



2010-2011

The Rx&D International Report on Access to Medicines

Canada's Research-Based
Pharmaceutical Companies



Les compagnies de recherche
pharmaceutique du Canada

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FOREWORD

This is the 5th Annual *International Report on Access to Medicines (IRAM)*. This report has evolved from just a snapshot of past reimbursement decisions to also become a new discussion on ideas and approaches to improving health outcomes and health policy in Canada.

In the last year, we have seen colleagues from around the world take note of our report. We have also seen governments commission similar reports to better understand what access to pharmaceutical care looks like in very specific disease areas in relation to other jurisdictions.

When we started this work in 2006, it was aimed at answering a straightforward question: how does Canada's access to innovative medicines compare to other countries? Since that time, the scope of this report has expanded from a handful of comparator countries to now cover almost all members of the Organization for Economic Cooperation and Development (OECD).

Innovation in pharmaceutical review and approval processes is required if innovative medicines are to reach Canadian patients in a timely manner. Given the value and success of innovative pharmaceuticals in improving health outcomes, saving downstream health care costs and improving the productivity and well-being of Canadians, we are beginning a broader policy dialogue that will live beyond this report.

Our health systems continue to evolve, in all their forms. Achieving better patient outcomes and health sustainability requires a commitment to dialogue and partnership among all those affected by the system of care we all choose to build. We believe this report will help guide the development of pharmaceutical policies that can improve health outcomes while supporting a sustainable, innovative health care system for all Canadians

Sincerely,



Russell Williams,
President,
Rx&D

EXECUTIVE SUMMARY

Today, Canadians are living healthier lives and are faced with an increasing number of medical options to improve chances of survival and quality of life. Much of this is due to a better understanding of risk factors associated with disease, improvements in safe medication practice and advancements in the art and science of medicine¹. Now, thanks largely in part to pharmaceutical innovation, children with leukemia live instead of die; adults with serious cardiovascular conditions remain active family members and productive contributors to society; and, people who suffer from arthritis can avoid pain and costly, disruptive joint replacement. However, despite the benefits of appropriately prescribed medicines for people over time, not all new medicines reach patients in Canada at the same rate as patients in other developed nations.

Successive iterations of Rx&D's *International Report on Access to Medicines* have shown how uneven access to new medicines is across Canada's public drug plans, as well as Canada's public plans' relatively lower access to as wide a range of choice of new medicines compared to other developed nations' public drug plans. Listing averages of new medicines in Canada have hovered around 50 per cent over the last 7 years, including in this year's report. This is not surprising, as Canada's public drug plans generally account for one of the lowest shares of total expenditures on drugs in the OECD².

About the Report

The 2010-2011 *International Report on Access to Medicines* reviews a total of 173 drugs covering 213 indications. The report reviews how drug plans in Canada and 31 OECD countries publicly reimbursed:

1. 123 drugs covering 142 indications that were the object of CEDAC recommendations, and
2. 50 oncology drugs covering 71 indications approved for use in Canada between 2004 and December 2010. Public reimbursement status is current to July 31, 2011.

1 "If it were not for the great variability among individuals, medicine might as well be a science and not an art." Sir William Osler (1892) cited in Woodcock, J. and Lawrence Lesko, *Tailoring Treatments for the Outliers*, *NEJM*, 360: 811-813.

2 See notably OECD 'Medical Goods Dispensed', *System of Accounts 2010*, and CIHI, *Drug Expenditure in Canada 1985-2010*, Table 3, p. 27.

Key Findings

- The Canadian listing average for all 173 drugs representing 213 indications in the analysis is 48%. This percentage represents both full (LIST) and restricted listings (List with Criteria or LWC) on public formularies and special plans.
- The reimbursement percentage for the 31 other OECD countries is 83.5%. The range goes from a low of just above 32% in Estonia to a high of 100% in 6 OECD countries.

Cancer Drugs

- Canada's public drug plans or special plans cover, on average, 57% of the 50 cancer drugs covering 71 indications approved between 2004 and December 2010.
- The average reimbursement percentage for the coverage of cancer drugs/indications in the 31 other OECD countries is 79.9%, ranging from just below 23.5% in Austria to a high of 100% in 8 OECD countries.

Disease Comparisons (Other than cancer)

- When comparing access to medicines that treat specific diseases in Canada compared to other OECD countries, the Canadian listing average is lower than the international average in all disease areas, compared to five out of sixteen disease areas in last year's report.
- In 13 out of 15 disease areas, Canada's public drug plan reimbursement falls far behind that of other OECD countries.

First-in-Class Drugs

- There are 55 first-in-class³ drugs covering 72 indications in this report. Canada ranks in 31st position when it comes to access to first-in-class drugs, with a listing average of 38% on public drug plan formularies in Canada.
- On average, 81.4% of first-in-class drugs/indications are listed in the other countries in the study.

³ For the purposes of this report, and after consultation with leading stakeholders in drug development, Wyatt Health defines "First-in-Class" drug as a drug having one or more of the following characteristics: Represents a new chemical entity in a new class of drugs; First drug for a specific disease where no other effective treatment is available; First drug type to be taken in a new format (e.g. oral vs. intravenous); An innovative drug that the medical community generally feels represents a medical breakthrough; and/or Combination products of already existing products are not considered to be "First-in-Class" drugs. First-in-Class does not necessarily confer "Best-in-Class" status.

