DIA Annual Canadian Meeting 2016

HEALTH

Short Courses: October 17 | Meeting: October 18-19 | Ottawa Marriott Hotel | Ottawa, Ontario, Canada

PROGRAM CO-CHAIRS

Marilena Bassi, MA Acting Director, BPSIP Health Canada

Deirdre Cozier

Keith McIntosh

Regulatory Affairs

Devices Bureau

Health Canada

Directorate Health Canada

Matthew Ryan

Senior Manager, Regulatory Affairs (Canada) Pendopharm, Division of Pharmascience

Executive Director, Scientific and

Innovative Medicines Canada

Marc F. Poitras, PhD. MBA

Scientific Manager, Marketed

Pharmaceuticals and Medical

Senior Policy Analyst; Policy,

Planning and International Affairs

PROGRAM COMMITTEE

Loretta Del Bosco

Director, Regulatory Affairs and Quality Assurance Operations AbbVie Corporation, Canada

Laura Durno, MSc

Acting Chief, Viral Vaccines Division, Biologics and Genetic Therapies Directorate Health Canada

Karen Feltmate

President Redstone Health Group, Inc., Canada

Maggie Graham

Senior Policy Advisor, Natural and Non-Prescription Health Products Directorate Health Canada

Vratislav Hadrava, MD, PhD

Vice President and Medical Director, Global Innovative Products Pfizer Canada, Inc., Canada

Overview

Innovation to support collaboration, engagement, and openness across the Canadian health care landscape.

What does innovation mean to you? Join key thought leaders, industry experts, academics, medical professionals, and Health Canada representatives, and explore how innovation can drive and support new initiatives, regulatory processes, research, transparency, engagement, personalized medicine, use of real-world data, and much more!

Who Should Attend

Professionals involved in:

- Regulatory Affairs
- Policy
- Pharmacoeconomics
- Clinical Development
- Medical Affairs

- Drug Safety/
 Pharmacovigilance
- Patient Safety
- Medical Communications
- Quality Operations

Highlights



Keynote Speaker Joelle Pineau, PhD The AI Revolution: New Perspectives on Health Care in the Information Age

- Short Course: Plain Language Labeling: Implementing Health Canada's Guidance for Industry October 17 | 8:30AM-12:00PM
- Short Course: Innovation in Rx-to-OTC Switch
 October 17 | 1:30-5:00PM
- Community Outreach Activity with the Children's Hospital of Eastern Ontario (CHEO) October 17 | 5:00-6:00PM
- Tabletop exhibitors

DIA

800 Enterprise Road Suite 200 Horsham, PA 19044 USA

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As of 10/06/2016

Schedule At-A-Glance

SHORT COURSES MONDAY, OCTOBER 17		
7:30AM-5:00PM	Short Course Registration	Cartier Foyer, Lower Level
8:30AM-12:00PM	Short Course 1: Plain Language Labeling: Implementing Health Canada's Guidance for Industry	Cartier III, Lower Level
1:30-5:00PM	Short Course 2: Innovation in Rx-to-OTC Switch	Cartier III, Lower Level
5:00-6:00PM	Community Outreach Activity with the Children's Hospital of Eastern Ontario (CHEO)	Victoria Ballroom B, Ballroom Level

DAY ONE TU	JESDAY, OCTOBER 18	
8:00AM-5:00PM	Registration	Victoria Ballroom Foyer, Ballroom Level
8:00-9:00AM	Continental Breakfast, Exhibits, and Networking	Victoria Ballroom Foyer, Ballroom Level
9:00-9:15AM	Welcome and Opening Remarks Victoria Ballroom, Ballroo	
9:15-10:00AM	Session 1: Keynote Address The AI Revolution: New Perspectives on Health Care in the Information Age	Victoria Ballroom, Ballroom Level
10:00-10:30AM	Refreshments, Exhibits, and Networking Break	Victoria Ballroom Foyer, Ballroom Level
10:30AM-12:00PM	Session 2: Plenary Session Setting Strategic Direction - A View from the Regulators and Industry	Victoria Ballroom, Ballroom Level
12:00-1:30PM	Luncheon and Networking	Cartier I - III, Lower Level
1:30-3:00PM	Session 3: Track A: Regulatory Processes – Innovations Track B: Regulatory Operations Track C: Science and Product Development	Victoria Ballroom A, Ballroom Level Victoria Ballroom B, Ballroom Level Laurier Salon, Lower Level
3:00-3:30PM	Refreshments, Exhibits, and Networking	Victoria Ballroom Foyer, Ballroom Level
3:30-5:00PM	Session 4: Track A: Enhancing Innovation Track B: New Digital Solutions for Canadian Product Monograph Track C: Personalized Medicine	Victoria Ballroom A, Ballroom Level Victoria Ballroom B, Ballroom Level Laurier Salon, Lower Level
5:00-6:00PM	Exhibits and Networking Reception	Victoria Ballroom Foyer, Ballroom Level

