INSIDER UPDATE

DIA's Annual Canadian Meeting: New Realities/New Frontiers

Tutorials: October 28 | Meeting: October 29-30

Ottawa, Ontario, Canada

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Insider Update

This edition of *Insider Update* provides insights from key industry thought leaders about how New Frontiers are driving pipelines forward taking into consideration the ever changing regulatory environment. In line with New Realities, the Pharmaceutical Industry and Health Canada continue to recognize the need to provide the patient and the health care professionals with increased accessibility to drug information and comprehension of drug labels.

All of the experts interviewed will speak at this year's Annual Canadian Meeting: New Realities/New Frontiers meeting in Ottawa.

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"Cooperation is the means to continuing to facilitate access to safe and effective products in a timely, efficient, and responsible manner."

Are YOU Ready to Get the Insider Scoop?

#1

Karen Feltmate

President
Redstone Health Group, Inc.

Q: What is the impact of patient's voice in the ever changing regulatory environment?

A: "As with much of society today, communication is fast and plentiful. So we should not be surprised to find patients communicating with each other about their medical conditions and the treatments they may or may not have access to. Those who are in the pharmaceutical industry and those in the regulatory realm need to acknowledge the patients' voice and perspective. Gone are the days of the ' learned intermediary' being the only conduit for patients to voice their concerns. In many ways, the patient has/is doing a 'work around' the learned intermediary as they gain more information faster from social media that meets their needs.

Industry has traditionally been hesitant to enter the social media world. Perhaps just listening would be a baby step forward. We might learn that the compliance pack that was designed to aid in dosing compliance is not so intuitive after all and is in fact driving patients to alternative therapies. Or even more importantly, we might learn of adverse reactions that could not be seen in prior clinical trials. Better to know sooner than later. Dare I suggest the newest marketing strategy is to listen to patients?"

#2

Co Pham

Scientific Manager
HPFB, Health Canada

Q: What role should the drug industry play in seeking to bring the patient voice into the drug development process?

A: "Having the patient voice within the drug development process is integral to improving the gaps between scientific knowledge and it's application. As such, the drug industry and its partners have a clear responsibility to bridge these gaps and knowledge translate these aspects in the development process."