Discussion and Principles for Creative Dialogue on Pharmaceutical Policy in Canada

Much has been written about the need to foster and adopt a common understanding about the challenges that we face within health care systems, and the range of available solutions we may wish to pursue. This common understanding between sectors and stakeholders is necessary to develop the best possible options and actions needed to address challenges successfully⁴.

Based on its organizational mission and objectives, Rx&D has developed several principles that could form the basis of a public dialogue among all stakeholders on how pharmaceutical policies in Canada can evolve to find a place for new, innovative medicines:

1. Put patients first;
2. Promote appropriate use of medicine;
3. Make clinical and therapeutic choice paramount;
4. Ensure that Canadians, regardless of their financial status, have access to the best medical care;
5. Enshrine innovation as a guiding principle of our health care system; and
6. Recognize the value of pharmaceuticals in improving patient health outcomes and contributing to a sustainable health care system.

⁴ WHO, *Intersectoral Action on Health: A Path for Policy-Makers to Implement Effective and Sustainable Intersectoral Action on Health*, p. 5, Discussion Paper presented to First Global Ministerial Conference on Health Lifestyles and Noncommunicable Disease Control, Moscow, April 28-29, 2011.

INTRODUCTION

Broadly defined, 'health' is "a dynamic state of well-being characterized by a physical and mental potential, which satisfies the demands of life commensurate with age, culture, and personal responsibility"⁵. We know that 'health systems' and 'health care' exist to maximize our potential, to allow all of us the opportunity to reach, in the words of the World Health Organization, "a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity"⁶.

Importantly, WHO stresses that "Health is a resource for everyday life, not the object of living."⁷ It is in this spirit that people, societies and governments all around the world pursue efforts, individually and collectively, aimed at improving people's well-being and their capacity to contribute actively in their families and communities.

The pursuit of 'better health' involves many actors and a complex array of policies and programs. Practically speaking, achieving 'better health' means having access to appropriate, essential care and fighting against transnational threats (i.e. communicable disease) with the goal of achieving the "highest attainable standard of health"⁸ for all.

Today, Canadians are living healthier lives and have access to an increasing number of medical options to improve chances of survival and quality of life. Much of this is due to a better understanding of risk factors associated with disease, improvements in safe medication practice and advancements in the art and science of medicine⁹. Now, thanks largely in part to pharmaceutical innovation, children with leukemia live instead of die; adults with serious cardiovascular conditions remain active family members and productive contributors to society; and, people who suffer from arthritis can avoid pain and costly, disruptive joint replacement.

But our health care system is much more than just pharmaceuticals. With this in mind, the 5th Annual *International Report on Access to Medicines* offers not just a look at trends and rankings, but also aims to provoke a needed discussion around options for designing the health care systems we want. A necessary starting point for this discussion is to situate the issue of access to innovative pharmaceuticals within the context of the broader required discussion on building a sustainable health care system and its ability to deliver successful patient outcomes for Canadians.

5 Bircher J., "Towards a dynamic definition of health and disease", *Med. Healthcare Philos* 2005;8:335-41.

6 World Health Organization (WHO), *Preamble - Constitution of the World Health Organization*, April 7, 1948.

7 WHO, *Ottawa Charter for Health Promotion*. WHO, Geneva, 1986.

8 Id.

9 "If it were not for the great variability among individuals, medicine might as well be a science and not an art." Sir William Osler (1892) cited in Woodcock, J. and Lawrence Lesko, *Tailoring Treatments for the Outliers*, *NEJM*, 360: 811-813.

ABOUT RX&D

Rx&D is the association of leading research-based pharmaceutical companies dedicated to improving the health of all Canadians through the discovery and development of new medicines and vaccines. Our community represents over 15,000 men and women working for 50 member companies and is responsible for generating 60,000 jobs across Canada. Our member companies come in all sizes. They perform and fund over 25% of all health research and development in Canada.

Our Mission

Advocate for policies that will bring the best innovative medicines and vaccines to Canadians in a timely and appropriate manner; improve Canada's global competitiveness; and make Canada a world leader in attracting pharmaceutical and biotechnology investments, which are key components of the knowledge-based economy.

Our Objectives

- To conduct and promote health research in Canada
- To strive for full access to innovative medicines for all Canadians
- To inform Canadians about the contribution of the research-based pharmaceutical companies in improving their quality of life
- To communicate the role of Canada's research-based pharmaceutical companies in the advancement of an effective, integrated and accessible health care system
- To work cooperatively with our partners in Canada's health care system
- To promote a competitive intellectual property protection and regulatory framework that encourages the discovery and development of new medicines in Canada
- To communicate high standards of safety and quality of medicines
- To educate health professionals and consumers in the optimal use of medications

ABOUT THE REPORT

The research was conducted for Rx&D by Wyatt Health Management. Wyatt Health Management has conducted research for the international report for Rx&D since 2006.