DAY TWO V	/EDNESDAY, OCTOBER 19	
7:30AM-3:00PM	Registration	Victoria Ballroom Foyer, Ballroom Level
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking Break	Victoria Ballroom Foyer, Ballroom Level
8:30-10:00AM	Session 5: Track A: Transparency and Openness Track B: Data/Analytics Track C: Generics and Biosimilars	Victoria Ballroom A, Ballroom Level Victoria Ballroom B, Ballroom Level Laurier Salon, Lower Level
10:00-10:30AM	Refreshments, Exhibits, and Networking Break	Victoria Ballroom Foyer, Ballroom Level
10:30AM-12:00PM	Session 6: Track A: Policy Development and Direction Track B: Patient Care/Patient Voice/Engagement – Role of Patient Associations	Victoria Ballroom A, Ballroom Level Victoria Ballroom B, Ballroom Level
	Track C: Risk Assessment and Risk Management	Laurier Salon, Lower Level
12:00-1:30PM	Luncheon and Networking	Cartier I-III, Lower Level
1:30-3:00PM	Session 7: Plenary Session Health Canada's International Regulatory Forum Speakers: International Perspectives	Victoria Ballroom, Ballroom Level

Learning objectives

At the conclusion of this meeting, participants should be able to:

- Describe the current and evolving regulatory environment in Canada
- Analyze the current innovations in Canada's health care and medical product development landscapes
 - Summarize methods and approaches to instill innovation in various aspects of clinical trials, patient engagement, supply chain, and manufacturing
- Discuss the compliance, medical, legal, and regulatory considerations for social media use in the medical product development process
- Review and examine the various levels of transparency that have been introduced into Canada's health care landscape

Continuing Education Credit



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If you would like to receive a statement of credit, you must attend the conference or short course, sign in at the DIA registration desk each day, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, November 2, 2016.**

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MONDAY, OCTOBER 17

7:30AM-5:00PM Registration

8:30AM-12:00PM Short Course 1: Plain Language Labeling: Implementing Health Canada's Guidance for Industry

Instructors

Rebecca Bose Policy Analyst Health Canada

Sonya DaCosta, RN

Regulatory Affairs Labeling Manager Apotex Inc., Canada

Christine Leroux

Senior Regulatory Project Manager Health Canada

Veronica Yip

Acting Manager, Labeling Division Health Canada

Rocelyn DelCarmen

Director, Regulatory Affairs and Quality Assurance AstraZeneca, Inc., Canada Building upon the content presented during the 2015 Plain Language Labeling Short Course, this course will review Health Canada's requirements for Plain Language Labeling, discuss operational changes that have been implemented over the past year, and offer an opportunity to discuss concrete examples. Tips and strategies to facilitate the implementation of Health Canada's Guidance for Industry will also be discussed.

