceutical and biotechnology companies. The estimated total economic footprint of Innovative Medicines Canada members is in the order of almost \$20B and over 30,000 jobs. Members contribute across the health care value chain, from contributions to R&D, clinical trials, and innovation; to patients' ability to access medicines through patient support programs; and the use of rebates to help public payers manage their budgetary challenges. As payers continue to use the tools at their disposal to manage drug budget expenditures, it is critical that innovative pharmaceutical companies, including Innovative Medicines Canada members, seek opportunities to constructively collaborate with payers, to ensure that the impact on these contributions is minimized, and optimize the overall balance of the health care ecosystem. For example, regulatory changes focused on ensuring payer budget sustainability may ultimately erode members' impact if their response is to scale back investments in certain aspects of their operations to compensate for payers' reduced expenditures on drugs. In addition, delays in product listing impact the effective length of patent-protected sales once a product has been approved for marketing in Canada and may lead to foregone member revenue.

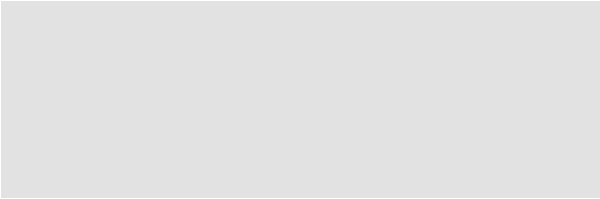
The social costs of disease in Canada

The ultimate goal of the system is to bring better care to patients and improve their overall health, quality of life, and societal impact. In

addition to the directly measurable financial drug and healthcare costs, if one takes a broader societal view, there are associated costs of delayed treatments to the quality of patients' lives, and to society as a whole, including caregivers, employers, and governments who may be required to support these patients while they are unable to be productive due to their illness. Conducting more detailed quantitative assessments of the social costs of the disease burden will be a useful tool in understanding the potential economic impacts beyond the healthcare system.

Opportunities for Innovative Medicines Canada to work collaboratively with Government

Given the shared objectives of both Government and manufacturers to improve patients' health, a new approach, built on trust and collaboration, may be considered critical. The findings from this study demonstrate that there are clear benefits for Innovative Medicines Canada members to seek to engage governments, both payers and policy makers, in co-developing solutions to the industry's sustainability challenges that will lead to longer term certainty of outcomes for patients, payers, and manufacturers. Three potential areas of collaboration are identified below.



Improving system efficiencies

The analysis suggests that system efficiencies are a key potential area of common ground between Innovative Medicines Canada members and policy makers. In theory, faster access to medicines benefits patients, productivity and potential benefits to employers, and the economy as a whole, although the impact on payers' budgets needs to be considered. In this context, Innovative Medicines Canada members may also consider working with payers to identify more mature, under-performing products which could be candidates for alternative contracting approaches, price reductions or eventual de-listing, although de-listing should always be approached with caution so as not to disrupt continuity of patient care. At the same time, improving time to listing may mean that some products may have a value gap as listing agreements are being negotiated. For example, payers and manufacturers may not be able to agree on the value of a product that has concluded Phase 3 trials, as the targeted value end points may not have been adequately demonstrated through randomized clinical trials, due to study design limitations or other considerations. Nevertheless, if the product is agreed to hold great promise for patients, the parties may agree that the product merits an initial listing while value is being proven, as shown in Figure 17.

The question of how the product should be priced, however, remains outstanding. Performance-based risk-sharing agreements, also known as value-based, or outcomes-based agreements, are frequently cited as a solution

to this challenge.

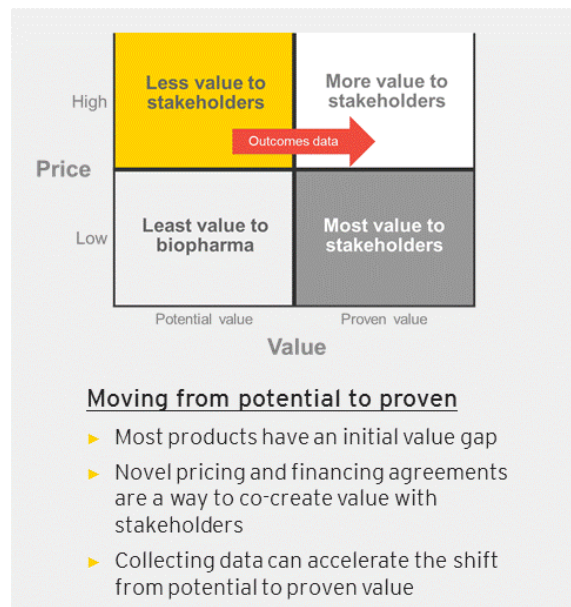


Figure 17. Value matrix.

