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SELF-CARE FRAMEWORK



IN OUR NEXT ISSUE:
Rx TO OTC SWITCH

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Feature articles based on issue themes: **1500-2500 words**.
Letters to the Editor: **300 words maximum**.

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MESSAGE FROM YOUR EDITORIAL COMMITTEE

Through its Self-Care Framework initiative (SCF), Health Canada is working with industry and other stakeholders to update its approach to regulating self-care products, which include cosmetics, natural health products and non-prescription drugs. The objective of the SCF is to modernize the regulatory approach to self-care products, while continuing to allow for a wide range of products to be available for Canadian consumers, and better supporting consumers' ability to make informed choices. Canadian consumers buy these products freely and use these "self-care products" frequently - to care for themselves and their families, for improving appearance, maintaining health and treating minor ailments. In this publication, please find the update on this key framework by Shan Chaudhuri.

John Wong's article is on Health Canada getting tougher on opioid and illegal advertising. This is a critical and timely article, especially in light of the on-going and escalating opioid crisis. The Minister of Health has asked for volun-

tary moratorium on opioid marketing and advertising to healthcare professionals (HCPs). Health Canada believes that advertising and promotion of opioids is one of many factors that may be contributing to the increase in opioid prescriptions and sales.

The CAPRA Education Day 2019 took place on June 11th 2019. The committee members worked very hard to plan and host such a stellar event. In case you missed the event, please find in this issue a recap of the day.

We hope you continue to like the young professional series "RA: Next Generation". Monaly Mistry is our regular contributor to this column.

Happy reading!

By Your Editorial Committee

INDUSTRY NEWS

By Ray Lim



■ **ABBVIE INC.** and Ireland-based **ALLERGAN PLC** announced June 21 that the companies had entered into an agreement under which AbbVie will acquire Allergan for \$63 billion. AbbVie will keep its incorporation in Delaware and retain its corporate offices in Illinois, USA. The deal is expected to close by early 2020.

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following its separation from Abbott Laboratories. AbbVie develops and commercializes biopharmaceuti-

cal and small molecule drugs, with a focus on immunology, oncology, virology, and neuroscience. The company owns Humira, the most lucrative drug in the world used to treat rheumatoid arthritis, psoriasis and related diseases. It employs more than 28,000 people worldwide and markets medicines in more than 170 countries. Its Canadian headquarters is in Saint-Laurent, Quebec. Allergan plc, headquartered in Dublin, Ireland, develops, manufactures, and commercializes branded pharmaceutical, device, biologic, surgical, and regenerative medicine products worldwide. The company markets a portfolio of products primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. Its most famous drug is Botox, which is used to treat muscle spasms and migraines but is also commonly used as a cosmetic agent to reduce skin wrinkles. Allergan has global marketing and sales capabilities with a presence in more than 100 countries. In Canada, Allergan employs more than 170 people and has its corporate head office in Markham, Ontario.

■ **AGILENT TECHNOLOGIES INC.** announced July 11 it had signed an agreement to acquire privately-owned **BIO TEK INSTRUMENTS, INC.** for \$1.165 billion. BioTek, headquartered in Vermont, USA, is a global leader in the design, manufacture, and distribution of innovative life science instrumentation. Its comprehensive product line includes cell imaging systems, microplate readers, washers, dispensers, automated incu-

bators and stackers. These products enable life science research by providing high performance, cost-effective analysis across diverse applications. The transaction is expected to be completed in the fourth quarter of 2019.

Agilent Technologies Inc., a global leader in life sciences, diagnostics and applied chemical markets, is an American public research, development and manufacturing company established in 1999 as a spin-off from Hewlett-Packard. The company provides analytical instruments, software, services, and consumables for the entire laboratory workflow. Agilent focuses its products and services on six markets: food, environmental and forensics, pharmaceutical, diagnostics, chemical and energy, and research. In Canada, Agilent employs over 130 employees across two main sites, Mississauga, Ontario and St. Laurent, Quebec.

- **AMGEN INC.**, the world's largest biotechnology company, agreed on May 22 to acquire Scandinavian biopharmaceutical company **NUEVOLUTION AB** for \$167 million to boost its position in drug discovery. Nuevolution focuses on developing drug treatments for oncology and chronic inflammatory diseases. The company employs 40 full-time professionals and offers a drug discovery platform, Chemetics, which enables the discovery of small molecule drug candidates. Nuevolution is headquartered in Copenhagen, Denmark and now operates as a subsidiary of Amgen Inc.

AMGEN discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, the company has its Canadian headquarters in Mississauga, Ontario and a research facility in Burnaby, British Columbia, and has been an important contributor to Canada's biotechnology sector since 1991. Amgen contributes to the development of new therapies or new uses for existing medicines in partnership with many of Canada's leading healthcare, academic, research, government and patient organizations.

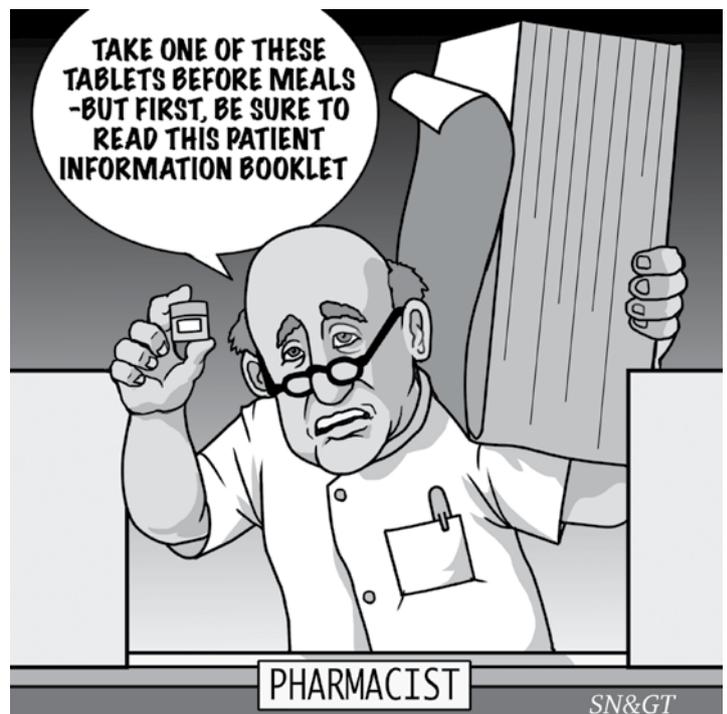
- **BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.** announced July 15 its acquisition of **AMAL THERAPEUTICS SA**, for \$365 million. Amal is a private Swiss biotechnology company focused on cancer immunotherapy and advancing first-in-class therapeutic cancer vaccines derived from its technology platform KISIMA. Boehringer Ingelheim plans to develop new therapies by combining assets from its cancer immunology portfolio with Amal's proprietary KISIMA immunization platform.

Boehringer Ingelheim's Cancer Immunology group is built to discover therapies that engage triggering of immune responses against non-inflamed, "cold" tumors, which represent a large group of cancer types refractory to many treatments, including checkpoint inhibitor drugs. Amal's KISIMA vaccine technology, designed to stimulate potent immune responses, is a promising therapeutic option for patients with these types of cancers.