Learning Objectives

At the conclusion of this short course, participants should be able to:

- Explain the principles and concepts of Plain Language Labeling
- Describe Health Canada's requirements for Plain Language Labeling and understand the
- operational changes that have been implemented
- Prepare drug label and packaging documents according to Health Canada's Guidance for Industry

1:30-5:00PM

Short Course 2: Innovation in Rx-to-OTC Switch

Instructors Angelina Habimana, MSc

Regulatory Lead, GEM, CHC and Operations Sanofi Canada

John Wong, MPharm

Executive Director, Regulatory Drug Advertising and Promotion Therapeutic Products Inc., Canada

Kristin Willemsen, MS

Director of Scientific and Regulatory Affairs Consumer Health Products Canada

Ratna Bose, PMP

Health Canada

Michelle O'Connor Coughlan

AmerisourceBergen, Director, Strategic Consulting Innomar Strategies, Canada With the ability to do direct-to-consumer advertising and limited price controls, the regulatory professional is often solicited to evaluate the potential applicability of the switch process to many drug candidates. As the switch process is one that involves regulators at both the federal and provincial level, a detailed understanding of the process is crucial. When asked to evaluate potential switch candidates, regulatory professionals need to be able to answer some of the following questions:

- How long will the switch take and what will it cost?
- Will competitors be able to use the switch to their advantage?
- Will the labeling be similar? Are there any specific packaging requirements? (such as tamper/child-resistant)? Can we add promotional claims to the packaging?
- What data is needed to support the switch?

Learning Objectives

- At the conclusion of this short course, participants should be able to:
- Review the process to switch a RX product to OTC status
- Discuss the challenges and benefits in Rx-to-OTC switch for key stakeholders

5:00-6:00PM Join us in giving back to the community!

This year, we are partnering with the Children's Hospital of Eastern Ontario (CHEO) to kick off the *DIA Annual Canadian Meeting 2016* with a community outreach activity!

Help us say 'thank you' by supporting the leaders of tomorrow at CHEO, whose focus is on creating cures and implementing the newest technologies and advancements in medicine to ensure children can thrive in their community.

TUESDAY, OCTOBER 18

00AM-5:00PM	Registration		
8:00-9:00AM	Continental Breakfast, Exhibits, and Net	working	
:00-9:15AM	Welcome and Opening Remarks		
	Sudip Parikh, PhD		
	Senior Vice President and Managing Director,		
	DIA Americas		
	DIA		
):15-10:00AM	Session 1: Keynote Address		
	The AI Revolution: New Perspectives on Health Care in the Information Age		
	Session Co-Chairs	Explore new methods for automatically discovering and optimizing	
	Marilena Bassi, MA	sequential treatments for chronic and life-threatening diseases	
	Acting Director, BPSIP	using recent methods from Artificial Intelligence and Machine	
	Health Canada	Learning. In particular, we will focus on how you can use data	
		collected in multi-stage sequential trials to automatically generate	
	Deirdre Cozier	treatment strategies that are tailored to patient characteristics	
	Senior Manager, Regulatory Affairs (Canada)	and time-dependent outcomes. We will also examine promising	
	Pendopharm, Division of Pharmascience, Canada	methods to improve the efficiency of clinical trials through adaptation. Examples will be drawn from several ongoing research	
	Keynote Speaker	projects on developing new treatment strategies for epilepsy,	
	Joelle Pineau, PhD	mental illness, diabetes, and cancer.	
	Associate Professor, School of Computer Science		
	Director Cognitive Science Program	Q&A	
	McGill University, Canada		
0:00-10:30AM	Refreshments, Exhibits, and Networking	ı Break	
0:00-10:30AM 0:30AM-12:00PM	Session 2: Plenary Session		
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	Session 2: Plenary Session Setting Strategic Direction - A View fron	n the Regulators and Industry	
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TUESDAY, OCTOBER 18