The 2010-2011 *International Report on Access to Medicines* reviews a total of 173 drugs covering 213 indications. The report reviews how drug plans in Canada and 31 OECD countries publicly list and reimburse:

1. 123 drugs covering 142 indications that were the object of CEDAC recommendations, and
2. 50 oncology drugs covering 71 indications approved for use in Canada between 2004 and December 2010. Public reimbursement status is current to July 31, 2011.

The study was limited to OECD nations. Since our last report, the OECD increased its membership from 30 to 34 countries. New OECD member countries are Chile, Estonia, Israel and Slovenia. Countries were included in this report where Wyatt Health Management was able to obtain reimbursement information.

Canada	CA	Ireland	IE	Scotland	SCT
Australia	AU	Italy	IT	Slovak Rep.	SK
Austria	AT	Israel	IL	Slovenia	SI
Belgium	BE	Japan	JP	Spain	ES
Czech Rep.	CZ	Republic of Korea	KR	Sweden	SE
Denmark	DK	Luxembourg	LU	Switzerland	CH
Estonia	EE	Netherlands	NL	Turkey	TR
Finland	FI	New Zealand	NZ	United Kingdom	GB
France	FR	Norway	NO	USA	US
Germany	DE	Poland	PL	Wales	WLS
Greece	GR	Portugal	PT		

Countries Studied

IRAM 2010-2011

Data were gathered for this report from all OECD countries except Chile, Hungary, Iceland and Mexico. Unfortunately, data that had been previously available from Iceland for previous reports is no longer available this year. Finally, Wales has been added as a national program in the UK, as it has its own public reimbursement program similar to Scotland. Therefore in this report, the United Kingdom (GB) refers to data collected from England.

Data were collected from public sources, i.e. publications, bulletins and web sites. Wyatt Health Management also has personal contacts within several international public drug plans. Finally, local consultants have been used in some cases where data gathering is complex.

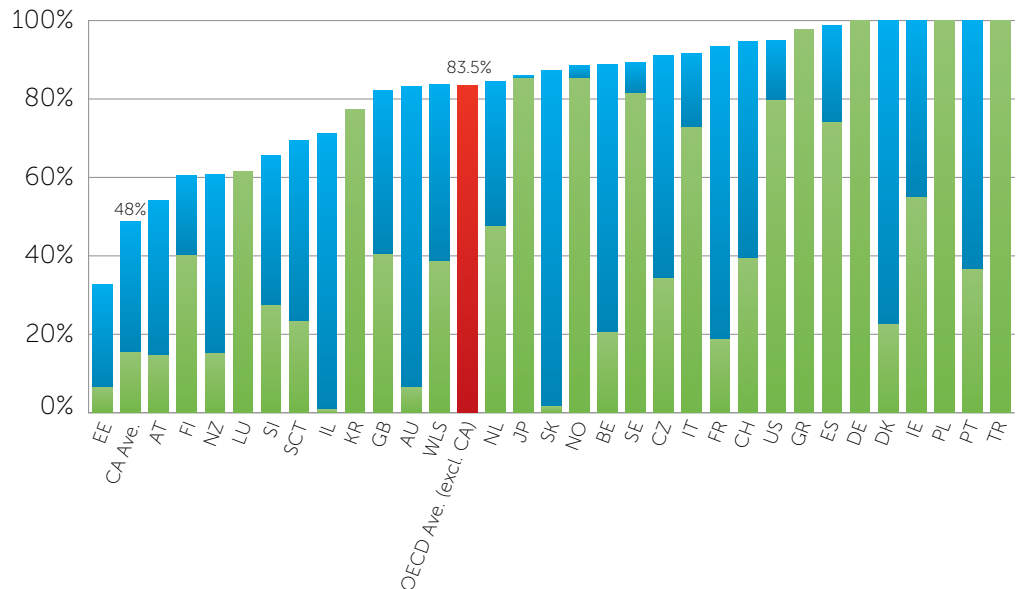
Health care systems are massive, complex constructions that reflect various political, social and cultural norms and priorities. It is clear that there are differences with respect to the public listing and reimbursement of new, innovative pharmaceuticals depending on where one lives in Canada, and indeed, depending on where one lives in the world. These differences create limitations in conducting such a study as this. Limitations can be consulted in the Appendix at the end of this report.

INTERNATIONAL REPORT ON PUBLIC ACCESS TO NEW MEDICINES

Comparing Public Listing of New Medicines on Public Drug Plans in Canada and OECD Countries

On average, 48% of CDR-reviewed drugs/indications and cancer drugs/indications are publicly listed in Canada, as at July 31, 2011. When looking at the chart below, we see that the reimbursement percentage for the 31 other OECD countries is 83.5%. The range goes from a low of just above 30% in Estonia to a high of 100% in 6 OECD countries.

International - Reimbursement Quality
All Country-Specific Drugs/Indications (Canada n = 213)



Data Source: Wyatt Health Management

Nota: Drugs and indications approved and publicly covered in some countries are not available in other countries. This, among other factors described on the following page, has been taken into consideration when calculating reimbursement percentages for each country.

All 173 drugs and 213 indications are available for public reimbursement on public plans in Canada, as these drugs have been approved by Health Canada for use in Canada.

