The Biosimilar Landscape in Canada: An Update

CBA Biotechnology Committee and OBA Information Technology & Intellectual Property Law Section

Live Webcast

This program is eligible for up to 2.5 Substantive Hours.

Date: Friday October 14, 2016 | 9:00 am – 11:30 am

Location: Twenty Toronto Street Conferences and Events
20 Toronto Street, 2nd Floor, Toronto

Program Chair: **Geoffrey D. Mowatt**, Dimock Stratton LLP (Chair, CBA Biotechnology Committee)
Katharine McGinnis, McGinnis Law

Biosimilars are a rapidly emerging segment in the global biopharmaceutical sphere. Explore the current biosimilar approval pathway in Canada, including Health Canada's recently proposed revisions to the guidance documents. Experts from Health Canada and industry will share an update on the biosimilars approved for marketing in Canada to date, along with some challenges these products have encountered. With litigation already heating up, hear from those involved on recent biosimilar proceedings that may frame the litigation landscape for biosimilars in Canada into the future.

Agenda:

9:00 am **Introduction**
Geoffrey D. Mowatt, Dimock Stratton LLP (Chair, CBA Biotechnology Committee)

9:05 am **Approval Pathway for Biosimilars in Canada**
Bobby Chauhan, Office of Policy and International Collaboration, Biologics and Genetic Therapies Directorate (BGTD), Health Canada
Nancy Pei, Smart & Biggar | Fetherstonhaugh

- Update on Canada's Subsequent Entry Biologics regulatory approval pathway
- Proposed revisions to the Guidance for SEB Sponsors
- Health Canada's approvals to date – What have we learned?
- Canada's approval pathway compared to the FDA and EMA approach
- Data protection and patent listing for biologics

9:50 am **Challenges for Biosimilars in Canada and Abroad**
Jody Cox, Vice President, Biosimilars Canada

- Experience with SEBs approved to date – regulatory and market factors
- Market acceptance of biosimilars – naming, interchangeability, extrapolation and other issues
- Current and future challenges for regulatory agencies in Canada and abroad

10:25 am Networking Break

10:35 am **Update on Biosimilar Litigation**
Andrew Bernstein, Torys LLP
Richard Naiberg, Goodmans LLP

- Litigation experiences with SEBs and biologics
- SEB litigation versus small molecules – is there any difference?
- Considerations for future litigants

11:25 am **Concluding Remarks**
Katharine McGinnis, McGinnis Law (Program Co-Chair)

11:30 am Program Concludes