30-3:00PM Session 3	Session 3			
30-3:00PM Session 3 Track A Regulatory Processes - Innovations Session Chair Maggie Graham Senior Policy Advisor, Natural and Non-Prescription Health Products Directorate Health Canada Canadian consumers have access to Core and are making more decisions about how to improve and maintain their health with the use of products that they can choose and use on their own. Health Canada is modernizing the way these consumer health products are regulated. Understanding the consumer experience with self-care products is key to developing an effective regulatory framework and ensuring Canadian consumers have the information and tools that support informed decision-making. This session will provide an overview of the ways Health Canada is engaging with consumers and stakeholders beyond the use of traditional consultation methods. Amand Moir Senior Policy Advisor, Consumer Health Products Modernization Health Canada Kristin Willemsen, MS Director of Scientific and Regulatory Affairs Consumer Health Products Canada, Canada Senior Policy Advisor, Natural and Non-Prescription Health Products Directorate Health Canada	Track B Regulatory OperationsSession Chair Matthew Ryan Senior Policy Analyst; Policy, Planning and International Affairs Directorate Health CanadaThe regulatory operations field is one that has always quickly evolved to leverage opportunities to improve processes through technological innovations in the areas of document and information management. These health authority initiatives also come with challenges and increasing complexities. In order to fully leverage these innovative technologies, process adaptation will be required. This session will provide you with an overview of innovative technologies and processes available or under development by Health Canada to improve operational effectiveness. Presenters will discuss the tools (REP, eCTD v4.0, SPL, ESG) and the strategies to fully leverage these innovations and highlight potential issues and challenges to overcome.ECTD v4.0: The Path to ImplementationJared Lantzy, PMP Manager, Global Regulatory Agencies and Processes: LORENZ Life Sciences GroupInnovation Through Regulatory Operational Processes: Impact on Compliance, Efficiency, and CompetitivenessKhaled Yahiaoui, MSc, RAC Manager, Regulatory Operations Pharmascience Inc., CanadaVianney Caron Manager Electronic Regulatory Activities Health Canada	Track C Science and Product Development Session Chair Laura Durno, MSc Acting Chief, Viral Vaccines Division Biologics and Genetic Therapies Directorate Health Canada Developing and implementing new technologies, manufacturing processes and clinical trials in the biotechnology industry requires an understanding and cooperation between the innovator and the regulator. The session will discuss the challenges and conversations that need to happen between both parties regards to innovative approaches in or to advance a product through clinical development and, ultimately, to marked Interacting with Regulators to Facilitate New Technologies in the Biotechnology Industry Anthony R. Mire-Sluis, PhD Head of Global Quality Astrazeneca Product, Process Understanding, and Statistical Process Control: Pr Life Cycle Approach Marzena Ingram Manager, Process Validation, GSO-Technical Operations Validation Apotex Inc Signet, C		

TUESDAY, OCTOBER 18

3:30-5:00PM	Session 4			
	Track A Enhancing Innovation	Track B New Digital Solutions for	Track C Personalized Medicine	
		Canadian Product Monograph		
	Session Co-Chairs		Session Co-Chairs	
	Rocelyn DelCarmen Director, Regulatory Affairs and	Session Chair	Karen Feltmate President	
	Quality Assurance	Vratislav Hadrava, MD, PhD Vice President and Medical Director.	Redstone Health Group, Inc., Canada	
	AstraZeneca, Inc., Canada	Global Innovative Products	Redstone nearth Group, me., Canada	
	Astrazeneca, me., canada	Pfizer Canada, Inc., Canada	Laura Durno, MSc	
	Keith McIntosh	Flizer Callada, Inc., Callada	Acting Chief, Viral Vaccines Division	
	Executive Director, Scientific and	This session will describe the challenges	Biologics and Genetic Therapies	
	Regulatory Affairs	and solutions that are being explored	Directorate	
	Innovative Medicines Canada	by pharmaceutical manufacturers with	Health Canada	
		the Canadian Pharmacists Association		
	Encouraging an environment in which	to ensure that Health Canada approved,	This session will provide a scientific	
	innovation thrives is a priority for the	Patient Medication Information is made	overview and definition of personaliz	
	government and for industry alike. The	easily available to pharmacists across	medicine. Presentations will include	
	regulatory processes that govern the conduct	Canada.	advances in the field and challenges	
	of business within the pharmaceutical		faced with respect to intellectual	
	sector must be aligned to achieve this goal	Justin Scanlon	property rights, regulatory approval reimbursement policies, and patient	
	as well as being competitive with other similar jurisdictions to attract, retain, and	Vice President, Digital and Print Offerings	confidentiality.	
	deliver innovative health care solutions to	Canadian Pharmacists Association, Canada	connuentianty.	
	the Canadian population. In this session,	Callaud	The Keys to a Successful	
	Health Canada and industry speakers will	Arshia Ghani	Personalized Medicine Strategy	
	discuss options to close the gaps in the	Associate Director, Regulatory Affairs		
	current regulatory framework and processes	Pfizer Canada Inc., Canada	Stephen Amato, PhD, MBA, RAC Head of Graduate Faculty, Regulator	
	surrounding new product submissions to		Affairs; Associate Teaching Professor	
	enable faster access to new therapies.	The 2016 Canadian Product	Northeastern University – College of	
		Monograph Guidance	Professional Studies	
	Progress on Implementation of	Michelle Remillard		
	Vanessa's Law to Date and Future	Manager, Health Products and	George Wyatt	
	Amendments	Food Branch	Managing Director	
	Kristen Beausoleil	Health Canada	Wyatt Health Management, Canada	
	Senior Policy Advisor, Office of Legislative			
	and Regulatory Modernization		Katherine M. Soltys, MD	
	Health Canada		Manager, Health Products and	
			Food Branch	
	Supporting Innovation in the		Health Canada	
	Regulatory Landscape – Thoughts			
	from Innovative Medicine Canada			
	Loretta Del Bosco			
	Director, Regulatory Affairs Quality			
	Assurance Operations			
	AbbVie Corporation, Canada			

