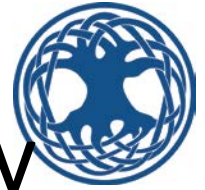


Extended Producer Responsibility for Waste Pharmaceuticals and Sharps in Canada



2016 Used Oil and Household Hazardous Waste
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Extended Producer Responsibility and product stewardship

- Regulated EPR:
 - Liability for meeting regulated end-of-life/post-consumer product performance standard rests with individual producer even where producers discharge obligations collectively
 - Ontario, Canada (pharma & sharps)
 - Regulated performance standard
- Regulated Product Stewardship:
 - Producer or 3rd party agency assumes legal liability from producers upon their subscription
 - British Columbia (pharma), Manitoba (pharma), Prince Edward Island (pharma & sharps)
 - Stewardship plan based
- Health Products Stewardship Association (HPSA) administered (see: <http://www.healthsteward.ca/sites/default/files/EPRobligations.pdf>)

EPR Regulation under Ontario EPA

– pharmaceuticals and sharps



- May 2012: Ontario government absolves Stewardship Ontario from responsibility for managing Phase 2 MHSW materials incl. waste pharmaceuticals and sharps
- O. Reg. 298/12 Collection of Pharmaceuticals and Sharps — Responsibilities of Producers in force October 1 2012
 - Individual Producer Responsibility (IPR) approach to assignment and discharge of liability

EPR Regulation under Ontario EPA – pharmaceuticals and sharps



- Coverage
 - 80% of retail locations in Ontario in pervious year sales or accredited pharmacies under the *Drug and Pharmacies Act*
 - One collection location in each local municipality with a retailer
- Free service to consumer
- No quantity limit for returns

EPR Regulation under Ontario EPA – pharmaceuticals and sharps



- Producers must ensure:
 - Minimum collection coverage
 - Agreement between collection locations (i.e. pharmacies) and approved (ECA) operator of a waste management system
 - Onsite handling at point of collection
 - Promotion and education
 - Performance reporting to government

EPR Regulation Ontario EPA – producer requirements (continued)



- Producers must ensure collectors and managers of waste pharmaceuticals and sharps has ECA,
- Has an agreement with each collection location stipulating:
 - Types of container for collecting the post consumer waste pharmaceuticals and sharps;
 - Procedures related to how post consumer waste pharmaceuticals and sharps will be handled;
 - Segregation of the wastes;
 - Labeling of containers;
 - Storage of post consumer waste pharmaceuticals and sharps; and
 - Requirement to keep a copy of the protocol/agreement and related documents on site.”

EPR Regulation – waste service providers



- Waste service providers are regulated under **existing regulation** under EPA
- A environmental compliance approval (ECA – an effective “license”) to manage post consumer waste pharmaceuticals and sharps in accordance with section 27 of the Environmental Protection Act; and
- Operating in accordance with Guideline C4: The Management of Biomedical Waste in Ontario that requires proper handling and management of the waste including collection, transportation and processing/safe disposal

MOE Enforcement



- EPA grants a broad array of powers of inspection and investigation to provincial officers
 - Issue orders to comply with regulations
 - Fines and/or jail terms
 - In addition to fines or jail terms, EPA grants courts the discretion to impose requirements for remediation and restitution, as well as the power to strip profits earned from the actions that breached the EPA.
 - Administrative monetary penalties for breaches of the EPA that do not depend on a conviction (typically applied for each day that the breach continues)



Route to producer compliance

- Producers can establish own compliance or nominate a stewardship “agency” to act on its behalf
- Agency acts as a “compliance clearinghouse” on behalf of producers:
 - Enter into master service agreement with ECA holder and manage future collection and management tendering processes
 - Manage producer billing by prorating total monthly costs to participants (based on market share data)
 - Provide producers with verification of compliance
 - Collect data and prepare interim and annual reports
 - Contract for 3rd party audits of performance results
 - Develop promotion and education program

Notable characteristics



- No government involvement in how producers finance their obligations or set fees
- Irrespective of collective agency service, individual producer remains liable
- Market-driven, whereby responsibilities assigned to individual producers are discharged in market transactions between producers and service providers,
 - Government focus is on setting standards, ensuring compliance and measuring performance



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