When comparing the availability of new medicines in different countries' public drug plans, we know that not all drugs available in Canada are approved for use in other OECD countries. From a practical point of view, it would be very difficult for this report to determine whether or not any of these drugs are in the process of being or will ever be submitted for national market authorization in other OECD countries. In short, we would never expect that the 173 drugs covering 213 indications would be available in all 31 other OECD countries.

Several factors explain this; chief among them:

1. Drugs available in Canada may not have received regulatory approval or may not be launched in other countries; and
2. Many drugs have more than one indication, meaning that one drug could treat different diseases. Not all indications are approved uniformly across different countries.

Therefore, when calculating reimbursement percentages for drugs in each OECD country, we only include drugs in the calculation that had received national market authorization in each country and had been launched in each specific country (aka 'country-specific approved drugs').

It is important to recall that a reimbursement average of 100% would mean that a patient could receive public coverage of all new medicines that have been approved for use in that country, either because the drug is listed on the public drug plan as an unrestricted or restricted benefit. In this latter case, a restricted benefit means that the drug is listed on the formulary, but that the patient needs to meet specific eligibility requirements, criteria or other conditions required to access that drug. In other words, public coverage may not be automatically available to a patient just because a doctor prescribes a specific drug.

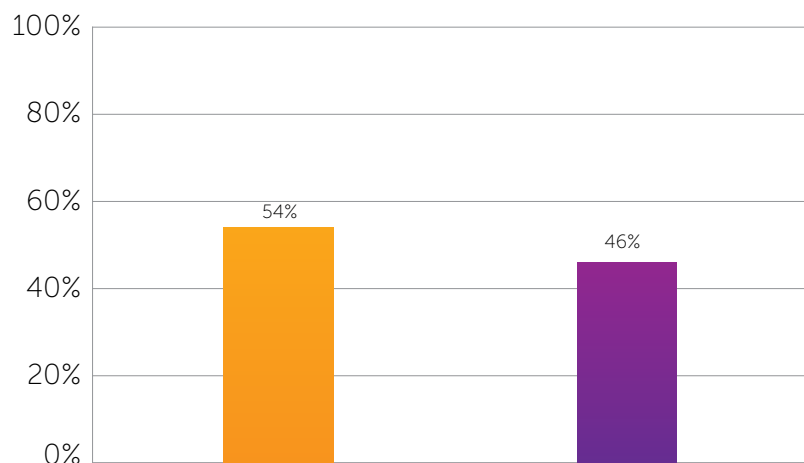
When looking at only CDR-Reviewed drugs (i.e. cancer drugs have been excluded from the following calculation), the Canadian Expert Drug Advisory Committee (CEDAC)¹⁰, the expert committee associated with the Common Drug Review (CDR), has recommended that a drug be listed 54% of the time since the inception of CDR.

This recommendation rate is marginally higher than the public drug plan listing average of CDR-reviewed drugs (46%).

Canada - CEDAC Recommendations vs. Public Plan Listing Average (2004-2010)

CDR Drugs/Indications
(Canada n = 150)

- CEDAC Recommendations
- CA. Ave. Full and Restricted Listings (CDR Reviewed Drugs)



Data Source: Wyatt Health Management

¹⁰ In April 2011, the expert committee's name changed to the Canadian Drug Expert Committee (CDEC). More information regarding CDEC's mandate and responsibilities can be consulted at www.cadth.ca

Cancer Drugs

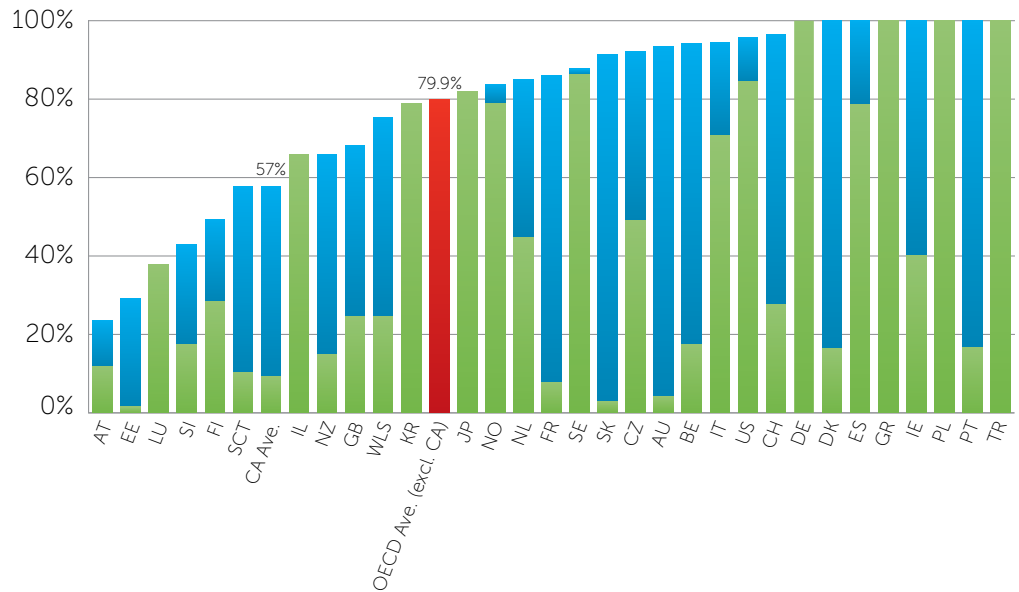
Last year we expanded the scope of this report beyond CDR-reviewed drugs to include new drugs that have been approved for sale in Canada over the last five years, but did not go through the CDR process. All of these drugs/indications treat various forms of cancer and represent a significant therapeutic category for Canadians that had been under-represented in previous reports.