Performance-based risk sharing agreements

There is a significant learning curve in implementing such agreements to create value, as shown in Figure 18 below. For example, certain types of agreements may work better with certain drug types. Products for chronic diseases may be contracted differently than those that address acute conditions. The current paradigm in Canada, focused on traditional discounting and patient support schemes, has significant potential for a shift over the long term toward performance-based risk-sharing agreements.

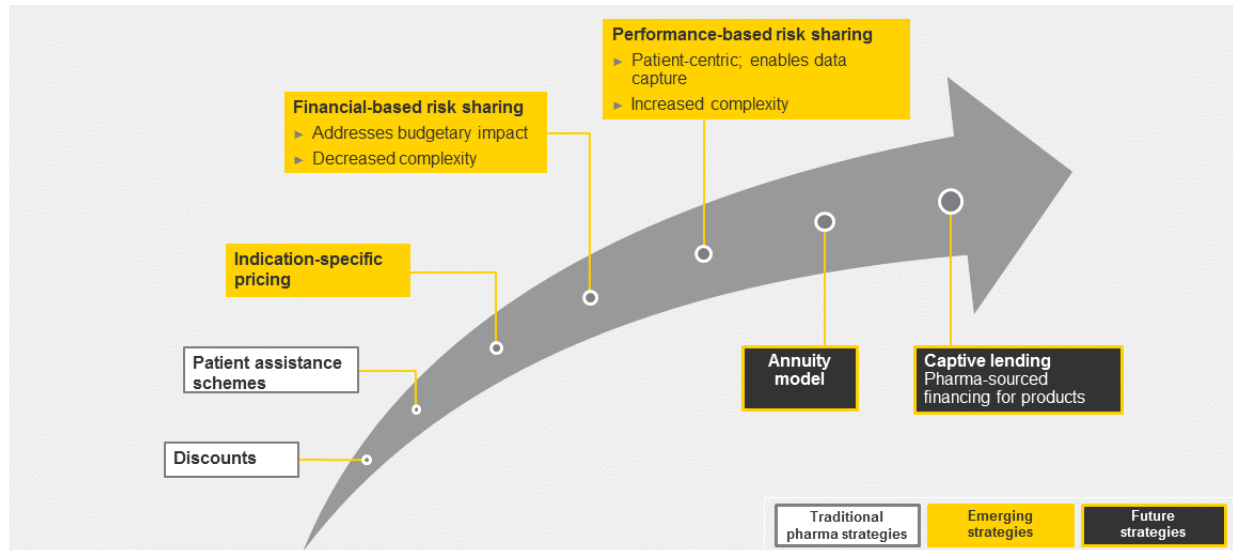


Figure 18. Evolution data requirements to support performance-based risk sharing.

In order to effectively implement risk-sharing agreements, the objective of the agreement must be clear. Experience from other jurisdictions demonstrates that specificity in the design of the agreement is critical to

effective implementation. Figure 19 below, which is based on EY internal research, describes several types of agreements that have been implemented in Europe, and provides examples of their specific application.