WEDNESDAY, OCTOBER 19

':30-8:30AM	Continental Breakfast, Exhibits, and Networking		
8:30-10:00AM	Session 5		
	Track A	Track B	Track C
	Transparency and Openness	Data/Analytics	Generics and Biosimilars
	Session Chair	Session Chair	Session Chair
	Vratislav Hadrava, MD, PhD	Karen Feltmate	Loretta Del Bosco
	Vice President and Medical Director,	President	Director, Regulatory Affairs Quality
	Global Innovative Products	Redstone Health Group, Inc., Canada	Assurance Operations
	Pfizer Canada, Inc., Canada	Mabile Health (milealth) and nations	AbbVie Corporation, Canada
	The session will review the pre-market	Mobile Health (mHealth) and patient access to their own health records offer	This session will provide an overview of
	transparency initiatives underway within	two of the strongest opportunities	generics and biosimilars from a regulator,
	the Health Products and Food Branch,	to deliver best value for money by	industry, and industry consultant
	provide updates and next steps, the	significantly reducing inappropriate	perspective. The field of generics
	evolution of the post-market clinical data	admissions and readmissions by	continues to evolve and Canada is
	transparency within industry, the differ-	extending care into our communities	entering into the new era of biosimilars.
	ent models of data sharing initiatives, and	and to the care-giver/patient. This	What are the challenges? What are the
	industry endorsement of data sharing principles.	session will present as a panel discussion, assessing the challenges	opportunities? How are generics and biosimilars different? Hear from Subject
	principies.	and opportunities for adoption of	Matter Experts on this exciting and
	Jessica S. Scott, DrMed, JD, MD	mHealth solutions and patient access/	sometimes controversial topic.
	Director, North America Medical	input to their own health records,	
	Advocacy and Policy	as well as the regulatory and policy	Donald Elrick, PhD
	GlaxoSmithKline	options to eliminate barriers to	Director, Regulatory Affairs, Immunology
		adoption of mobile and digital health	Janssen Inc., Canada
	Update on Premarket Transparency in the Health Products and Food	solutions.	Policy in the Development of
	Branch, Health Canada	Mobile Health Lead Canadian	Policy in the Development of Generics and Biosimilars in Canada
		Advanced Technology Alliance	
	Laura Johnson		Anne Tomalin, RAC
	Project Manager Health Canada	David Farnes, MA Mobile Health Lead	President Therapeutic Products Inc., Canada
		Canadian Advanced Technology	
	Rebecca Bose	Alliance, Canada	Dawn Culp
	Policy Analyst		Vice President, Global Regulatory
	Health Canada	Shurjeel Choudhri, DrMed, FRCP	Affairs Policy
		Senior Vice President and Head,	Mylan Inc.
	Clinical Trial Data Transparency:	Medical and Scientific Affairs	
	A Brief History and Current Directions	Bayer Inc., Canada	Agnes Klein, DrPH, MD Director, Evaluation of
	Sandra Morris, PhD, PMP	Suzanne Rochford, MSc	Radiopharmaceuticals and
	Vice President, Strategic Realization	Director, User Centered Design,	Biotherapeutic Products
	Johnson & Johnson	Documentation and Training	Health Canada
	Marla Jo Brickman, PhD	TELUS Health, Canada	
	Senior Director/Team Leader,		
	Clinical Trial Disclosure Group	Tyson Roffey	
	Pfizer Inc.	Head of Canadian Healthcare Solutions and Social Innovation	
		Hitachi. Canada	

