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LIFE SCIENCES LAW IN CANADA, 2ND EDITION

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Life Sciences Law in Canada provides a roadmap for protecting the intellectual property associated with medicines, medical devices, and natural health products in Canada, for getting them on to the market and for keeping them on the market. All the legislation and regulations applicable to companies carrying on business in Canada in the life sciences, be they major, established pharmaceutical companies or small, fledgling start-ups, is examined in detail.

This release features updates to Appendix 8H (Quantum Table), Appendix K (Food and Drugs Act), Appendix P (Cannabis Act) and Appendix Q (Cannabis Regulations). A new Appendix I.1 (Patented Medicines Prices Review Board — Interim Guidance) has been added.

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Highlights

APPENDIX I.1 – PATENTED MEDICINES PRICES REVIEW BOARD – INTERIM GUIDANCE – In order for the PMPRB to move forward with implementing the basket of comparator countries, the Board proposes to amend the Interim Guidance to give early guidance and greater predictability to certain New Medicines (i.e., medicines without a MAPP or NEAP as of July 1, 2022) regarding their review status. The Board proposes that the provisions of the Interim Guidance related to the patented medicines without a MAPP or projected NEAP be amended to indicate that they will be considered as reviewed if their list price is below the median international price for the PMPRB11 countries. New Medicines that do not meet this criterion will continue to be under review until new guidelines are in place.

APPENDIX 8H. QUANTUM TABLE – DAMAGES PURSUANT TO SECTION 8 OF THE PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS – The plaintiff, Apotex, a manufacturer of generic drugs brought an action for damages against the defendants (collectively "Eli Lilly") for damages that allegedly resulted from delays that Apotex encountered in bringing a drug known as Apo-Atomoxetine to market. Apo-Atomoxetine is a generic copy of Eli Lilly's branded and patented drug Strattera the active ingredient of which is atomoxetine. The claim for damages arose out of s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, (the "Regulations") which allows a generic manufacturer to claim damages in certain circumstances where a patent holder has taken steps to delay the generic manufacturer's entry into the market. If those circumstances are found to exist, then the generic manufacturer has a right to claim for losses it sustained during the period of delay. Those losses are determined by reference to a hypothetical world wherein the court is asked to calculate what the generic manufacturer's losses would have been had it been allowed to enter the market without the delay that gave rise to the claim for damages. In the court's view, the circumstances did not trigger a right to compensation under the Regulations. Even if they had, Justice Koehnen concluded that Apotex had not sustained any damages because it would not have entered into the market any sooner in the hypothetical world than it did in the real world: *Apotex v. Eli Lilly*, 2023 CarswellOnt 5224 (Ont. S.C.J.).

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