The following chart looks only at the reimbursement status of cancer drugs on public plans and special plans.

When looking at the public coverage of 50 cancer drugs covering 71 indications approved in Canada between 2004 and December 2010, we see that 57% of the reimbursement opportunities are covered publicly in Canada¹¹. The reimbursement percentage for the coverage of cancer drugs/indications in the 31 other OECD countries is 79.9%, ranging from just above 20% in Austria to a high of 100% in 8 OECD countries. Canada's public coverage of new cancer drugs ranks 26th out of 32 countries in the study.

International - Reimbursement Quality

Country-Specific Cancer Drugs/Indications
(Canada n = 71)



Data Source: Wyatt Health Management

¹¹ Federal drug plans are excluded from the Canadian average, as 80% of available cancer drugs are generally available in acute care settings (i.e. hospitals) in each province, as opposed to on an out-patient basis. Furthermore, due to a limitation in being able to access data regarding the public coverage of cancer medications in New Brunswick, its listing average would have been artificially low had it been represented separately. It is important to note that cancer treatments are available both on the public drug plan and in regional hospitals in this province. While information was available for the public plan, it was not possible to obtain complete information on publicly-covered cancer drugs in the hospital environment at the time of report finalization, although we did receive confirmation from New Brunswick that these data can be obtained. A similar challenge in obtaining data was initially experienced in other provinces that exclusively or partly manage cancer drugs through some form of Agency or special plan outside the public drug formulary; however data on public coverage of cancer drugs was eventually obtained through public drug plan managers in those other provinces in time for inclusion in this report.

First-in-Class Drugs

There are 55 first-in-class drugs covering 72 indications in this report.

For the purposes of this report, and after consultation with leading stakeholders in drug development, Wyatt Health defines “First-in-Class”¹² drug as a drug having one or more of the following characteristics:

- Represents a new chemical entity in a new class of drugs;
- First drug for a specific disease where no other effective treatment is available;
- First drug type to be taken in a new format (e.g. oral vs. intravenous);
- An innovative drug that the medical community generally feels represents a medical breakthrough; and/or
- Combination products of already existing products are not considered to be “First-in-Class” drugs.

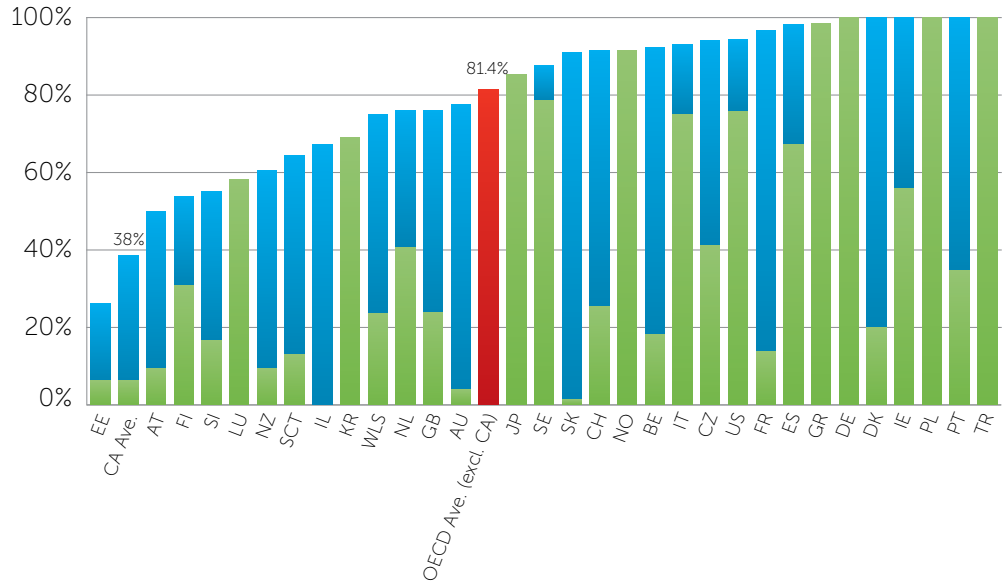
First-in-Class Findings

Whereas, the CDR positively recommended that 30% of these first-in-class drugs be reimbursed on public plans, we see that the Canadian public plans actually list, on average, 38% of these first-in-class drugs. On average, 81.4% of first-in-class drugs/indications are reimbursed in the other countries in the study. Canada ranks in 31st position when it comes to access to first-in-class drugs.

¹² Note that First-in-Class does not necessarily confer “Best-in-Class” status.

As mentioned previously, participating public plans in Canada make decisions on whether or not to provide public coverage for medicines and take into consideration various factors, including recommendations from CDR, which are not binding.