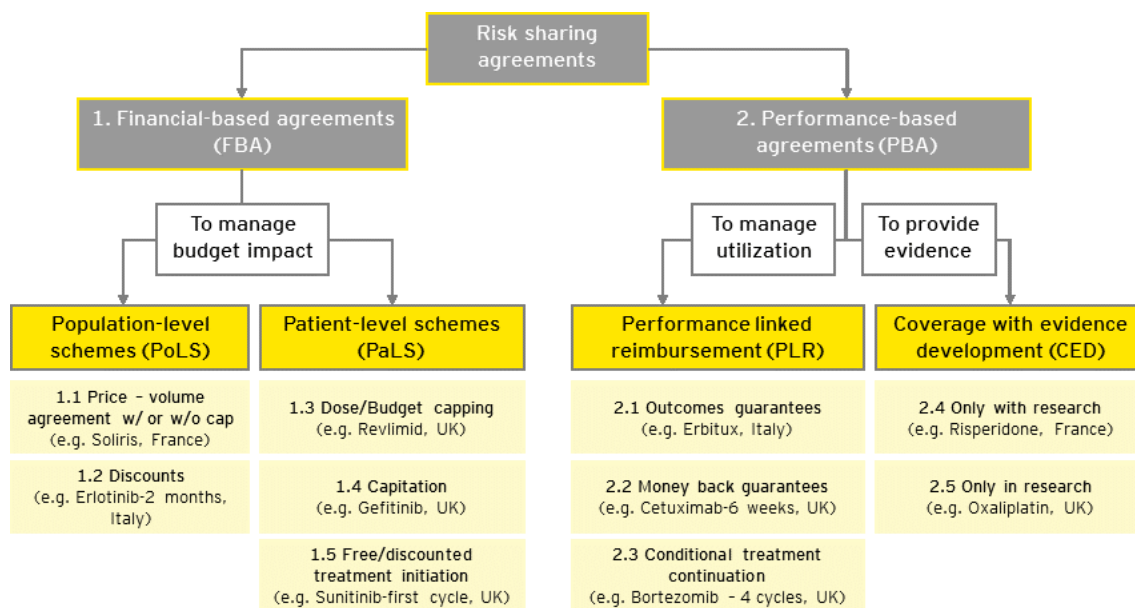


Figure 19. Examples of data-driven performance-based risk sharing agreements (EY research)



Data sharing and infrastructure

Implementation of risk sharing agreements is not without challenges. These challenges include the resourcing and administrative burdens; the governance model to manage the agreements transparently; addressing legal issues regarding individual patient data collection and transfer; and agreeing on methodology, such as the definition of effectiveness and the appropriate clinical outcome indicators. Moreover, objective clinical measures may not be readily available in all disease areas. As such, the cost of implementing such schemes may be perceived to outweigh the benefits.

Key to the implementation of such agreements is a data infrastructure that will reduce the associated resource impact, and create trust in the data, through transparency to all involved. At present, although Canada benefits from highly centralized datasets of public administrative data which could facilitate the implementation of such agreements, the investment required to integrate and govern an infrastructure to manage such a system on a widespread basis over the long term, enabled by real-world-evidence collected at the point of patient care, is significant. Member participation and investment in such infrastructure could be seen as an act of collaboration in the eyes of governments,

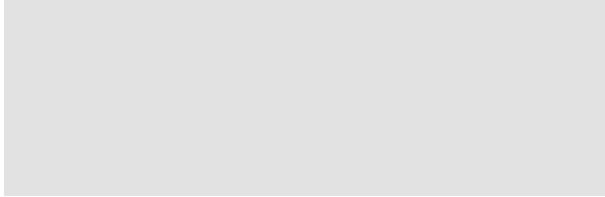
payers, and patients, given that these stakeholders may not have the internal capacity or experience to implement these measures on their own. Moreover, the collaboration required for this exercise of jointly building such a new model will by necessity require all parties to build trust over time, which will be an essential component for any future framework agreement between stakeholders.

Moving forward

This study may be seen as one step in a long-term journey to a more sustainable system. While a critical mass of data has been captured and analysed, providing a critical window into the economic impact of a substantial subset of Innovative Medicines Canada members, and informing a range of potential responses and solutions, it is important that the exercise not stop at this early stage. It is essential that efforts be made to maintain and build on the current dataset, to establish a longitudinal and robust set of information that can be analysed over time to both assess impacts of any new policy measures, as well as identify solutions that may be proposed to government. Innovative Medicines Canada's actions should continue in a transparent fashion, which will help build the trust needed to co-create sustainable solutions to the drug expenditure challenge in Canada over the long term.

Appendix





Appendix

Glossary

Appendix A

Acronym	Text
CADTH	Canadian Agency for Drugs and Technologies in Health
CAPCA	Canadian Association of Provincial Cancer Agencies
INESSS	Institut national d'excellence en santé et en services sociaux
pCPA	Pan-Canadian Pharmaceutical Alliance
PMPRB	Patented Medicines Pricing Review Board
R&D	Research and Development
NOC	Notice of compliance
PSP	Patient Support Program
SR&ED	Scientific Research and Experimental Development
GVA	Gross Value Added
CRO	Contract Research Organization



Appendix B

Methodology details

This section outlines the key methodologies used to collect and analyse data associated with this project. It includes a detailed overview of the methods used to collect and aggregate individual Innovative Medicines Canada member data, as well as an outline of the analytical approaches to capture insights from the collected data.

Data Collection Approach

Data description

The analyses in the current report are based in part on data solicited from the members of Innovative Medicines Canada. The data solicited from the member firms included sensitive information concerning:

- ▶ Gross Revenues generated from sale of patented prescription medicines in Canada
- ▶ Volumes of medicines sold in Canada as reported to the PMPRB
- ▶ The geographic distribution of sales
- ▶ The distribution of sales across different buyers and payers
- ▶ The volume of investment in research and Development carried out in Canada in terms of dollars spent and R&D activities (e.g. clinical trials)
- ▶ The volume and distribution of investment and spending in non-research activities including patient support, provider education, charitable giving, and other operations.