Amal Therapeutics SA, a biotech company, engages in the research and development of therapeutic vaccines in oncology. It uses its cell penetrating peptide platform to develop and progress therapeutic vaccines in oncology, including cancer vaccines, immunotherapy, and therapeutic cancer vaccines. The company was founded in 2012 and is based in Geneva, Switzerland. Amal Therapeutics SA now operates as a subsidiary of Boehringer Ingelheim GmbH. Boehringer Ingelheim is the world's largest privately-owned research-based pharmaceutical company. Headquartered in Ingelheim, Germany, it operates globally with 145 affiliates and more than 42,000 employees. The company researches, develops, and manufactures pharmaceutical products, as well as offers prescription medicines and consumer health care products for human and animal health. **BOEHRINGER INGELHEIM CANADA LTD.** was established in 1972 in Montreal, Quebec and is now located in Burlington, Ontario. It employs approximately 600 people across Canada and its businesses consist of prescription medicines and animal health.

- **MEDTRONIC PLC**, a global leader in medical technology, announced May 9 that it had entered into an agreement to acquire Titan Spine, Inc., a privately held titanium spine in-

OFF LABEL



terbody implant and surface technology company. Terms of the transaction were not disclosed.

Interbody implants are spacers that can be inserted between the vertebrae during spinal fusion surgery to help relieve pressure on nerves and hold the vertebrae in place while fusion occurs. Implant material and shape is thought to play a role in the bone growth process during fusions, and there is currently a growing demand from surgeons for titanium interbody devices. Medtronic's acquisition of Titan Spine strengthens Medtronic's position as a leading innovator in procedural solutions for spine surgery. In bringing the two companies together, Medtronic will acquire Titan Spine's complete portfolio, which consists of a comprehensive line of titanium, surface-enhanced interbody fusion devices. The acquisition is expected to close by July 26.

Titan Spine, Inc. is a surface technology company focused on the design and manufacture of interbody fusion devices for the spine. Headquartered in Wisconsin, USA, the company markets a full line of endoskeleton interbody devices featuring its proprietary textured surface in the USA, Europe, and Australia through its sales force and a network of independent distributors. Medtronic plc, headquartered in Dublin, Ireland, is the global leader in medical technology. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. **MEDTRONIC OF CANADA LTD.** has its headquarters in Brampton, Ontario with regional offices in Vancouver and Montreal, including a manufacturing facility, Medtronic Cryo-Cath, located in Pointe-Claire, Quebec. Medtronic Canada employs more than 700 Canadians and delivers innovative health system solutions and advanced medical technologies to alleviate pain, restore health, and extend life in the areas of cardiovascular medicine, diabetes, spinal and neurosurgery, and ear, nose, throat surgery.

- New Jersey, USA drug maker **MERCK & CO. INC.**, known as Merck Sharpe and Dohme outside the USA and Canada, announced May 21 that it had agreed to acquire **PELTON THERAPEUTICS INC.** for \$2.2 billion, gaining access to the privately held company's lead kidney cancer drug candidate. The acquisition is expected to strengthen Merck's presence in the field of Renal Cell Carcinoma and bolster its cancer drug portfolio. Merck's blockbuster immunotherapy Keytruda was approved last month in the United States for treating renal cell cancer. The acquisition is expected to close in the third quarter of 2019.

Peloton Therapeutics, Inc., headquartered in Texas, USA, is a clinical-stage biopharmaceutical company focused on translating novel scientific insights into first-in-class medicines for patients with cancer and other debilitating or life-threatening conditions. The company's lead development program is evaluating a small molecule inhibitor of HIF-2, a transcription factor implicated in the development and pro-

gression of clear cell Renal Cell Carcinoma and a variety of other disorders. Merck & Co., Inc. is a leading global biopharmaceutical company with a diversified portfolio of prescription medicines, vaccines, and animal health products. Its headquarters is in New Jersey, USA. In Canada, Merck markets more than 250 pharmaceutical and animal health products. Merck is a leader in a broad range of areas such as cardiology, infectious diseases, respiratory, vaccines and women's health, and is focused on expanding offerings in other areas, including virology, oncology, and diabetes. Based in Montréal, Québec, Merck employs approximately 775 people across Canada and is one of the top R&D investors in Canada, with investments of more than \$1 billion since 2000.

- **PFIZER INC.** announced June 17 its agreement to spend \$10.6 billion to acquire **ARRAY BIOPHARMA**, a biopharmaceutical company that is developing small molecule medicines, primarily to treat cancer. Array's portfolio includes two drugs in more than 30 clinical trials for different kinds of cancer, particularly colorectal cancer, believed to be the third most common form of cancer in men, the others being lung and prostate cancers. Pfizer expects to complete the acquisition in the latter half of 2019.

Array BioPharma Inc. focuses on the discovery, development, and commercialization of small molecule drugs to treat patients with cancer and other diseases in North America, Europe, and the Asia Pacific. The company was founded in 1998 and is headquartered in Boulder, Colorado. It employs 298 people across 11 locations. Pfizer Inc. is a research-based, global biopharmaceutical company headquartered in New York City, and with its research headquarters in Connecticut, USA. Pfizer develops and produces medicines and vaccines for a wide range of conditions including in the areas of immunology and inflammation, oncology, cardiovascular and metabolic diseases, neuroscience and pain. **PFIZER CANADA INC.** has its headquarters in Kirkland, Quebec and Pfizer's footprint in Canada also includes Pfizer Vaccine Immuno-therapeutics in Ottawa, Ontario, Pfizer Consumer Healthcare and Pfizer Global Logistics in Mississauga, Ontario, and Pfizer Global Manufacturing in Brandon, Manitoba and Montreal, Quebec. The Wyeth Pharmaceuticals division of Pfizer Canada Inc. is in Markham, Ontario.



Ray Lim recently retired as Director of Global Affiliates, Global Quality Assurance for Shire Canada Inc. and has been writing the Industry News Articles since 2001. He has over 40 years experience in the pharmaceutical industry in R&D, regulatory and scientific affairs, and quality assurance. Aside from work, Ray has completed over 100 marathons in the past 7 years.

UPDATE ON EVOLVING **SELF-CARE** FRAMEWORK





There is a long standing discrepancy that Health Canada is trying to rectify. Currently, three different sets of regulations apply to self-care products (Cosmetic Regulations, Natural Health Product Regulations and Food and Drug Regulations). This creates confusion in the market place and often makes it difficult for consumers to make informed choices.

In the fall 2017 edition of the NOC (publication number 100), we carried the feature articles on the Regulation of Self Care Products Framework. In this edition, we wanted to provide an update on the framework.

RECAP - WHAT ARE SELF-CARE PRODUCTS?

Canada is a modern, developed country. With modern life style come challenges that self-care, along with good habits like diet and exercise, can help. Canadians use self-care products every day. These include vitamins, minerals, probiotics, pain relievers, sunscreen and lipstick, to name a few. These products in Canada are available for purchase without a prescription from a doctor. Self-care products comprise of:

1. Cosmetics
2. Natural health products (NHPs)
3. Non-prescription drugs, Over-the-counter pharmaceuticals (NPDs)

Canadians use self-care products to maintain their health, treat minor ailments or improve overall appearance.

WHY ARE THE CHANGES HAPPENING NOW?