International - Reimbursement Quality
 Country-Specific First-in-Class Drugs/Indications
 (Canada n = 72)



Data Source: Wyatt Health Management

Disease Comparisons

Reimbursement of Drugs by Disease Category

The following table illustrates Canadian and International listing averages by disease area. Please note that cancer is not mentioned in this table. Cancer drugs and indications are discussed earlier in the report.

As described earlier in the previous section on International Findings, we know that not all new drugs available in Canada are approved for use in other OECD countries. The same methodology has been applied here to compare access between Canadian and OECD countries public coverage of new medicines.

International Reimbursement – By Disease (Country-Specific Drugs*)

Therapeutic Area	Number of Indications	Positive CEDAC Recommendation	Canadian Average	International Average (*)
Addiction	3	100%	56%	80%
Arthritis	11	91%	73%	83%
Urology	4	100%	79%	92%
HIV/AIDS	14	93%	82%	88%
Blood Disorders	6	50%	51%	84%
Cardiovascular	11	55%	53%	85%
Dermatology	4	67%	59%	95%
Ophthalmology	6	67%	69%	83%
Infectious Diseases	12	58%	53%	85%
Gastrointestinal	3	33%	47%	90%
Women's Health	8	38%	39%	76%
Neurology	18	22%	28%	85%
Diabetes	10	30%	40%	96%
Rare Disorders	13	54%	47%	80%
Mental Health	8	25%	44%	91%

(*) Other OECD countries' reimbursement percentage is based only on the drugs and indications available in each specific jurisdiction.

It is clear that the *CEDAC Positive Recommendation Rate* is higher for some disease areas than others. The same can be said of the Canadian listing average when comparing access to medicines that treat specific diseases in Canada and in other OECD countries. In fact, Canada does poorly when comparing its listing average across various disease areas versus other countries. The Canadian listing average is lower than the international average in all disease areas, compared to five out of sixteen disease areas in last year's report. This is most concerning for disease areas where we know that choice of medicines is important to appropriately address the needs of different patients, some of whom will respond to some drugs and others who will respond to other drugs in the same therapeutic class.

Findings Conclusion

In all cases described above, it is important to remember that although the public drug plans in several countries may reimburse 100% of the drugs eligible for sale in those countries, it does not mean that they will reimburse 100% of the cost of those drugs or reimburse all drugs 100% of the time. Sometimes, drug plans will put expenditure limits on those drugs and sometimes the drugs may be subject to special authorization criteria. The same applies in Canada.

Furthermore, in some countries, drugs are reimbursed as soon as they receive approval for sale (which is different from how drugs are reviewed separately in Canada: first by Health Canada from a regulatory perspective and secondly, by the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR) from a cost-effectiveness perspective, and then thirdly, by individual drug plans for a listing/reimbursement decision).

Finally, in some countries, national regulatory approval can be tied to price negotiations, which may influence whether or not a drug is available as a publicly covered benefit.

In short, regulatory approval (or national market authorization) and public reimbursement practices vary from country-to-country, and from province-to-province. These differences will have an impact on when and how new medicines are listed on public formularies or reimbursed as a public benefit outside of the formulary (under certain conditions).

DISCUSSION

This 5th Annual *International Report on Access to Medicines* looks at the public reimbursement status of 173 drugs (covering 213 indications) in 32 Organization for Economic Co-operation and Development (OECD) countries. It comes at a time of numerous, ongoing health research and scientific advancements that are driving the development of the next generation of innovative diagnostics and medicines.

It also comes at a time where we see the lifecycle of innovative medicines (from premarket to listing and reimbursement to real world surveillance) changing. Arrangements between manufacturers and payers are also evolving and becoming more sophisticated to accommodate the need to incentivize innovation, manage public resources, and provide appropriate care to the right patients at the right time. Numerous initiatives by multiple stakeholders globally are being explored, including changes in real-world research methodologies and data collection; introduction of appropriate use, adherence and other patient-support programs; improved patient engagement and payer/industry collaboration on health and pharmaceutical policy.

Increasingly faced with a wider array of choice of technologies to address patient needs, governments around the world are interested in figuring out “which one therapy, which one intervention works best for a specific medical condition, and is it worth paying for given the other available options”. While tempting, we know that this approach assumes that all patients are the same, and assumes that all patients with a given condition will benefit in the same way from the “chosen therapy or intervention” that is financed by the public purse. Sometimes a range of individual characteristics and unknowns make diagnosis and preferred treatment options more specific to a patient¹³, rather than to a disease or to a population at-large. Indeed, according to the Institute of Medicine, individualized medicine implies “going beyond the average effect to the effect in subjects with common clinical characteristics”¹⁴.

We know that “there is more to health than just health care”.

“While the general public tends to be preoccupied with the health care system, the determinants of a population’s health are much broader than health care and systems to manage that care. These determinants include a host of other factors— genetics, socio-economic status and government policies and programs in areas as diverse as transportation, education, zoning and early child development—that lie beyond the traditional boundaries of health care institutions and providers.”¹⁵

13 “The central focus must be on increasing value for patients — the health outcomes achieved per dollar spent. Good outcomes that are achieved efficiently are the goal, not the false “savings” from cost shifting and restricted services. Indeed, the only way to truly contain costs in healthcare is to improve outcomes: in a value-based system, achieving and maintaining good health is inherently less costly than dealing with poor health.” Michael Porter, “A Strategy for Healthcare Reform — Toward a Value-Based System” in *NEJM*, 2009 Jul 3.