Solicitation of this data took two forms, the first being the use of standard reporting forms all pharmaceutical companies in Canada are required to provide to the Canadian patented pharmaceutical pricing regulator, the PMPRB, on a regular basis, and the second being a series of customized questionnaires prepared

by EY and emailed to each member firm.

PMPRB Forms

Member firms were asked to provide the following forms which they provide annually or semi-annually to the Patented Medicine Prices Review Board (PMPRB):

- ▶ Form 2 - Information on the Identity and Prices of the Medicine
 - Block 4 - Sales of the Medicine by the Patentee in Final Dosage Form in Canada
 - Block 5 - Publicly Available Ex-Factory Prices for Canada and Other Countries
- ▶ Form 3 - Revenues and Research and Development Expenditures

The use of PMPRB data confers a number of advantages to the data pool used for the analysis in this report including:

- ▶ Enhanced and timely participation by member firms as the data has previously been produced and formatted
- ▶ Consistent treatment of the data across firms and across time as the PMPRB defines the data required
- ▶ Enhanced data integrity given the role the forms play in regulatory compliance

EY questionnaires

In addition to standardized data provided to the PMPRB, the member firms were solicited to respond to four questionnaires that were prepared by EY, soliciting key data for the analyses in this report. The questionnaires covered the following data areas:

R&D and Clinical Trials - The EY questionnaire concerning R&D and Clinical Trials complemented PMPRB Form 3 through questions looking specifically at who was carrying out R&D work: the patentee, Clinical



Research Organizations (CROs) or Investigator-Led Trials. It also solicited a more granular view of R&D-related investment by soliciting data regarding:

- ▶ R&D expenditure supported by Canada's Federal Government (SR&ED-eligible expenditures)
- ▶ Breakdown of R&D spending by categories including salaries, facility costs, etc.
- ▶ Clinical Data transparency
- ▶ Real World Evidence
- ▶ Phase 4 studies and their reach in terms of patients enrolled or number of sites involved

Patient Support Programs (PSP) - Data was solicited from member firms concerning their investment in Patient Support Programs including:

- ▶ Total spending for such programs
- ▶ Spending by type of patient support or clinical area
- ▶ Spending on internally managed programs vs. 3rd party managed programs
- ▶ Reach in terms of number of patients assisted
- ▶ Volume of activity in terms of number of employees or resources employed to deliver support

Corporate Info - Data was solicited from member firms to examine the economic role played both in the healthcare domain and in the broader Canadian economy. Detailed questions concerning investment and spending related to promoting health and well-being include the following:

- ▶ Investment in provider education
- ▶ Investment in community programs
- ▶ Expenditures on regulatory compliance

With regards to the broader economy, member firms were solicited to provide data on:

- ▶ Capital investment by category (R&D vs. non-R&D)

- ▶ Salaries and benefits
- ▶ Taxes at the federal, provincial and municipal levels
- ▶ Non-health promotion investment including charitable giving to promote, the arts, education and the environment

In order to provide common-form analysis across the different areas of data solicited, member firms were also asked to provide normalizing data such as the number of full-time equivalent employees (FTEs) by employment category, the number of different drugs sold based on Drug Identification Number, and the number of manufacturing, R&D or other sites occupied in Canada.

Each questionnaire was prepared and sent by email as a Microsoft .XLSX file for use in Microsoft Excel. Questions solicited data for each of the following years: 2014, 2015, and 2016. In addition, for each question type, member firms were asked to provide a subjective assessment of the quality of the data being provided by indicating their level of confidence in the question responses as high, medium or low. Respondents were provided both a set of instructions (included as a cover page in each questionnaire) as well as an area to provide pertinent assumptions that may have been used in preparing the data.

In certain cases, the questionnaires solicited data that overlapped with or was redundant with data captured on PMPRB forms. This allowed for analysts to identify and investigate data that was inconsistent between the PMPRB submission and the EY questionnaires. The EY questionnaires, however, probed in much greater detail certain areas that PMPRB forms covered lightly and other areas not covered in any regulatory submissions. The EY Questionnaires also allowed member firms to aggregate data by soliciting provincial and territorial level data.

Data collection process

A data collection process was developed which balanced the needs for assuring the confidentiality of the data being solicited with the flexibility required to manage a broad

solicitation which touched several different functional areas within each member firm including regulatory (market access), finance, legal, and government relations functions. The process and system developed is illustrated in Figure 20.