There is long standing discrepancy that Health Canada is trying to rectify. Currently, three different sets of regulations apply to self-care products (Cosmetic Regulations,

Natural Health Product Regulations, Food and Drug Regulations). This creates confusion in the market place and often makes it difficult for consumers to make informed choices. For example, a consumer looking to purchase a lip balm would find various options that look very similar (brand name, trade dress, merchandising), and are also located close to each other on the retail aisle or ecommerce website. However, depending on the use, ingredients, and the claims made, a lip balm can be regulated as NHP, NPD, or a cosmetic.

Health Canada is proposing to put in place one new framework that treats self-care products with similar risks equally; that takes away current discrepancy and does not introduce new additional burdens for industry. The proposed approach would also give Health Canada the added authority to recall any product that may pose a danger to Canadians – while continuing to treat them differently than prescription drugs, which can pose more serious safety concerns.

Health Canada has heavily consulted with various stakeholders on this framework and it will roll it out in phases. Since fall of 2016, Health Canada has held a series of public consultations seeking input on modernizing the approach to regulating self-care products. This file has evolved, undergone significant scope changes, changed courses several times and is now entering the phase

of getting down into the details. Substantive heavy work will commence now.

All Canadians – consumers, businesses, trade associations, NGOs, etc. will have the opportunity to provide comments on both Phase ONE and Phase TWO of the Self-Care Framework during the Canada Gazette, Part I public comment period, which is expected to take place in spring 2020 and will last 70 days.

THE TIMETABLE:

1. Phase ONE – Spring 2020 – Health Canada will begin consultation on targeted amendments to the Natural Health Products Regulations to improve labeling of NHPs. This proposal will require essential risk information, product facts to be presented in a standardized format, with minimum font size and black-on-white contrast. Health Canada feels this will make it easier for consumers to read, understand and compare similar self-care products such as cosmetics or non-prescription drugs readily available on store shelves. Additionally, Health Canada is also implementing the use of simple language, as has been done for NPDs, since they feel it will ensure the information provided on NHP labels will be better understood by consumers.

2. Phase TWO – Spring 2020: Health Canada will begin consultation on targeted amendments to the Food and Drug Regulations to



The pre-cleared information (PCI) remains of paramount importance to success of this program. PCI is any form of information supporting the safety, efficacy or quality of a medicinal ingredient or NHP that NNHPD has reviewed and determined to be acceptable.

introduce a risk-based approach to regulatory oversight for non-prescription drugs/over-the-counter pharmaceuticals (NPDs). These include: expedited pathways for lower-risk products. These changes are intended to align the oversight for NPDs with other self-care products of comparable level of risk.

3. Phase THREE – Targeting 2021: Health Canada will begin consultation on regulatory amendments to address: evidence standards for similar health claims and extending risk-based regulatory oversight, seeking additional powers for Health Canada, such as the ability to require a recall or label change for all self-care products.

As it develops this framework, Health Canada is not losing sight of domestic and international cooperation efforts, level appropriation and doing the right thing to ensure that the framework attains parity with similar risk products in other jurisdictions.

DOMESTIC:

The Framework proposals are already integrated and in line with other major Health Canada priorities underway (i.e. Regulatory Review).

INTERNATIONAL:

Phase ONE – The proposed regulatory changes align with similar steps taken in Australia, Europe and the United States to improve labeling of consumer health products.

Phases TWO & THREE – The proposed regulatory changes to introduce a proportional risk-based approach for all self-care products (Phase TWO - NPDs; Phase THREE – NHPs and cosmetics) align with international best practices in Australia, Europe and the United States.

Impacts – the Framework when implemented will:

Help consumers make more informed choices and support the safe use of self-care products by improving labeling on NHPs, building on the approach in place for NPDs.

Establish proportional risk-based rules for all self-care products, which would result in significant reductions in regulatory costs to industry.

These proposals have also anticipated positive impacts on international trade by removing barriers to free trade.

In the meantime, the business of current self-care products remains ongoing. In particular, the NHPs are in the Canadian market place since last 15 years. The pre-cleared information (PCI) remains of paramount importance to success of this program. PCI is any form of information supporting the safety, efficacy or quality of a medicinal ingredient or NHP that NNHPD has reviewed and determined to be acceptable. PCI can be used to speed up the evaluation of the NHP, and serves as a reliable source of product information for consumers. PCI includes many single NHP ingredi-

ent monographs and product monographs. NNHPD will continue to update them while adding additional PCIs for Canadian consumers and businesses to use in order to bring innovations and improved products to Canada.

With 20 years of varied and progressive



*experience in various geographies of the world, **Shan Chaudhuri** brings his unique and extensive knowledge of government legislations*

and regulations and their impact to the industry. His strengths are in the area of interpretation and application of laws, guidances and frameworks to business areas. He is considered an industry expert in complex regulatory strategic planning in light of understanding of market realities and consumer preference trends. He leads Regulatory Affairs for The Clorox Company of Canada Ltd. Shan is responsible for managing all aspects of the Global Stewardship initiative in Canada that includes Product Safety, Environment, Sustainability and Regulatory Compliance. Previously, Shan was the worldwide head of Regulatory Affairs at Iovate and managed international regulatory compliance for Jamieson Labs.

REGULATORY REFORM AND IMPACT ON EXCLUSIVITIES



These are complex times for life sciences companies in Canada. There has been reform or proposed reform on multiple fronts, affecting marketing decisions and the period of exclusivity that may be available for a new drug.

Regulatory professionals must now have a working understanding of patents, patent linkage, supplementary protection and data protection, and how each of these pillars of exclusivity interact with market access issues, such as the Patented Medicine Prices Review Board (PMPRB). This article provides practical insights to aid in understanding these complex issues.

PATENTS

Patents are the primary means by which most companies, including biopharmaceutical companies, protect the market for their innovative product.

Patents provide a patent owner or its licensee with a right to prevent non-licensed users from infringing their patent rights. The patent rights are defined by what is “claimed” in the patent, such as a new chemical or biologic entity, or a new formulation or dosage form of a drug, or a new use of the drug. A patent normally has a 20-year term.

Patent rights are established by the *Patent Act*. Since 2015, there have been a number of significant amendments to the *Patent Act*, but many of these changes are only coming into force and effect on October 30, 2019.

Most of these amendments need not be noted by Canadian regulatory teams as they impact on day-to-day Patent Office practice and procedure and matters that may arise in the context of patent enforcement.

There are certain changes, however, which may impact on business planning for the Canadian market, including:

- **Supplementary protection:** As of September 21, 2017, a patent may have an additional two years of supplementary protection in the form of a Certificate of Supplementary Protection (CSP). The CSP takes effect at the end of the 20-year patent term.
- **Shorter timelines to grant of a patent:**

The regime is similar to the regime relating to European Supplementary Protection Certificates, and provides an additional patent-like protection term to partly compensate patentees of human or veterinary drugs for the time required for research and obtaining regulatory approval in Canada.



With the various changes to Patent Office practice coming into effect on October 30, 2019, patents will likely grant more quickly.

- **Earlier deemed expiry of a patent:** Patent rights may expire within the 20-year patent term if annual fees to maintain a patent are not paid, and once the law changes on October 30, 2019, a patent may be deemed expired one year earlier than under the current law. Under the current law, if such a maintenance fee is not paid on the due date, there is a one-year late payment period after which the patent is deemed expired if the fees are not paid. When the law changes on October 30, 2019, if these maintenance fees are not paid by the original due date, the patent may be deemed expired on that date.