WEDNESDAY, OCTOBER 19

10:00-10:30AM Refre

1 Refreshments, Exhibits, and Networking

10:30AM-12:00PM Session 6

Track A Policy Development and Direction

Session Chair Deirdre Cozier

Senior Manager, Regulatory Affairs (Canada) Pendopharm, Division of Pharmascience, Canada

This session will overview the process of policy development at Health Canada, from conception to finalization. It will include presentations from industry on the engagement of stakeholders and thought leaders, such as patient groups and industry associations, and the different models used to interact with these groups. Additionally, we will discuss how individual companies (from small and medium sized firms to the large multinational enterprises) can contribute to policy development at the local and international level by implementing innovative regulatory intelligence processes and tools.

Health Policy Initiatives: Ideas Becoming Official Policy and Beyond

Jane Mitchell, PhD, RAC

Associate Director, Regulatory Affairs Mapi Life Sciences Canada Inc., Canada

Stakeholder Involvement in Guidance Development

Keith McIntosh

Executive Director, Scientific and Regulatory Affairs Innovative Medicines Canada

Linda F. Bowen, MSc, RAC

Head, US Regulatory Science and Policy Sanofi

Track B Patient Care/Patient Voice/ Engagement – Role of Patient

Session Chair Loretta Del Bosco Director, Regulatory Affairs Quality Assurance Operations AbbVie Corporation, Canada

This session will provide an overview of how Patient Associations participate and are being engaged by various stakeholders from the pharmaceutical industry to the regulator and payer to ensure that the patient voice makes a difference in patient care.

Julie Bouchard

Associations

Clinical Coordinator CACTUS Montreal, Canada

Janet Yale

President, Chief Executive Officer, Chair of the Arthritis Alliance of Canada Arthritis Society of Canada

Agnes Klein, DrPH, MD

Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products Health Canada

Track C Risk Assessment and Risk Management

Session Chair Marc F. Poitras, PhD, MBA Scientific Manager, Marketed Pharmaceuticals and Medical Devices Bureau Health Canada

This session will discuss processes related to annual summary reports (PSUR/PBRER), Issue Related Summary Reports, and Risk Communications, summarizing Health Canada expectations and addressing questions/concerns. Industry/Health Canada perspectives on the implementation of related guidelines will also be presented.

Melissa Hunt, MSc

Scientific Manager Health Canada

Patricia Carruthers-Czyzewski,

MSc, RPh Manager, Risk Communication Section Health Canada

Agnes Jankowicz, MSc

Executive Director, PV Certus PV Services Inc., Canada

WEDNESDAY, OCTOBER 19

12:00-1:30PM	Luncheon and Networking
1:30-3:00PM	Session 7: Plenary Session Health Canada's International Regulatory Forum Speakers: International Perspectives
	This year Health Canada is collaborating with DIA to host the <i>Health Canada International Regulators Forum</i> (IRF) immediately following the <i>DIA Annual Canadian Meeting</i> . The IRF is an annual forum hosted by Health Canada, which brings together regulators from around the globe to focus on information sharing, regulatory best practices, and capacity building. In this Closing Plenary you will hear from speakers from various regulatory agencies. This an opportunity to learn more about experiences and updates from other regulatory agencies around innovation, capacity building, challenges, and opportunities. There will be an opportunity to ask questions and explore the concepts in more detail.
	Speakers Invited
3:00PM	Meeting Adjourns

I Exhibiting Companies

- CAPRA
- Certus PV Services Inc.
- Clinical Trials Ontario
- LORENZ Life Science

- Mapi
- Proficio Scientific Affairs
- Schlafender Hase Inc.
- Therapeutic Products Inc.

We Hope to See You Next Year!

DIA Annual Canadian Meeting 2017

Short Courses: October 16 Meeting: October 17-18

Ottawa Marriott Hotel Ottawa, Ontario, Canada

*Picture provided by Ottawa Tourism



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