14 Institute of Medicine (IOM), *Initial Priorities for Comparative Effectiveness Research*, Washington D.C., National Academies Press, pp. 37-38, 2009.

15 Statistics Canada and Canadian Institute for Health Information (CIHI), *Making Sense of Health Rankings*, 2008, http://secure.cihi.ca/cihiweb/products/MakingSense_HealthRankings_web_secure_e.pdf

We also know that prescribed care, whatever it is, is far less-effective in achieving optimal health outcomes, if it is under-used, over-used or used inappropriately. These are all familiar challenges that are being addressed around the world at a time of growing demand for health care in an environment of resource constraints (financial, human, labour market, tax base and other).

Health care systems in Canada and around the world will continue to be organized and financed in different ways. As new ways are developed to promote healthy lifestyles, better prevent and diagnose disease, better predict who will respond to which health intervention, and better treat and rehabilitate people stricken with disease, health care systems in Canada and across the globe are working hard to provide equitable access to the care people need to be productive members of society, in our communities, our families and our economies. There is an appropriate role for innovative pharmaceuticals within this larger context.

Principles for Creative Dialogue on Pharmaceutical Policy in Canada

As a starting point, Rx&D has developed a series of guiding principles that stretch beyond the role of pharmaceuticals only to consider our health care system in its wider context:

- 1. Put patients first:** Health care system performance should be measured by its ability to deliver better health outcomes for patients.
- 2. Make clinical and therapeutic choice paramount:** Health care professionals and patients are critical to optimizing the quality and efficient use of pharmaceuticals.
- 3. Financial hardship should not be a barrier to receiving appropriate care and achieving optimal health outcomes for individuals:** No Canadian should suffer undue financial hardship as a result of out-of-pocket expenditures on essential health care, including access to drugs.
- 4. Enshrine innovation as a guiding principle of our health care system:** Canada can be a stronger leader in life sciences globally and can attract more investment in research, create more high-quality jobs in the knowledge economy, ensure the sustainability of our health care system and achieve the best possible health outcomes for Canadians.
- 5. Recognize the value of medicines in improving patient health outcomes and contributing to a sustainable health care system:** Investing in pharmaceuticals ultimately saves money for the health care system by ensuring that conditions are treated earlier, reducing wait times for primary health care and reducing pressures on other areas of the system.

Ultimately, our collective goal is to ensure good health outcomes for Canadians, without falling prey to short-term fixes:

“Excessive “short termism” in health policymaking can result in reduced or less equitable access to care, can even poorer quality of services and delayed access to new health technologies, leading to worse health and higher demand for health spending in the future”¹⁶.

Financing health care should not be a “zero-sum” game, where one party (or a segment of the population) routinely benefits at the expense of another.

We trust that this report, and the discussions we will have with Canadians, will help us to explore creative ways to continually improve patients’ health outcomes through the provision of appropriate pharmaceutical care.

¹⁶ Pearson, Mark, “Cures for Health Costs, in *OECD Observer*, Number 281, October 2010, http://www.oecdobserver.org/news/fullstory.php/aid/3319/Cures_for_health_costs.html, accessed October 17, 2011.

APPENDIX

Important Considerations for the Reader

Interprovincial comparisons of public drug plans are not represented in this year's report, but data from individual public plans across Canada were used to calculate the average listing rate for Canada used in the international comparisons. Clearly, we have seen changes in all provinces over the last 6 years¹⁷ and are eager to examine these changes from the perspective of patients who rely on public drug plans in a subsequent report.

With regard to this year's report, it is possible that some new drugs reported as "not listed" in this report may have been listed in Canada or in other countries since the cut-off date of the report (July 2011).

Not all drugs that have been approved by Health Canada are submitted to CDR prior to a provincial decision regarding the public coverage of a new medicine. For example, as of March 2007, CDR no longer conducts reviews of cancer drugs. Up until recently, these new cancer drugs were submitted to the Joint Oncology Drug Review (now the pan-Canadian Oncology Drug Review or pCODR). As with last year's report, we have included a special section in this year's report that looks at the reimbursement status of cancer drugs in Canada and OECD countries.

It is worthwhile recalling that in Canada a drug does not need to be listed on a public drug formulary for it to be publicly reimbursed by a provincial or a federal drug plan. For example:

- Some provinces have agencies specifically dedicated to determining how they will publicly cover drugs. Also, some drugs are used mainly in hospitals, as these drugs can only be administered by a health care professional. Hospitals have formulary committees that decide which new drugs it will consider making available to their patients.
- Some plans also have a mechanism to allow the "exceptionally public coverage" of certain drugs not covered on any public plan within that jurisdiction. For example, in Quebec, some drugs can be publicly covered through an exceptional program called "medicament d'exception". In Saskatchewan, the province may decide to publicly reimburse a non-covered drug if doing so is required in an exceptional circumstance particularly to save an individual's life. Finally, in a number of public drug plans, it is possible for a drug to be covered on a case-by-case basis. It is important to recognize that having a drug available for public reimbursement on an 'exceptional' or 'case-by-case basis' does not mean that patients can always depend on their prescribed medicine(s) being covered by their public drug plan.