These changes may impact on the effective period of market exclusivity in Canada, and may be relevant to reporting obligations, such as to the PMPRB.

It is also possible that there will be further changes in the next few years that may affect patent term, and thus the period of market exclusivity. There are changes to the *Patent Act* that have been proposed

under the Canada-United States-Mexico Agreement (CUSMA), which would provide additional patent term to compensate for Patent Office delays in granting a patent. Even if the CUSMA is entered into force, it will likely be 4.5 years as of the entry into force date before this change is implemented, given the transitional provisions in the agreement.

CERTIFICATES OF SUPPLEMENTARY PROTECTION (CSPS)

The CSP regime was introduced as a consequence of the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA). The regime is similar to the regime relating to European Supplementary Protection Certificates, and provides an additional patent-like protection term to partly compensate patentees of human or veterinary drugs for the time required for research and obtaining regulatory approval in Canada.

The CSP term is calculated by subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the Notice of Compliance (NOC) is issued. The maximum term is two years, without the possibility of a pediatric extension.



Regulatory professionals should be aware that, under the present *PMNOC Regulations*, there is now greater certainty in litigation. The amendments to the *PMNOC Regulations* eliminated “dual litigation” by replacing the previous summary proceedings—which did not finally decide patent infringement or validity—with full actions to determine patent infringement and validity issues.

Since CSPs first became available in Canada, and as of July 11, 2019:

- 29 CSPs have been issued for drugs for human use;
- 2 CSPs have issued for drugs for veterinary use;
- 7 CSP applications have been refused for drugs for human use; and
- 4 CSP applications are pending.

Details of the CSPs, such as the patent information, medicinal ingredient(s) and CSP term, can be found on the Register of Certificates of Supplementary Protection and Applications, maintained by Health Canada, and available on-line.

There are a number of limitations on the availability of a CSP; notably:

- **No prior approval:** The medicinal ingredient or combination of medicinal ingredients cannot have been previously approved (including before September 21, 2017).
- **One CSP per drug product:** A CSP is only available where no other CSP has been issued with respect to the medicinal ingredient/combination.
- **12-month timely NDS filing:** A CSP can only be granted where the new drug submission (NDS) for the medicinal ingredient/combination is filed with Health

Canada within 12 months of the first filing for a marketing authorization for the medicinal ingredient/combination in the European Union (or any member country thereof), the U.S., Switzerland, Japan and Australia.

- **Only product/use patents are eligible:** Only patents protecting (i.e., “claiming”) the medicinal ingredient/combination, or uses thereof, are eligible for a CSP.
- **Patent must be in force and not void:** When the CSP application is filed, the patent cannot be expired, for instance.
- **Timely CSP application:** Applications for CSPs and the requisite application fee must be filed with the Office of Patented Medicines and Liaison (OPML) at Health Canada, and are due (i) before the end of the 120-day period that begins on the day the NOC is issued, or (ii) before the end of the 120-day period that begins on the day the patent is granted, if the patent is granted after the NOC issued.

Of these requirements, the 12-month timely NDS filing requirement may be the most important for Canadian regulatory professionals, as they will likely need to educate their colleagues in other countries of this requirement.

Once a CSP is granted, the CSP effective-

ly grants the same rights as the relevant patent in respect of the drug. The CSP will also automatically be added to the Patent Register by the OPML, and thus may be asserted in patent linkage litigation.

PATENT LINKAGE: THE PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS

At the same time the CSP regime was introduced, the *Patented Medicines (Notice of Compliance) Regulations (PMNOC Regulations)* were significantly revised to address many of the criticisms that had developed since their inception in 1993.

Under the *PMNOC Regulations*, if a patent is listed on the Patent Register, Health Canada will not grant a subsequent entrant (e.g., a generic or biosimilar manufacturer) an NOC for the subsequent entry product (SEP) until issues of patent infringement are addressed. If a court proceeding seeking a declaration of patent infringement is commenced, this stay on the grant of the NOC for the SEP may last for up to 24 months.

Regulatory professionals should be aware that, under the present *PMNOC Regulations*, there is now greater certainty in litigation. The amendments to the *PMNOC Regulations* eliminated “dual litigation” by replacing the previous summary

proceedings—which did not finally decide patent infringement or validity—with full actions to determine patent infringement and validity issues.

The amendments also introduced a full right of appeal for both the generic/bio-similar and the drug sponsor, which was previously only available to the SEP manufacturer. The *PMNOC Regulations* further now permit a parallel infringement proceeding to be commenced for unlisted patents, or patents listed after the SEP manufacturer files its NDS or abbreviated NDS with Health Canada, providing for greater protection for an innovator's product.

- Regulatory professionals should rest assured, however, that the basic requirements for patent listing have not changed. That is, the patents that are eligible for listing and the timing requirements for listing have remained the same: A patent can be listed in relation to an NDS, if the patent claims the approved medicinal ingredient, formulation, dosage form or use;
 - The patent can be carried forward to a supplemental NDS (SNDS); and/or
 - The patent can be listed for the first time in relation to an SNDS, if it claims the very change in formulation, dosage form or use that is the subject of the SNDS.
- And, the patent lists **must** be filed:
- Together with the NDS or SNDS, if the patent had previously granted; or
 - If the patent grants after NDS or SNDS

filing, within 30 days after grant of the patent.

The patent must also have a filing date that precedes the NDS or SNDS filing date.

It therefore remains important for regulatory professionals to keep the patent department apprised of any new regulatory filings. The patent group can then ensure that patent applications are timely filed; the patent appropriately includes claims to the medicinal ingredient, formulations, dosage forms and/or uses that may be approved; and all relevant patents are timely included in the patent lists.

In addition, the regulatory group must keep the patent departments aware of any questions raised by the OPML in its review of the patent listing forms. There will likely only be a 30-day period to reply to any questions or preliminary objections raised by the OPML, or 30 days to seek a judicial review of any final decision not to list or to delist a patent.

DATA PROTECTION: NEW CHEMICAL ENTITIES AND BIOLOGICS

Data protection for innovative drugs was enacted in 2006. Initial challenges were made to the regime, but none were successful. Data protection is therefore a robust form of protection.

A drug—chemical or biologic in nature—may be entitled to data protection if the medicinal ingredient was not previ-



Under CUSMA, Canada has agreed to provide an expanded period of data protection to innovative biologics. That is, the eight-year market exclusivity period will be extended to 10-years. However, even if when CUSMA enters into force, Canada has five years to implement this change in the law. The timing of these changes is thus uncertain.

CHARLENE L SUMMERFIELD

Prospective Quality Assurance
& Regulatory Affairs Associate

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ously approved, or if it is not a salt, ester, enantiomer, solvate or polymorph variation of a previously approved medicinal ingredient.

If data protection applies, there is a six-year “no file” period from the first NOC for the innovative drug. During the “no file” period, an SEP manufacturer cannot file a submission for regulatory approval.

There is also an eight-year market exclusivity period measured from the first NOC for an innovative drug. During this period, Health Canada cannot grant an NOC to the SEP.