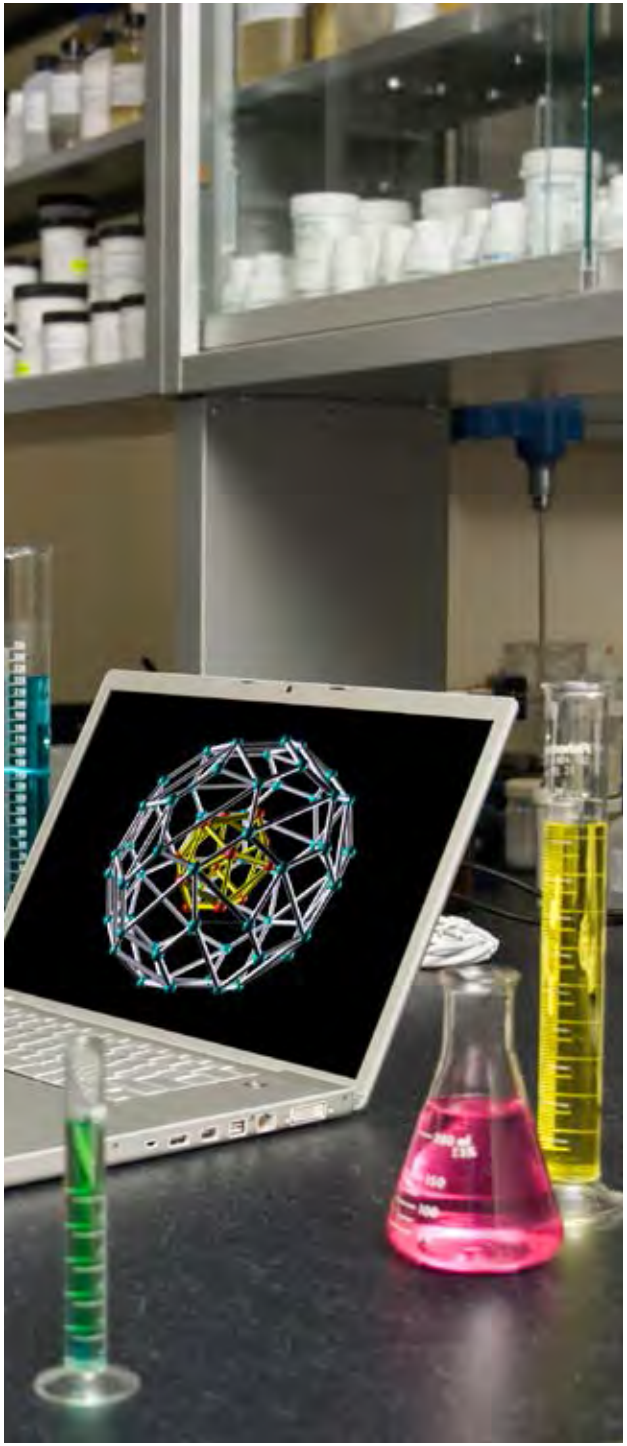
#3

Matthew Ryan

Senior Advisor, Director General's Office
Therapeutic Product's Directorate
Health Products and Food Branch, Health Canada

Q: What does international regulatory cooperation mean to key stakeholders in the development and regulation of health products?

A: "With increased globalization of the pharmaceutical industry, from upstream activities around research and clinical trials to downstream marketed product activities such as manufacturing supply chains, and postmarket surveillance, the international landscape is evolving and becoming much more integrated and complex. From a regulator's perspective, this is also the case. In order to be effective in fulfilling the regulator's mandate, new approaches and collaborations are required to keep up with the realities of the pharmaceutical industry today, as well as the expectations of key stakeholders such as patients and consumers. International regulatory cooperation means thinking strategically and leveraging the work and efficiencies of international partners. Cooperation is the means to continuing to facilitate access to safe and effective products in a timely, efficient, and responsible manner."



#4

Chanez Kebache

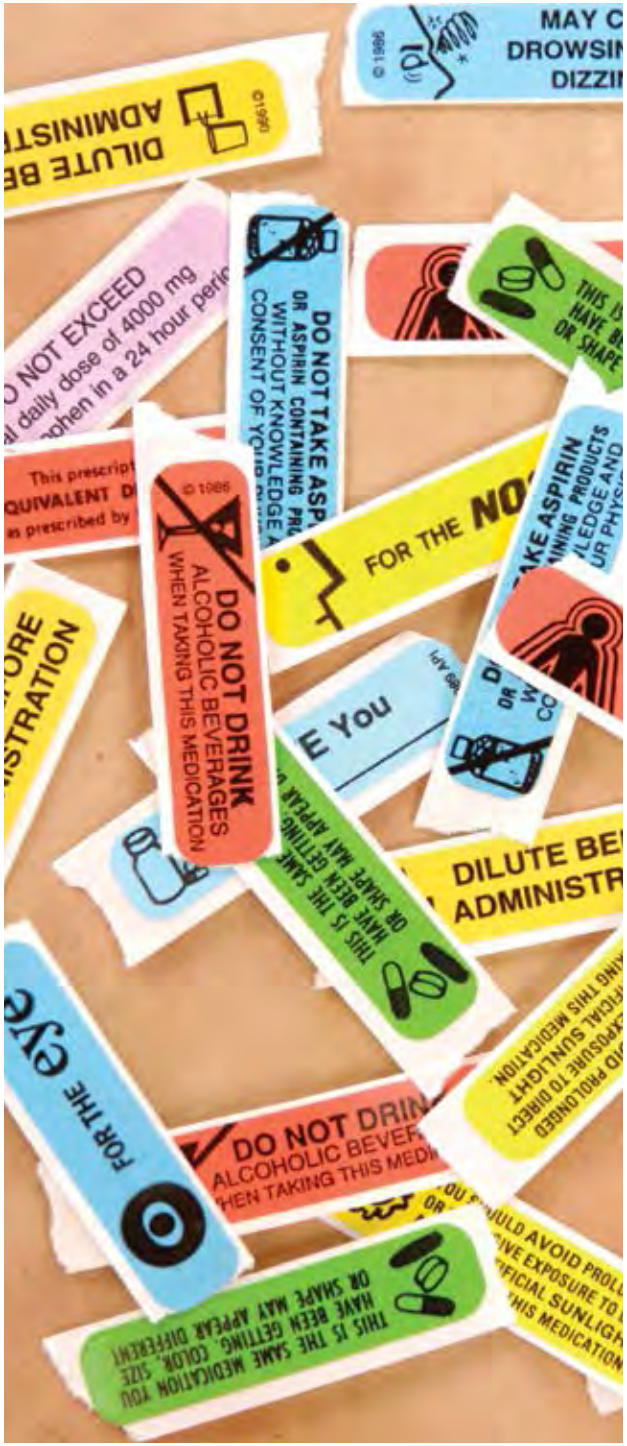
Manager, Pharmacovigilance
Mallinckrodt Pharmaceuticals