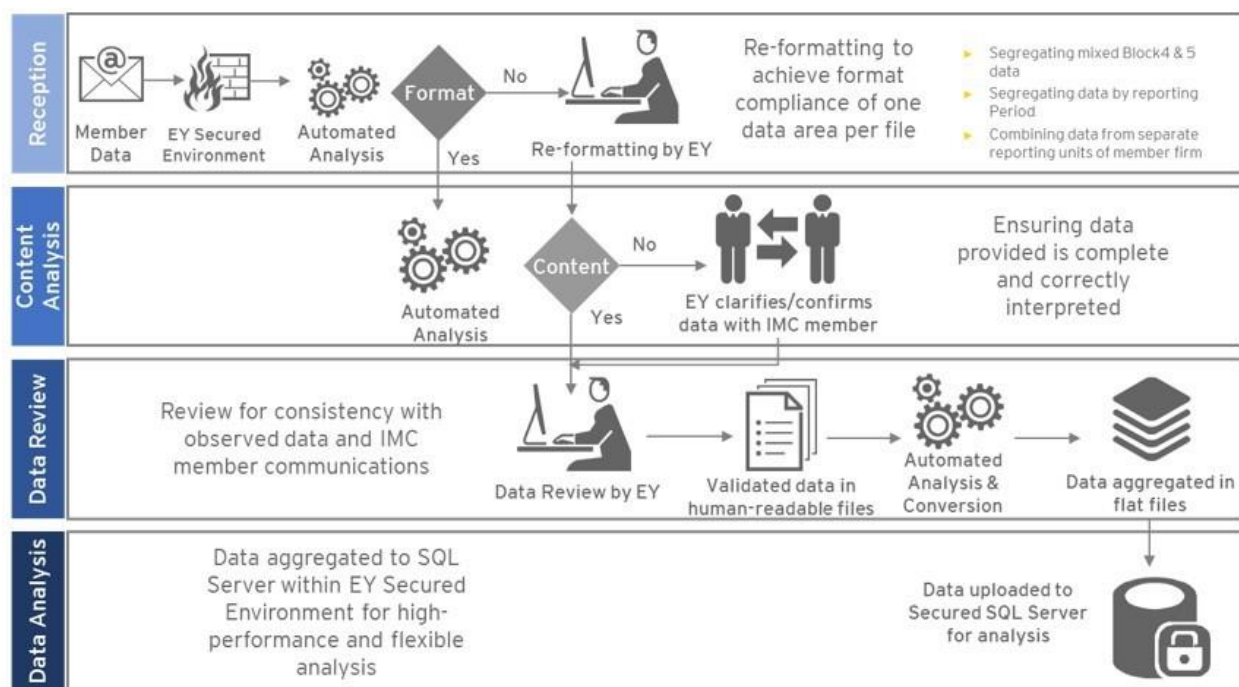


Figure 20. Data Collection Process


The data collection process was designed to rely on email and Microsoft Excel as the primary tools for carrying out data collection because of their ubiquity across functional areas in each member firm and also because these tools mirrored the PMPRB data submission process member firms undertake each year (PMPRB forms are completed in an Excel spreadsheet provided by the PMPRB and are submitted via email). This similarity enhanced the ease of expanding the data gathering and submission process by member firms.

The confidentiality of the member firm data

was promoted by the use of a unique email address created and hosted within EY's secured IT infrastructure. Member firms were instructed to submit data only to that email address and the number of EY analysts with access to the submitted emails was restricted.

Data collection was organized in two phases.

The first phase was focused on soliciting PMPRB Form 2 Block 4 and Form 2 Block 5 data. This phase was kicked off with a comprehensive communication campaign targeting all of the Innovative Medicines Canada members. This communication campaign included emails from Innovative



Medicines Canada executives and repeated webinars where Innovative Medicines Canada member firms were presented with the data collection process by both Innovative Medicines Canada staff and EY staff. Subsequent to these communications, an EY project team

member was designated as the point of contact for all questions concerning data collection in order to ensure the confidentiality of communications with Innovative Medicines Canada members.

A second wave of member data collection included PMPRB Form 3 data as well as responses to three EY-produced Questionnaires:

- ▶ Corporate Information: Information on members' investments and economic activity in Canada
- ▶ Patient Support Programs: information on investments and numbers of patients enrolled in PSPs in Canada
- ▶ R&D and Clinical Trials: information on all clinical trial, additional breakdown for SR&ED-eligible contributions reported on Form 3, and other R&D, and innovation activities in Canada

This data collection exercise was initiated with a communications campaign of emails from Innovative Medicines Canada executives and repeated webinars where Innovative Medicines Canada members interacted with Innovative Medicines Canada staff and EY staff who answered questions clarifying the type of data being solicited. The three EY questionnaires were emailed to designated contacts at member firms.