This eight year period may be extended to 8.5 years, if the pediatric extension applies. For the pediatric extension to apply, the NDS must include the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations, or an SNDS must be filed within five years of the first NOC for the innovative drug with this information. Regulatory professionals should alert their global colleagues to this five-year deadline, as different rules apply in other jurisdictions with respect to pediatric extensions.

Under CUSMA, Canada has agreed to provide an expanded period of data protection to innovative biologics. That is, the eight-year market exclusivity period will be extended to 10-years. However, even if/when CUSMA enters into force, Canada has five years to implement this change in the law. The timing of these changes is thus uncertain.

For the time being, regulatory professionals should therefore expect the current 8-years (or 8.5 years) of market exclusivity to apply to all innovative drugs. For those biologic drugs that are early in the development cycle, it should be kept in mind however that a longer period of data protection may be available.

Finally, as a reminder, it is the OPML that will decide whether a drug is an innovative drug, and whether a drug is eligible for the pediatric extension. The OPML may raise questions as to eligibility or preliminarily refuse to grant innovative drug status. In such circumstances, there should be a 30-day period to reply to any questions, or seek a judicial review



Regulatory professionals should keep in mind the various pillars of exclusivity: patents, CSPs and data protection. In addition, it is important for Canadian regulatory professionals to educate their international colleagues on the unique aspects of our law so that important deadlines are not missed.

of a final negative decision. The regulatory group should promptly alert the legal team of any such decisions.

THE PMPRB

The PMPRB has been in existence for about 30 years, and is very familiar to regulatory professionals.

While there are proposed amendments to the *Patented Medicines Regulations* and related guidance that are relevant to the pricing of a patented medicine, the nature of the rights that will trigger PMPRB review are not expected to change.

The patents that are relevant to the PM-

PRB jurisdiction are defined by the *Patent Act*. Under the *Patent Act*, if a patented invention “is intended or capable of being used for medicine or for the preparation or production of medicine”, then it may be relevant to the PMPRB. Regulatory professionals should also be aware that a CSP may be relevant to the PMPRB jurisdiction.

The question of whether a patent is intended or capable of being used for medicine or for the preparation or production of medicine may be straightforward. For instance, as a general rule, if a patent is listed on the Patent Register in respect of a product, then it should be reported to the

PMPRB for that product. However, there may be other patents, including patents that are not eligible for listing on the Patent Register, which may need to be reported to the PMPRB.

For these other patents, prior judicial and Board decisions may be a guide, although the law in this area is evolving. For instance, a recent decision of the Federal Court of Appeal relating to DIFFERIN (see 2019 FCA 196) has provided greater clarity on how to assess what is the patented invention. In this case, the Court also remitted to the Board for further consideration the question of whether the subject patent pertains to DIFFERIN. We therefore expect a further decision of the Board.

The Board's jurisdiction also requires a sale in any market in Canada, which includes sales not only pursuant to a NOC, but also sales under the Special Access Programme (even if sold from the US, provided the customers are in Canada) and through Clinical Trial Applications. Since

the PMPRB is a uniquely Canadian approach to addressing the price of patented medicines, Canadian regulatory professionals should ensure that their international colleagues understand the role that patents play in the pricing of drugs.

CONCLUDING REMARKS

In trying to assess exclusivity, regulatory professionals should keep in mind the various pillars of exclusivity: patents, CSPs and data protection. In addition, it is important for Canadian regulatory professionals to educate their international colleagues on the unique aspects of our law so that important deadlines are not missed.

Daphne Lainson specializes in securing patent protection for chemical, pharmaceutical and biotechnology related inventions. She is sought out to provide advice and guidance to many of the top global innovators with clients and



colleagues calling her “indispensable” for life science issues and has “deep knowledge of the area, provides practical, well-grounded advice and is highly responsive.



Nancy Pei is a leading lawyer who advises clients on patent and regulatory matters and related litigation. Her training and hands-on experience as

a pharmacist coupled with the expertise gained through her highly focused practice afford her a unique position in examining broader patenting and regulatory issues of importance to her clients.

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<input checked="" type="checkbox"/> Food & Nutrition	<input checked="" type="checkbox"/> Natural Health Products
<input checked="" type="checkbox"/> Cannabis	<input checked="" type="checkbox"/> Medical Devices
<input checked="" type="checkbox"/> OTC & Drugs	<input checked="" type="checkbox"/> Veterinary Products
<input checked="" type="checkbox"/> Biologics	<input checked="" type="checkbox"/> Pest Management Products
<input checked="" type="checkbox"/> Cosmetics	

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DATA UTILIZATION: MANAGING DATA

Part II of the Data Utilization series will cover managing data, which is the focus of part II of the book "Infonomics". In this section, the author, Douglas B. Laney, emphasizes the importance of developing an information asset management maturity model, how the concept of the supply chain (network) and ecosystem principals apply to managing data, and how existing methodologies from other fields can be applied by organizations in the development of information management strategies.

This article will not delve into the details of conceptualizing information in terms of a supply chain or ecosystem¹, nor the methodologies available in other fields that have established information management methodologies and guidelines. However, below is a list of fields that have well established information management methodologies and guidelines that can be further investigated²:

- IT asset management
- IT service management
- Record information management

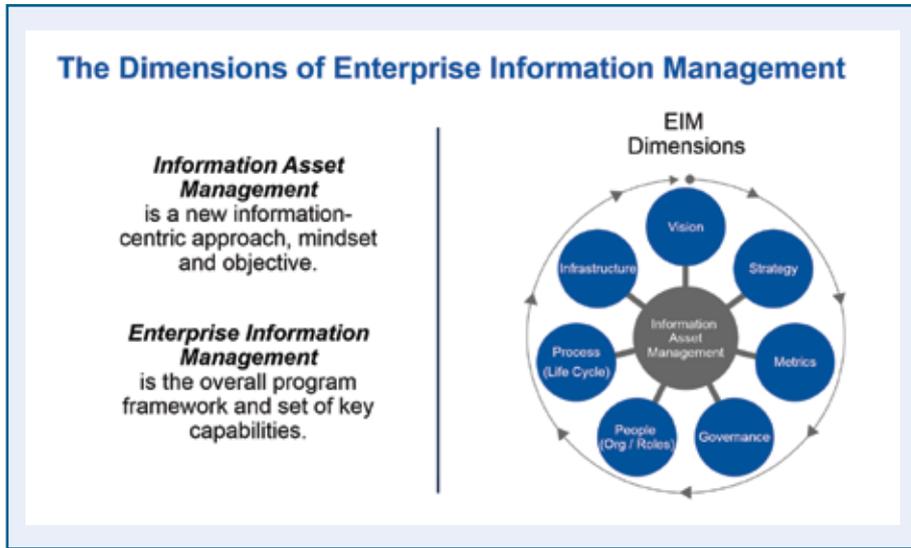
- Content management
- Knowledge management
- Library sciences

PART II: MANAGING INFORMATION

Managing information is not a static process, such that, once a management system is implemented, it will never need to be revised and revamped; rather, it is a dynamic process because as business needs, directions, and priorities change, so does the type of information needed. This is particularly true in the regulatory field as changes in regulations may affect what in-

formation needs to be submitted to have a product marketed and also for maintaining regulatory compliance. Regulatory changes affect information capture both for the regulator and the regulatee. Therefore, first developing a model and having it mature as the company does is important when managing information as an asset. So, what is required to establish and maintain information as an asset? Before answering this, one must be aware of what has previously been done and understand the current situation because no matter where an organization is on their journey to managing information

