



## Your Regulatory Responsibilities in Canada

Entering the Canadian Pharmaceutical Market has its challenges, but with the right partner, all your regulatory, importation, distribution and compliance needs can be serviced.

All drugs available in Canada must receive approval by Health Canada through a Notice of Compliance (NOC) and possess a Drug Identification Number (DIN). The organization taking responsibility for this is called the "Market Authorization Holder."

- The Market Authorization Holder is responsible for:
  - Implementing a Post Marketing Safety Reporting Program
  - Ensuring the ongoing regulatory compliance of approved submissions
  - Ensuring all DINs are renewed annually
  - Paying Annual DIN Maintenance fees
- For a drug that is imported into Canada, it is mandatory that the importing agent possesses an Establishment License and be geographically located in Canada. This license does not need to be owned by the manufacturer, however, it can be if desired. The organization that takes responsibility for importing the drug into Canada is the "importer".
- The importer is responsible for:
  - Ensuring that drugs released in the Canadian market comply with Canadian "Good Manufacturing Practices" (GMP) including any interpretive guidelines and related Annexes or Schedules and the Lot Release program for Biologics.
  - Ensuring that the name and address of the Canadian importer appears on the inner and outer labels of the drug, the product monograph and any Package Inserts.
  - Is accountable to Health Canada for overall compliance with the *Food and Drugs Act* and its associated Regulations
  - Is subject to Health Canada's "Inspection Program"
  - Ensuring manufacturing occurred in accordance with GMP and is responsible for all activities relating to the manufacturing, packaging, labeling, testing and transportation to Canada.
  - Paying annual Establishment Licensing Fees
  - Ensuring that the Marketing Authorization Holder complies with the Post Market Reporting of Adverse Events and Product Quality Complaints

### GMD PharmaSolutions - Your Importation and Distribution Partner

Our focus at GMD PharmaSolutions is to bring new drugs to Canada through Patient Directs' **Complete Canadian Solution**. We can act as your Importer and facilitate your regulatory needs, and provide market access, importation and distribution services. For more information about our services, please contact Sam Tarantino, Director of Regulatory and Quality Operations. 905.825.4677, ext. 137. [starantino@patientdirect.ca](mailto:starantino@patientdirect.ca).