The data collection process was also designed for active solicitation of the requested data. EY staff provided regular status reports communicating the volume of data received and actively contacted Innovative Medicines Canada member firms throughout the data collection phases in order to enhance the quality of data by answering member questions, and to augment the volume of data by actively addressing areas where data was missing.

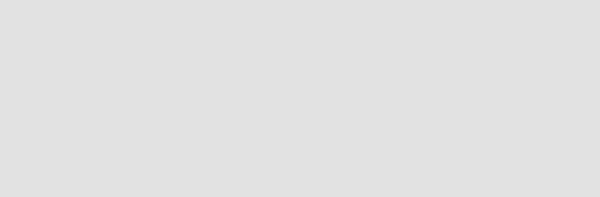
Data collection results

A critical mass of Innovative Medicines Canada member data (i.e. two-thirds or more of members contributed to one or more parts of the datasets collected as of August 9, 2017) has been collected through this exercise, with most major firms (i.e. those with significant revenues and portfolios in Canada) participating.

Data Validation

Overview

Data from Innovative Medicines Canada members was provided almost exclusively in Microsoft Excel files and submitted to EY by email with some exceptions. Within the Microsoft Excel files submitted by members, there were some variations in file structure and content when compared with the templates that were provided as EY questionnaires or PMPRB forms provided by healthcare regulators. As a consequence of the observed variations in data submissions, data handling was partially automated but also relied on the intervention of EY analysts who contacted member firms directly to verify and



validate any observed variations. Variations from expected data formats were either corrected by member firms and resubmitted or were adjusted by EY analysts, such adjustments having been fully documented.

Data handling

Data handling was automated to the extent possible using Visual Basic for Applications to examine data files sent as attachments and flag those that contained formats or structures that varied from the expected templates. The variations in data format and structure that triggered further analysis by EY staff included:

- ▶ PMPRB Form 2 and Form 3 data covering multiple reporting periods being submitted in a single file rather than each period being captured in its own file
- ▶ PMPRB Form 2 Block 4 data submitted in the same data file as Form 2 Block 5 data
- ▶ The addition of rows or columns, either blank or containing data, to the original templates
- ▶ The use of file formats other than Microsoft Excel XLS and XLSX files, including the submission of data in PDF format (either native or resulting from scanning documents containing the data)
- ▶ The presence of content (data or other) in fields which were meant to remain blank

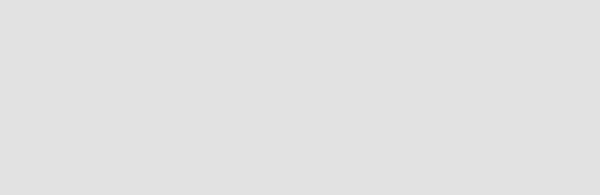
Automation was used to track data submissions by automatically downloading, counting, and saving data files attached to emails sent from Innovative Medicines Canada member firms to the secured email address in EY's network. EY staff manually intervened as in some cases, Innovative Medicines Canada member firms provided access to downloadable data files located on secured file sharing facilities rather than attach the files to email. Similar interventions were required for data files packaged as archives with password protection set by the sender. EY staff also manually intervened to format data to comply with the formats designated in the templates (i.e., EY Questionnaires and PMPRB forms) including disaggregating files containing multiple years of data or files containing mixed content (i.e., Form 2 Block 4 data and Block 5 data). A backup copy of each file as submitted by member firms was made and stored on a secured server within EY's Network.

Other interventions by EY staff were required in cases where

- ▶ Innovative Medicines Canada Members indicated in their submission that certain formatting or assumptions were used which would require manual adjustment (e.g., data was presented in thousands or millions instead of units)
- ▶ Submitted data was in PDF format and required manual transcription to an Excel XLSX file
- ▶ It was not clear if empty data field represented the absence of data or a value of zero

In cases where Innovative Medicines Canada members did not clearly document their assumptions, EY staff contacted members directly to verify the intent of the data and made adjustments where appropriate (e.g. placing a value of zero in blank fields). Other cases of EY staff intervening to adjust submitted data included the submission of amended PMPRB filings submitted by members. In these limited cases, EY staff examined the original PMPRB filing, the amendment and the member firm's commentary in order to produce a true representation of the reported activity.