FIGURE 1: GARTNER INFORMATION MANAGEMENT MATURITY MODEL^{3,5}



(starting to develop a plan or looking to revamp programs to better utilize information collected), the following considerations should always be addressed³:

- Be able to identify information assets (have an inventory, know the quality of the information, documentation on what it is used for, have metadata/data dictionary of the information);
- Identify barriers to information asset management;
- Be able to develop frameworks for in-

formation management and assess these frameworks over time; and
- Develop organizational roles³

To start being able to identify information assets and develop a management system, Laney emphasizes the importance of Enterprise Information Management (EIM), which encompasses Information Asset Management (IAM)³. To be able to manage information, he suggests the use of Gartner Information Manage-

ment Maturity Model (Figure 1)^{3, 4}. This model, allows for the assessment of the current maturity level (5 levels) of information management and what needs to be done for IM maturation. The model is comprised of seven dimensions: including vision, strategy, metrics, governance, people, process, and infrastructure (Figure 2). The five maturity levels (Figure 3) help identify where an organization is at in terms of information maturity. By using these seven dimensions and knowing what the current maturity level an organization is at for information management, will contribute to the development of an appropriate information management strategy foundation, which can then be further developed as an organization's information grows. To further assist with the development of an information management plan/strategy, Laney goes over the three dimensions of generally accepted information principles (assumptions, principles and constraints), which when combined can be used to develop organization specific guidelines, policies and standards. Assumptions address the agreed upon basic beliefs about information, which guide the understanding of how information (assets) should be perceived, managed and deployed³. Constraints focus on the agreed upon information regulations (ex. EU General Data Protection Regulation

FIGURE 2 CGARTNER INFORMATION MANAGEMENT MATURITY MODEL DIMENSIONS³

EIM DIMENSION	DESCRIPTION
VISION	How information is adding value to the organization (what do you want to accomplish?)
STRATEGY	How to accomplish the vision. This involves developing long term plans to develop the vision. For example, what metadata will be recorded, who information is shared with, and what the information will be used for.
METRICS	Developing measures to determine if the funding and resources used for information management is justifiable (i.e. does the information management system implemented align with an organizations goals and outcomes/deliverables; is the information being used)
GOVERNANCE	Establishing a framework/principles/guidelines for acquiring, valuing, creating, storing, using, archiving and deleting information.
ORGANIZATION ROLES (PEOPLE)	Defined roles and responsibilities which ensure accountability for information related responsibilities.
LIFE CYCLE	Establishing documentation for the flow of information, from creation to capture to archival/deletion.
INFRASTRUCTURE	Information technology used within the organization. This involves ensuring that the IT systems in place are enabling information management.

FIGURE 3 GARTNER LEVELS OF INFORMATION MATURITY³

LEVEL	DEFINITION
1	The organization is generally aware of key issues and challenges but lacks the budget/resources/leadership to make meaningful advances in EIM.
2	The organization operates in a reactive application-centric mode. They will wait until information-related problems manifest in significant business losses/lack of competitiveness before addressing them.
3	The organization has become more proactive in addressing certain areas of IM and has started to put enterprise in IM. However, there is little leverage/alignment across programs and investments.
4	The organization can manage and leverage information across more than two programs. There is a decidedly managed approach to IM, comprising enterprise level coordination throughout the organization with effective people, processes and technologies.
5	The organization is considered to be a model organizations that have optimized acquiring, administering and applying information as an actual enterprise asset with high functioning organization structures, top talent, and using leading edge architecture and technologies.

(GDPR)), confinement or bounds, which helps to identify the limitations of how well information (assets) can be managed and measured and to which extent the applicable principles are restricted³. Principles are the agreed upon propositions that dictate how information assets should be managed. These axioms lead to the development of organization specific detailed guidelines, policies, procedures, and standards³.

EXAMPLE: TRANSFORMING REGULATORY OPERATIONS (REGULATORY FOCUS, RAPS)⁴

To grasp the concepts above, we can look to a recent article published in the Regulatory Focus (RAPS News Article (published July 17th, 2019)). In this article, authors Schwarz and Cottrell describe a pharmaceutical company’s journey/process to modernizing its regulatory operations, which affects how information is managed for submissions. The authors first identified long term priorities – vision. They focused on improving three main areas: people (have defined roles and responsibilities – organization roles), processes (identifying areas of improvement for the pace and quality of submissions - governance), and technology (to increase efficiency in regulatory information management - infrastructure). The changes implemented in these three areas encompass the strategy for business transformation, which in turn affects information management. In this example, new

regulatory information management applications were developed to increase the efficiency of regulatory management, which in turn affects the business goal of being able to get products to patients faster while being compliant. Information management is an important part of the regulatory field and should not be an afterthought for business transformations. By taking a proactive approach and encompassing such improvements within business transformation (as the authors above have done), it allows for the opportunity to use the information collected for business value.

For the 2020 Next Generation articles, I am planning to create a team of writers. If you are interested in contributing please contact me at monaly.mistry@gmail.com.

REFERENCES:

1. Douglas B. Laney. (2018). Infonomics: how to monetize, manage, and measure information as an asset for competitive advantage (Chapter 6:Information Supply Chain and Ecosystems). New York, NY: Bibliomotion, Inc.
2. Douglas B. Laney. (2018). Infonomics: how to monetize, manage, and measure information as an asset for competitive advantage (Chapter 7: Leveraging Information Asset Management Standards and Approaches). New York, NY: Bibliomotion, Inc.

3. Douglas B. Laney. (2018). Infonomics: how to monetize, manage, and measure information as an asset for competitive advantage. New York, NY: Bibliomotion, Inc.
4. Schwarz E W and Cottrell A. “Transforming Regulatory Operations.” Regulatory Focus. July 2019. Regulatory Affairs Professionals Society. Accessed on July 21, 2019: https://www.raps.org/news-and-articles/news-articles/2019/7/transforming-regulatory-operations?feed=Regulatory-Focus&utm_campaign=Regulatory-Focus&utm_content=1563573117&utm_medium=social&utm_source=facebook%2Clinkedin
5. <https://blogs.gartner.com/doug-laney/gartner-enterprise-information-management-eim-maturity-qa/>



Monaly Mistry (HBSc, MRes) is currently a student in the Pharmaceutical Regulatory Affairs and Quality Operations program at Seneca College. She completed her undergraduate degree at the University of Toronto in Biology and Mental Health in 2013 and her MRes. in Animal Behaviour at Newcastle University (UK) in 2014.