Q: What are the emerging areas of change in Pharmacovigilance in Canada?

A: "Pharmacovigilance (PV) is a discipline that is continuously and rapidly evolving. We have seen over the years how requirements and regulations have progressed to support patient safety. In addition, the latest changes in the European PV legislation and the globalization efforts have had a positive impact on PV practices all over the world. We are seeing a great deal of improvement to existing practices, as well as a steady introduction of new practices. New technologies are also contributing to the development and management of PV activities by enabling optimization of existing processes.

Many of the emerging areas of change in Canada will be discussed in tutorials and sessions throughout this year's Annual Canadian Meeting, PV inspections being one of them. Health Canada has established new inspection rules with the release of the new Good Pharmacovigilance Practice (GVP) Inspection Guidelines and Policy. The Canada Vigilance eReporting Gateway for Market Authorization Holders and Clinical Trials Sponsors is an important area of change, which will allow the same electronic reporting capabilities that are currently found in Europe and the United States. The recent announcement from Health Canada regarding the acceptability of Periodic Benefit Risk Evaluation Reports (PBRERs), in place of Periodic Safety Update Reports (PSURs), is an important step towards globalization of PV regulatory report standards. Preparation of Risk Management Plans (RMPs) and Development Safety Update Reports (DSURs) are still hot topics in the PV community, due to their integration within the review process of various regulatory submissions, and into the surveillance of safety for drugs in development.

We can add to these areas of change the PV quality system and the concept of a PV master file that, while not required by Health Canada, is quickly gaining popularity in the industry."