Data validation



Data files with compliant formats were then further processed using automation to ensure the traceability of each submitted data point. A naming convention was applied that allowed EY analysts to identify the source of each data point by member firm, by reporting period, and by source. For example, 4-142-99 would indicate that the data point was from PMPRB Form 2 Block 4, covering 2014 2nd half reporting, and was from Innovative Medicines Canada member 99. This traceability of individual data points enhanced data integrity and allowed tracing of data downstream in the analysis back to its source. EY analysts manually renamed each data file using the above naming convention. Automation with VBA was used to append the naming convention to each row of data in the file.

For the EY Questionnaires and the PMPRB Form 3 data files, the data structure required additional processing to create a flat file where data points could have the data source appended. This was accomplished with VBA automation.

For each of the PMPRB Form 2 data files, a system of sums and row counts was used to enhance data integrity. A column containing numeric values was selected and the count and sum of those values was recorded. In subsequent processing steps, the sum of these sums and counts was used to identify any potential loss of data either due to processing errors or the use of inappropriate data types. Similar steps were applied to EY Questionnaire data received from members as well as PMPRB Form 3 submissions.

Automation was used extensively where possible as the Innovative Medicines Canada member base submitted data in a rolling fashion. The automated data handling and validation allowed for quick and consistent preparation of the updated dataset which was reloaded to SQL server.

The final steps of data processing relied on VBA automation to assemble the submitted data from across all Innovative Medicines Canada members into a flat file in CSV format where a single area of inquiry would have all of its data points aggregated. Each of these flat files was processed using VBA automation and metadata was included for each data point including the data source and the datatype of the individual value or record. This step was in preparation for upload of the data to SQL server where it would be available for analysis. Any inconsistent data types were automatically converted to the target type compatible with the SQL table structure waiting to receive the data. Other inconsistencies were flagged and investigated by EY analysts. Any modifications resulting from the data validation were documented.

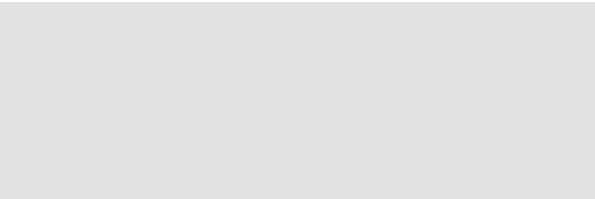
Overview of analysis approach

Total investments

Member survey data is analysed to describe investments across:

- ▶ R&D;
- ▶ Patient support programs; and
- ▶ Community and charitable expenditures.

For R&D, investments are divided into SR&ED and non-SR&ED components with information detailing spend for real world evidence, Phase IV studies, university professorships and spend by trial types and phases. For patient support programs, information is presented by disease level, number of patients supported and spend across Aboriginal Health programs. For community and charitable expenditures,



information is presented by grants awarded to entities that support health and well-being of Canadians (excluding research), programs that support and promote education/training, and other community programs.

Economic footprint and Gross Value Added (GVA) analysis

The pharmaceutical industry's productive activity generally, and that of Innovative Medicines Canada members specifically, contributes directly to Canada's economic activity which can be shown through the Gross Value Added which it produces. Members' activities support jobs across Canada. Direct effects of participating Innovative Medicines Canada members have been calculated using the revenue, expenditure, and workforce data provided by members.

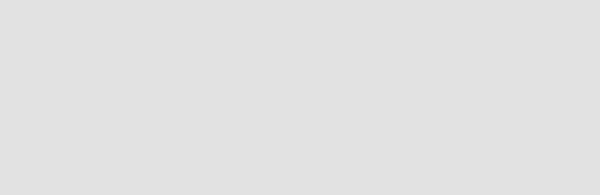
Economic activities are related to one another within the wider economy through a dense network of supplier-customer relations, and thus produce effects that cross corporate and sector borders. Each unit of output produced in a specific sector of the economy requires the production of additional units of goods and services in other parts of the economy to fulfil its input requirements. Production of an additional unit of any good or service also requires the application of additional amounts of labour.

Therefore any increase in the demand for goods and services in the economy will trigger yet more demand for other goods and services, to fulfil the input needs described above. The amount of labour as well as the quantity and type of goods and services necessary to produce an additional unit of output is industry specific and depends on the technology used. The Input-Output model developed by Wassily Leontief describes such relationships and allows quantifying such additional demand for labour, goods and services through the computation of industry-specific multipliers. Using the Input-Output model as its main building block, the Economic Footprint methodology allows quantifying a productive activity's total contribution to the wider economy.

