

Expert Opinion: New Canada Guidance of Biosimilars. Update about Canada Guidance of Generics

The challenges surrounding their Regulations and their Development.

Monday, June 21, 2010 - Salle de Reception PALACE – Laval.

Dear Participants,

The conference will be presenting about Biosimilars and Generics. It will look at different issues surrounding the biosimilars and the draft guidance of generics that is in review and development.

The biotechnology has changed the landscape of pharmaceutical market. Since the creation of the 1st biotechnology company, more than 150 biopharmaceutical products have been marketed across the globe. Biopharmaceutical is contributing 15% of the entire market. The expiration of patents, the pressure from patients, insurers and Government to reduce the expenditure has created opportunities for biosimilar products. The first biosimilar [was approved in US in 1998 and 28 products followed.](#)

As regulatory frameworks for biosimilars development is shaping worldwide, opportunities for generics companies are out there, to enter the biologics market.

However, while lower regulatory barriers in less regulated markets have allowed a biosimilars market to take off, the higher regulatory barriers in Europe and issues of interchangeability have resulted in a limited number of product launches so far and slow progress for those that are already in the market (i.e. *when Ortho Biotech unit made a change in the stabilizer of their biologic product, Eprex (epoetin alfa), in 1998 at the request of the European regulatory authorities, the company noticed an increase in reported immunogenetic responses, including a rare form of anemia called Pure Red Cell Aplasia — or PRCA — in patients receiving the product.*)

Top-selling biological agents in 2008 facing generic competition during the forecast period (2009-2013) were : Erythropoietins → insulins → etanercept → interferon-beta → G-CSFs → coagulation factors → enoxaparin → human growth hormone → interferon-alpha → imiglucerase → goserelin → somatostatin → cyclosporine → dornase alfa → tenecteplase → calcitonin → rHepB vaccine → desmopressin → botulinum toxin type A → GM-CSF → IL-2 ...

Biologics are complex and impossible to characterize fully. Other differences include the way they are manufactured and that all biologic medicines carry the potential for immunogenicity. Even small changes in how the biologic is made could have a significant impact on its safety and/or efficacy.

How will the legislation work and is it what the generic industry was hoping for?

For information about the conference, contact the organizers:

Lynda Cedar, Ph.D.

Executive Director, Clinical Trials. Atlantic Life Sciences, inc. – Montreal (Qc.) Canada.

Benoît Chedhomme, M.Sc. Sales Manager/Pharmaceutical Cold & Temperature Chain Expert. Alternatives, inc. – Laval (Qc.) Canada.

The organizers are thankful to Health Canada, the CADTH, Bio Pharma and CROs for contributing to the MFPD Events.

Altogether for healthier living!

PROGRAM CO-CHAIRS

- **D^r. Agnes Klein, MD, DPH.** Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, the Biologics and Genetic Therapies Directorate. Health Canada
- **Karen Burke, Ph.D.** Director, Regulatory Affairs. Amgen Canada Inc. Mississauga (ON.) Canada.

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For information: mfpdforum@alsclinic.com or b.chedhomme@alternatives-tech.com

514 750-6017 or (450) 661-5966

Register now: [registration form](#)

MFPD Conference: Expert Opinion: New Canada Guidance of Biosimilars. Update about Canada Guidance of Generics

The challenges surrounding their Regulations and their Development.

Monday, June 21, 2010

At: Salle de Reception PALACE.
1717 boulevard Le Corbusier. Laval, QC H7S 2K7

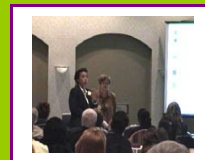
8:00 am. – 9:30 am.: Check-in and Breakfast

9:35 am. – 9:40 am.: Welcome by the organizer.
Benoît Chedhomme, M.Sc. Sales Manager/Pharmaceutical Cold & Temperature Chain Expert. Alternatives Techno Pharma, inc. Laval (Qc.).

9:40 am. – 9:45 am.: Word of Co-chair

- **Karen Burke, Ph.D.** Director, Regulatory Affairs. Amgen Canada Inc.