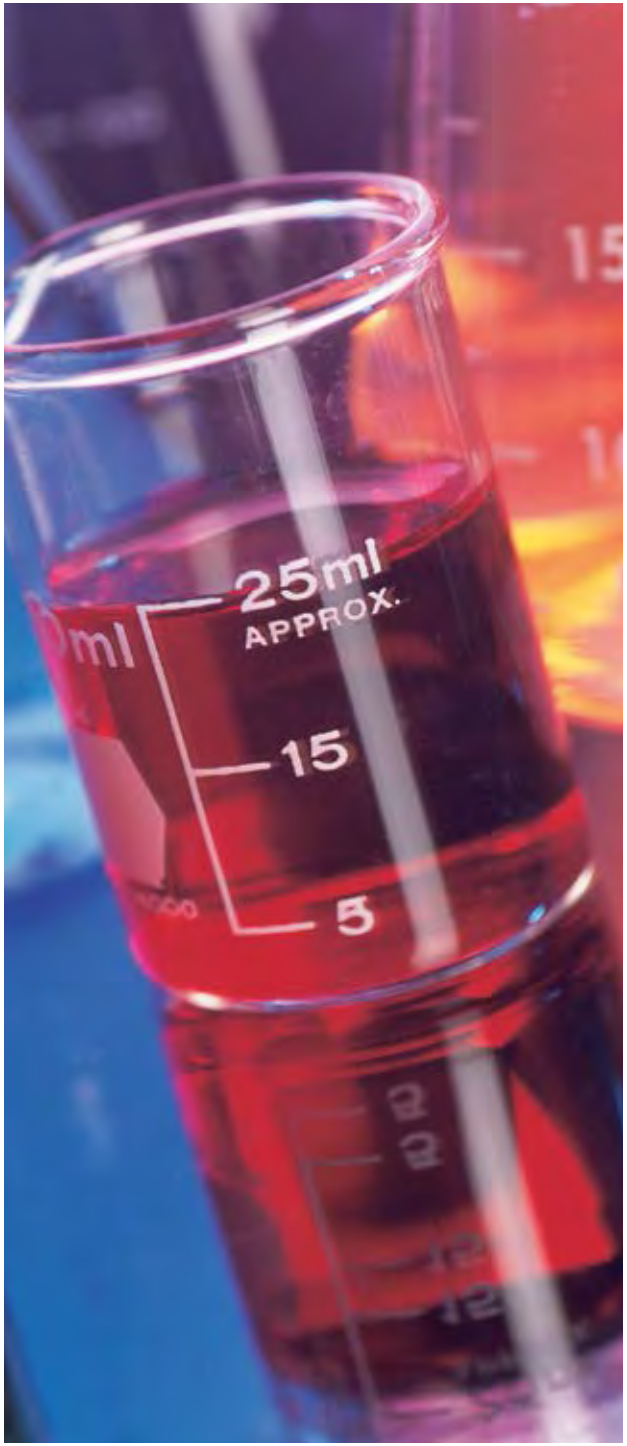
#5

Vratislav Hadrawa MD, PhD

Director, Regulatory Affairs
Pfizer Canada

Q: How will Plain Language Labeling improve the safe and effective use of medicines?

A: "The Plain Language Labeling project is part of Health Canada regulatory modernization initiative and will involve two types of changes: amendments to the existing regulations that govern drug product labeling and updates of guidances reflecting modification of processes related to labeling. Labels are the critical communication of information to health care professionals and consumers or patients. The changes will 1) make the consumer and patients information on drugs (prescription and OTC) easier to find and understand, 2) improve the prescribing information to health care professionals and 3) encourage reporting side effects. These changes aim to improve the safe and effective use of medicines, to reduce preventable medication errors, and to support Canadians in making informed choices about their health products. The draft regulations have been recently issued by Health Canada for comments and the new draft guidances shall be posted in the foreseeable future."



Are YOU Eager to Know More?

- What are the challenges faced by industry and regulators in the drug development, market access, and in the regulation in Canada?
- Where are agencies focusing their activities?
- How will the involvement of stakeholders in the regulatory harmonization process impact their future?
- How to make clinical trial information more available?
- How can drug shortages be avoided?

Where can you get answers
to these questions and more?

REGISTRATION FEES:

Member:
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Industry $1490

Nonmember:
Charitable Nonprofit/Academia $920
Government $770
Industry $1665

Tutorials $405

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Register Three, Get a Fourth Free!

You're Invited to DIA's Annual Canadian Meeting: New Reality/New Frontiers

We would like to invite you to DIA's Annual Canadian Meeting: New Realities/New Frontiers, being held October **29-30** in **Ottawa, ON, Canada,** where you'll get the answers to all your questions. Check out these featured highlights:

Opening Remarks:
Kathleen McDade
Assistant Deputy Minister of the Health Products and Food Branch
Health Canada

Workshop Topics:
- International Regulatory Cooperation
  - Trends and Impacts
  - Stakeholder Perspective
- It's BIG and It's Coming

Workshop Topics:
- Harmonizing in the Post-Approval Pharmacovigilance
- Social Media
- Research Networks and Translational Medicine
- Update on International Conference on Harmonization
- The Pursuit of Patient Advocacy
- Legislative and Regulatory Modernization Initiative
- Publicly Accessible Registrations
- Plain Language Labeling
- Managing Drug Shortages
- New Business Models
- IT Modernization
- Cool Tools in Medical Devices
- Plus More

Tutorial Topics:
- The Emerging PV Landscape in Canada
- Trends in Health Canada Inspections

Networking & Exhibits:
- Networking Reception: October 29 | 5:00-6:00PM
- Tabletop Exhibits: October 29-30

Who Should Attend?
Professionals involved in:
- Regulatory Affairs
- Policy / Pharmacoeconomics
- Clinical Development
- Drug Safety / Pharmacovigilance
- Patient Safety
- Medical Communications
- Quality Operations

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We look forward to seeing you in Ottawa!

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