¹⁷ We have taken note of the recent early-release article, *Gamble et al.*, "Analysis of drug coverage before and after implementation of Canada's Common Drug Review" published at www.cmaj.ca, October 24, 2011.

- Readers are advised to note that Quebec does not participate in the Common Drug Review or the interim Joint Oncology Drug Review (now called the pan-Canadian Oncology Drug Review: pCODR). Quebec conducts its own health technology and reimbursement reviews. As such, reimbursement results for Quebec are included in the report to calculate the listing average for Canada as a whole.

Limitations

Despite the increase in the availability of information regarding the reimbursement status of drugs that have been reimbursed in the countries included in this international comparison, there will always remain challenges in conducting such international comparisons owing mainly to the fact that some countries have different regulatory systems, health priorities, prevalence of disease, and pharmaceutical policies – to name only a few differences – all of which can influence the availability of new medicines. However, by focusing only on drugs approved and made available in Canada since the inception of the Common Drug Review (as opposed to conducting an international comparison of all drugs available in all countries), we believe that we have reduced the great challenges one would necessarily experience in trying to do the impossible: a complete apple-to-apples comparison of all drugs available across the OECD.

Furthermore, we recognize how difficult it can be to compare health care systems, let alone understand the reasons why differences in public coverage of pharmaceuticals might exist between one country and another.

There are differences with respect to the public reimbursement of new, innovative pharmaceuticals depending on where one lives in Canada, and indeed, depending on where one lives in the world.

For example, comparing public drug plan reimbursement in different jurisdictions is challenging because there are so many different factors in play. Some examples include:

1. Regulatory Approval

- Is the drug available for sale in each jurisdiction?
- Has the drug been approved for the same indications?

2. Reimbursement Quality

- Is the public drug plan reimbursement restricted or unrestricted?
- Does “restricted reimbursement” have the same application in all jurisdictions?
- What procedures does the public drug plan employ to obtain reimbursement for drugs that have restricted reimbursement?

3. Economic Factors

- How much does the patient have to contribute?

Given the obvious differences in health care systems, we agree with CIHI's assessment of reports that compare health care systems, notably that "Health rankings are often published to highlight important differences in the health status of populations, to evaluate the relative success of health care systems **and to compare the availability of health-related resources across jurisdictions**" [our emphasis].

The *International Report on Medicines* aims precisely to compare the availability of pharmaceuticals across jurisdictions. However, this is far from the extent of what we are seeking to do when it comes to comparing the "accessibility of a group of medicines across a very good subset of OECD countries".

To contribute to the multistakeholder and intersectoral dialogue that continues to develop in Canada around the sustainability of health care, our main goal is to ensure that all stakeholders have a clearer understanding of the ever evolving health policy environment related to access to medicines. Through this work, we seek to increase our collective chances of identifying and adopting good pharmaceutical policies and actions to improve the entire system of care to which people should have access.

Positive Listing Average

In this report, we reviewed **a total of 173 drugs representing 213 indications; this includes both CDR-reviewed drugs (123) covering a wide number of disease states and cancer drugs (50)**. If a Canadian public plan listed a drug on either their formulary or on a special plan, with or without criteria, the **Positive Listing Average** for that plan would be 100%. If that plan listed or listed with criteria 173 indications of the 173 drugs in the study, the **Positive Listing Average** would be:

$$\frac{173 \times 100}{213} = 81.22 \%$$

This calculation assumes that all 173 drugs and 213 indications are available for public reimbursement on public plans in Canada, as these drugs have been approved by Health Canada for use in Canada. Individual public plans make decisions on whether or not to list and/or provide some form of public coverage of medicines. These decisions are routinely based on a number of factors.¹⁸

¹⁸ These factors include, but are not limited to, Health benefit (mortality, morbidity); Cost-effectiveness (cost per quality-adjusted life year (QALY)); Necessity (e.g. disease burden, severity); Availability of treatment alternatives; Public health impact (population level); Price; Equity; Innovative characteristics (e.g. pharmacological properties, ease of use); Budget impact; Ethical/legal considerations; Feasibility of decision/guidance implementation; Projected uptake/utilization; and Quality of Submissions received from the market authorization holder.

Drugs that are covered publicly outside the formulary and are subject to more restrictive conditions are not counted in the LIST and LWC categories, and do not count toward the **Positive Listing Average**. These include drugs that are

- not listed on the formulary, but may be reimbursed on a case-by-case basis;
- not listed, but reimbursed with criteria,
- only reimbursed on a case-by-case basis;
- only reimbursed in exceptional cases.

In other words, these medicines are not listed on the public formulary and may or may not be available to patients even if they have been prescribed by a health care professional.

Finally, drugs that were removed from the market after they received a recommendation from the Common Drug Review, drugs that were not submitted for reimbursement to specific public payers and drugs that are not paid for explicitly by certain federal plans were not included in the calculation of positive listing averages in Canada.



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