Illustration / previous forums



About Biosimilars and Cold chain 101

9:45 am. – 9:15 am.: « **A compliant cold chain management for the integrity of biological products.** »

Cyril Chaput, Ph.D. Cold chain compliance specialist. Alternatives Technologies Pharma Inc. Laval (QC).

9:15am. – 9:45 am.: «**Subsequent Entry Biologics: Comparability and Other Product Quality-Related Issues.**»

Anthony Ridgway, Ph.D. Senior Regulatory Scientist. Biologics & Genetic Therapies Directorate. Health Canada.

9:45 am – 10:15 am.: Networking/Coffee Break.

10:15 – 10:45 - << **Guidance of Subsequent Entry Biologics (biosimilars) in Canada: Information and Submission Requirements** >>

D'. Agnes Klein, MD, DPH. Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, the Biologics and Genetic Therapies Directorate. Health Canada.

10:45 am. – 11:15 am.: << **Biosimilars in Canada: a Perspective from Innovative Industry** >>

Karen Burke, Ph.D. Director, Regulatory Affairs. Amgen Canada Inc. Mississauga (ON.) Canada.

11:15 am. – 11:45 am.: << **Subsequent Entry Biologics: Interchangeability/Substitution, Liability** >>

Lynda Cedar, Ph.D. Executive Director, Clinical Trials. Atlantic Life Sciences Inc. Montreal (QC.) Canada.

12:00 pm. – 1:30 pm.: Luncheon - Networking

About Generics

Scope: *Health Canada announced the release of the two draft guidance documents of below, for stakeholder comment before March 26, 2010.*

Consultation Document: Draft Guidance Document - Conduct and Analysis of Comparative Bioavailability Studies

Consultation Document: Draft Guidance Document - Comparative Bioavailability Standards: Formulations used for Systemic Effects

The purpose is to update and consolidate [eleven existing documents of Health Canada](#)

2:00 pm. – 2:30 pm.: « **Regulatory Requirements for Pharmaceutical Generics** >>

Eric Ormsby, M.Sc. Manager, Office of Science, Health Canada Therapeutic Product Directorate. Health Canada. Ottawa (ON.) Canada.

Speakers' Biography

Panel of Discussions: Biosimilars, Generics and cold chain.

Panelist: Sandy, Pagotto, Senior Director
Common Drug Review Directorate, CADTH. Ottawa.

4:30 pm : Conference concludes

Who should attend?

This forum is for anyone involved or interested to know about Canadian guidance of Generics and Biosimilars (called Subsequent Entry Biologics).

Rules of participation:

Participation fee:

Before June 16, 2010 375\$ (Industry), 100\$ (Government and Students).

After June 16, 2010 475\$

For information: email: mfpdforum@alsclinic.com or b.chedhomme@alternatives-tech.com
Tel.: 514 750-6017 or (450) 661-5966

Registration [Registration form](#)

Or complete the registration form of below and send it by e-scan

Payment: paypal only (any credit is accepted).

The fee of registration includes

- Handouts, paper copy and CD of presentations. Breakfast, Two (2) coffee breaks, lunch.
- The multimedia equipment.
- Government Speakers' accommodation.

Cancellation: No cancellation is allowed but replacement is possible. The MFPD association does not charge any membership fee or administrative fee. Therefore it is not able to cover cancellations. The fee of registration is aimed to cover the event expenses.

Registration form :

* First name :				
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No., Street/Blvd./Ave., City, State/Province, Post code:				
*Phone:				
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*E-mail:				
*Payment : Credit card:				
Type of card :	First and last names :	Full Number :	PIN (back of the card or at the front for Amex)	Expiration date : MM/YYYY

Insert a message below for the organizers.

Submit the registration form by:

- e-Scan to mfpdforum@alsclinic.com
- Register online [registration form](#)

Directions: click the [map](#) to view the location of the conference and drag the link for information about [Salle de Reception Palace - Laval](#) .