HEALTH CANADA GETTING TOUGHER ON OPIOID AND ILLEGAL ADVERTISING

In light of the on-going and escalating opioid crisis, the Federal Health Minister, Ginette Petitpas Taylor, issued a request in June 2018 to pharmaceutical companies seeking for a voluntary moratorium on opioid marketing and advertising to healthcare professionals (HCPs). Health Canada believes that advertising and promotion of opioids is one of many factors that may be contributing to the increase in opioid prescriptions and sales. Since then, we have seen little or no advertising of opioids. The request was sent to over 100 opioid drug manufacturers and distributors. To date 47 responded to the Minister's request to cease advertising activities of opioids.¹

Later in June 2018, Health Canada released a Notice of Intent to restrict the marketing and advertising of opioids to health care professionals. The Notice was open for a 30 day consultation period ending July 18, 2018. Forty-two responses were received from various stakeholders including HCPs, patient groups, industry, provincial governments and academia. In summary, respondents were supportive of federal action to address Canada's opioid crisis while maintaining access to treatments for those in need. With regards to the advertising of opioids, they were generally supportive of restrictions and noted the importance of unbiased educational information to encourage appropriate prescribing. Suggestions included better regulatory oversight of marketing and advertising of opioids, such as mandatory transparency and disclosure requirements. There was also recognition that the factors contributing to the opioid crisis are complex, and therefore, actions are required beyond addressing the marketing and advertising of prescription opioids.²

On March 11, 2019, Health Canada issued a Notice to Stakeholders regarding, "Further Restrictions to the Marketing and Advertising of Opioids". These proposed restrictions will apply to Class B opioids

FIGURE 1 HEALTH CANADA POSTER



products, which include opioids that are equal to or stronger than morphine such as fentanyl, oxycodone and tramadol. These proposals would limit all advertising materials of Class B opioids provided to HCPs to only statements that have been authorized by Health Canada in the Product Monograph (PM). Specifically, only information contained in the PM would be permitted in such advertising materials and would have to be presented verbatim while meeting fair balance requirements of benefits and risks. The advertising materials would also be required to undergo mandatory preclearance by a Health Canada recognized advertising preclearance agency (APA). These new restrictions are expected to take effect as of June 2019.³

Health Canada is also cracking down on illegal advertising and marketing of drugs and devices. This new campaign called Stop Illegal Marketing of Drugs and Devices (SIMDD) is self-explanatory and has several components including proactive monitoring of health product advertising, raising awareness and encouraging preclearance of

advertising. There is also a communication poster to be shared with HCPs aimed at identifying and reporting illegal marketing (see Figure 1).⁴

As a reminder, all advertising and promotion must comply with specific sections related to advertising of the Food and Drugs Act and the Controlled Drugs and Substances Act. Only drugs and devices that have been authorized for sale by Health Canada may be advertised in Canada. These are the three main areas Health Canada will be monitoring:

- Advertising of drugs and devices that are false, deceptive or misleading
- Advertising that does not provide a balanced presentation of risks and benefits
- Advertising that is not consistent with the terms of market authorization (e.g., product monograph)

REFERENCES:

1. <https://www.canada.ca/en/health-canada/services/substance-use/problematic-prescription-drug-use/opioids/responding-canada-opioid-crisis/industry-response.html>
2. <https://www.canada.ca/en/health-canada/services/substance-use/problematic-prescription-drug-use/opioids/responding-canada-opioid-crisis/advertising-opioid-medications/what-we-heard.html>
3. <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/additional-restrictions-advertising-opioids.html>
4. <https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/illegal-marketing/stop.html#a1>

John Wong is a Director, Regulatory Drug Advertising & Promotion at TPIreg/Innomar Strategies.

CAPRA EDUCATION DAY 2019



Congratulations to the CAPRA Education Day 2019 Committee members for another successful CAPRA Education Day. We appreciate the support from Mary Speagle, the facilitator of the event and Hareet Aujla, CAPRA Administrator. We offer special thanks to the Health Canada speakers and Paul Brooks, our keynote speaker from RAPS, for making the CAPRA Education Day 2019 very successful.

EDUCATION DAY 2019 COMMITTEE MEMBERS:

Anupama Patil, Bhavesh Patel, Hareet Aujla (Administrator), Joanna Czwarney, Himali Patel, Kate Rogucka, Krystyna Bienkiewicz (Chair), Mahdis Dokalam (Board Lead), Oxana Iliach, and Vivek Patel.

In contrast to the unusually rainy, gloomy and cold spring season in Canada this year, CAPRA held its annual Education Day on a rather beautiful, warm and sunny spring day on June 11, 2019. The CAPRA Education Day was an action packed, full day conference that took place at the Meadowvale Hilton hotel in Mississauga and was attended by approximately 150 people from across Canada. This year for the first time, the Education Day was also offered as a Webinar for CAPRA members who were not able to

attend in person to enable them to partake and listen throughout the event.

SUMMARY OF DAY'S DISCUSSIONS:

1. Role of Regulatory Affairs Globally, Keynote Speaker: Paul Brooks, Executive Director of Regulatory Affairs Professional Society (RAPS)

- The presentation included an overview and the role of RAPS to meet the needs of members across 82 countries worldwide. The priorities of RAPS were explained as addressing the evolving regulatory com-

petencies of a global profession, how to make learning for professional development more valuable and accessible, keeping the regulatory professionals up to date and informed on complex and evolving regulatory developments and growing and empowering the regulatory community with interactions and knowledge-sharing.

- Paul Brooks shed light on the EU Medical Device Regulations and how the Article 117 described products with integral device components that also contain an-

cillary pharmaceutical substance and requirements for medical device conformity assessment for these devices.

- The topic of Brexit was discussed and how the roadmap consists of the UK leaving the EU in October 2019, which would then lead to a transition period that ends in December 2020 and assess the future of the EU and UK relationship.
- Mr. Brooks closed off by concluding how the regulatory profession needs to continually learn, recalibrate and continually improve with the ever-changing regulatory landscapes.

2. Health Technology Assessments (HTA) Aligned Reviews between Health Canada and Health Technology Assessment Organizations; presentation by Kelly Robinson, Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, Health Canada

- Ms. Robinson provided an update on the Health Canada initiative to minimize time between HC market authorization to HTA recommendation in order to facilitate a more rapid public drug formulary/plan approval. Ms. Robinson was able to share the successes of this initiative, which included increased open dialogue and sharing of Health Canada reports such as the pre-submission meeting minutes and priority review reports through a formalized consent form process.
- Some pointers and tips to the sponsors that were provided through this experience included providing notification of any changes to the wording of the indication, dosage strengths to be approved, dosage forms that will be approved, and NOC/c qualifying studies, as these items would affect the clinical and pharmacoeconomic review reports. It was also highlighted that through INESS, all information made available from Health Canada is taken into consideration during the INESS assessment process.
- With 21 aligned reviews already completed and 13 ongoing, it was iterated that the process is continuously being monitored and is being adjusted as needed to support the goal of collaborating more with health partners.

3. International Work Sharing, presentation by Dr. Craig Simon, Associate Director Bureau of Metabolism, Oncology and Reproductive Sciences, TPD, HPFB, Health Canada

- With the continuation of globalization of the pharmaceutical industry and ever increasing costs to health care, the audience was provided with in-depth information on the work-sharing initiative between different regulators. This was done to perform better with existing resources, to promote convergence and harmonization of regulatory requirements and to strengthen the international partnerships in submission review.
- For the Generics Medicines Work Sharing files, the workload of sharing takes place over time in which one agency does a complete review of a particular submission and the other regulators do a “peer review”. Each regulator also reviewed their own respective country’s labelling. The results shows that in Canada, the submission was reviewed 4.5 months earlier than the standard target review timeline. For new chemical entities, the work was shared by dividing different parts of the submission. The division of labor allowed each regulator to evaluate their respective module and their own country’s labels.
- The results of reviewing a new chemical entity in this manner is first cycle approval in Australia and Canada with an early approval in Australia. Valuable information that was learned during the process includ-

ed increasing communication, creating an expression of interest form, preparation of a review plan with granular division of labor, and having regular teleconferences to ensure any issues are addressed. The future for this initiative will include biologics and adding more sponsors.