Within this framework, three distinct effects can be identified and measured:

- ▶ A Direct Effect arising from the initial increase in economic activity, the GVA it generates and the additional jobs it creates;
- ▶ An Indirect Effect arising from the additional demand of goods and services along an industry's supply chain; and
- ▶ An Induced Effect arising as an effect of households spending a share of the additional income generated through the provision of labour on the consumption of goods and services.

Indirect and induced economic impacts described in the economic impact analysis have been derived from direct economic impacts using multipliers for the life sciences sector in Canada. Output multipliers are obtained from Input Output tables, through a mathematical process known as Leontief Inverse. By applying industry GVA/Output ratios and apparent labour productivity measures to the Output multipliers thus obtained, industry level GVA multipliers and employment multipliers can be produced. These multipliers are described in the results section. GVA/Output ratios and apparent labour productivity measures are based on statistical data published by Statistics Canada.



Analytical limitations and caveats

Total investments

Not all members responded to the questionnaires concerning investments such as R&D, patient support programs, total costs, and other key investment measures. As such, where these results are presented, they are presented only for the subset of participating members who submitted such data.

References





References (Alphabetical Order)

- 2016 Canada's Top 100 Corporate R&D Spenders Report*. (2016). Retrieved from Research Infosource: https://researchinfosource.com/top100_corp.php
- Access to New Medicines in Public Drug Plans: Canada and Comparable Countries, IMC Annual Report*. (2015). Retrieved from http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524_Access_to_Medicines_Report_EN_Web.pdf
- Canada Statistics Cancer Registry, Conference Board of Canada*. (2017). Retrieved from <http://www23.statcan.gc.ca/imdb/p2SV.pl?Function=getSurvey&SDDS=3207>
- Current expenditure on pharmaceuticals and other medical non-durables, per capita*. (2015). Retrieved from OECD, Health Statistics: <https://data.oecd.org/healthres/pharmaceutical-spending.htm>
- Definitions of the different types of impacts eg direct/indirect/induced - ONS, Measuring the economic impact of an intervention or investment*. (2010). Retrieved from <http://webarchive.nationalarchives.gov.uk/20160129145340/http://www.ons.gov.uk/ons/rel/regional-analysis/measuring-the-economic-impact-of-an-intervention-or-investment/measuring-the-economic-impact-of-an-intervention-or-investment/index.html>
- GVA Canada vs UK - EY Analysis (ONS, What does the UK pharmaceutical industry look like today*. (2014). Retrieved from <http://webarchive.nationalarchives.gov.uk/20160106003953/http://www.ons.gov.uk/ons/rel/iop/index-of-production/april-2014/sty-pharmaceuticals.html>
- (2015). *Life Sciences in BC: Economic Impact now and in the Future*.
- National Health Expenditure Trends 1975 to 2016*. (2016). Retrieved from Canadian Institute for Health Information: https://secure.cihi.ca/free_products/NHEX-Trends-Narrative-Report_2016_EN.pdf
- Patentee's Guide to Reporting*. (2015, July). Retrieved from <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=523&lang=en>
- PMPRB annual reports*. (2014). Retrieved from <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1217>
- PMPRB annual reports*. (2015). Retrieved from <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273>
- Prescribed Drug Spending in Canada, 2013: A Focus on Public Drug Programs*. (2015). Retrieved from Canadian Institute for Health Information: <https://secure.cihi.ca/estore/productFamily.htm?locale=en&pf=PFC2896>
- Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations*. (n.d.). Retrieved from <https://www.canada.ca/en/health-canada/programs/consultation-regulations-patented-medicine/document.html>
- State of Canada's Aerospace Industry, 2017 Report*. (2017). Retrieved from ISED and AIAC: <http://aiac.ca/wp-content/uploads/2017/06/State-of-Canadas-Aerospace-Industry-2017-Report.pdf>
- The economic contribution of the UK Life Sciences industry*. (2017). Retrieved from ABPI:



http://www.abpi.org.uk/our-work/library/industry/Documents/The_economic_contribution_of_the_UK_Life_Sciences_industry.pdf

The Economic Footprint of Selected Pharmaceutical Companies in Europe. (2016). Retrieved from EFPIA:
https://www.wifor.com/tl_files/wifor/PDF_Publikationen/161219_Efpia_EF_report_WifOR_updated.pdf

EY | Assurance | Tax | Transactions | Advisory

About EY

EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization and/or one or more of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit ey.com.

© 2017 Ernst & Young LLP.

All Rights Reserved.

ey.com/ca