4. Cost Recovery: Fees in Respect of Drugs and Medical Devices, presentation by: Maria Koulouris, Senior Policy Analyst, Strategic Planning and Accountability Division, HPFB, Health Canada Speaker: Sylvia Knapczyk, Policy Analyst, Cost Recovery Team, HPFB, Health Canada

- In recent years, the topic of cost recovery has been a hot one with changes that will affect all types of sponsors when they are implemented. In addition, an overview was provided about the current status of the cost recovery updates.
- It was pointed out that Health Canada will meet with industry annually to discuss areas of interest, with the first annual meeting scheduled for Fall 2020. The implementation of revised fees will take effect on April 1, 2020.

6. Update on Health Product Inspections and Licensing, presentation by Julie Robert, Associate Director, Health Product Inspection and Licensing Division, ROEB, Health Canada

- Ms. Robert gave an insight on the updated regulations and policies that have come into practice in the recent year including the New Cannabis Act, Foreign notifications and An-



Antimicrobial Resistance Plan amendments for Veterinary drugs. In line with the Cost-Recovery presentation, Ms. Robert provided updates to the Drug Establishment License (DEL) fee and management of DEL submissions. More information and elaboration on how to split DEL amendments were also provided.

- Updates were provided on the Mutual Recognition Agreement between Therapeutics Goods Administration (TGA), Canada and the Regulatory Cooperation Initiative between Australia and Canada.
- Information was provided on the Pharmaceutical Inspection Cooperation Scheme (PIC/s) arrangement between 54 participating authorities in the field of GMP and human therapeutic products. PIC/s has plans to re-assess Health Canada in 2019/2020, which includes observation of GMP inspections and documentation review.

7. Personalized Health Care - Cell and Gene Therapies, Presentation by Dr. Jian Wang, Division Manager Clinical Evaluation Division – Hematology/Oncology, Centre for Evaluation of Radiopharmaceuticals & Biotherapeutics, BGTD, Health Canada

- As advances in biotechnology are taking place at a seemingly fast pace, this presentation from Dr. Wang gave information on how Health Canada is adjusting to these changing therapies and advances to make sure that Health Canada focuses on safety and efficacy, as it relates to biotechnology advancements. Dr. Wang explained how the regulations are performance based and provide flexibility with the evolving technologies.
- Initiatives are in place to increase and encourage advances in gene therapy and personalized medicine with Health Canada allowing for the Accelerated Review pathway in such cases.
- A proposal to include a new class of therapeutic products, Class G – Advanced Therapeutic Products, was described for emerging products that do not fit the current class structure. It was also recognized that traditional randomized clinical trials may not be a standard method to evaluate the safety and efficacy of some innovative products. Alternatively,



studies, such as basket, umbrella or platform studies may be more appropriate. It was iterated and encouraged that sponsors hold pre-submission meetings and consultations with Health Canada to receive feedback on the terms of data acceptability and filing strategies.

8. Strategies for Filing Efficient Submissions, presentation by Rachel Sampson (Licari), Regulatory Affairs Manager & Special Projects, Regulatory Project Management Division, TPD, Health Canada Speaker: Lynda O'Reilly, Regulatory Project Manager, TPD, Health Canada

- This presentation gave useful, notable suggestions and tips for facilitating the processing, screening and review of submissions filed to the Therapeutic Products Directorate at Health Canada. Some major administrative documentations for which tips were provided included the cover letter, foreign regulatory status, the note to reviewer, clarifax responses and courtesy copies of the clarifax responses and updated labelling documentations.
- For the quality documents, tips were provided for effective filing of the Quality Overall Summary (QOS) Introduction document, packaging information, dissolution methods, Certificate of Analysis for drug substance and drug product, and letters of access.
- For clinical documents, advice on how to provide appendices, study reports, comprehensive summary of bioequivalence and bioavailability studies, bridging studies and food effect studies was provided
- To assist with effective and efficient submission preparation, Health Canada has made

the screening report template available.

9. Submissions Relying on Third Party Data (from a Regulatory Perspective), presentation by Rachel Sampson (Licari), Regulatory Affairs Manager & Special Projects, Regulatory Project Management Division, TPD, Health Canada Speaker: Lynda O'Reilly, Regulatory Project Manager, TPD, Health Canada

- Ms. Sampson and Ms. O'Reilly provided clarity and recommendations with respect to submissions filed to the Therapeutic Products Directorate that rely on third-party data based on the guidance document provided by Health Canada.
- It was highlighted that although the source of information differs from a typical submission of clinical study reports of safety and efficacy, the standards for approval are still the same. Some examples of third party data would include articles from peer reviewed journals, meta-analysis of published studies, sections of published books, market experience and safety reports that monitor adverse drug reactions.
- Health Canada encouraged sponsors considering to use the SRTD pathway to request a pre-submission meeting to discuss the rationale for using the third party data.
- An explanation was provided on the breakdown of the fees associated with submitting SRTD submissions which includes published data that is provided instead of the pivotal clinical study reports.

Overall, it was a great day with eight great presentations from Health Canada and RAPS. CAPRA Education Day provided a dynamic exchange for all participants and better understanding of the ever changing and exciting field of regulatory affairs.

FROM APRIL 2019 TO PRESENT

If you have changed companies, addresses, etc. please be sure to change the information in your Membership File at the website www.capra.ca by going to the link "Edit Profile". If your email address has changed and you can no longer access your file, please provide your name and new email address to administrator@capra.ca.

NAME	CHANGE*
Lisa Milton	From Mapi Life Sciences to TPIreg, Innomar Strategies
Robin Loconte	Is now at AstraZeneca Canada Inc.
Anber Ikram	From Apotex Inc. to Avicanna Inc.
Adesola Adeyemi	From Shoppers Drug Mart to Bayer Canada
Judy Alarcon	From EMD Serono Inc. to AstraZeneca Canada Inc.
Sudheer Kumar Gumme	Is now at ICON Plc
Karen Kennedy	From Mapi an ICON plc to Intrinsik Corp.
Cathy Matthews	Is now at Alcon Canada Inc.
Maggie Chunmei Li	Is now at Fresenius Kabi Canada
Petra Hrabar	Is now at Nudestix
Kathy Truong	Is now at Nutrasouce/Humber College
Karen Luong	Is now at F. Hoffman-La Roche Limited
Vittoria Radnoff	Is now at Abbott Rapid Diagnostics
Rana Amache	Is now at Carleton University
Heather Bakdache	Is now at Intrinsik Corp.
David Wright	Is now at Seattle Genetics, Inc.

* This list is generated from the automated notices of change from the website. We apologize for any omissions or errors in interpretation.



Hareet Aujla is responsible for administration of CAPRA's professional services. She supports the Board of Directors and majority of CAPRA Committees in implementation of programs. Should members have any questions, comments or concerns, they may reach Hareet at administrator@capra.ca.

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