

Governance and Policy Instruments:
Regulatory Resources in Regulatory Compliance:
Schedule B and Navigating the Drug Product Database
Rahil Rashid
Oct 17, 2022

In Canada, foods, drugs, medical devices, and cosmetics are governed by the Food and Drugs Act (FDA) (Algonquin College, 2020 - a). Health Canada is the department of the government responsible for determining compliance with the regulations defined in this Act (Algonquin College, 2020 - a). Part I of the FDA deals with legislation concerning the sale of drugs, medical devices, foods and cosmetics, and their production, import, export, and transport (Algonquin College 2020 - a). The FDA is divided into Schedules A to H (Algonquin College, 2020 - c). This paper will be focusing on Schedule B and will also summarize components of the Drug Product Database (DPD).

Schedule B is found in section 10 of the FDA and specifies quality standards in terms of analytical testing procedures in the manufacturing and chemical characterization of raw ingredients involved in drug production (Algonquin College, 2020 - c). There are 8 internationally recognized pharmacopeial standards listed under Schedule B (Food and Drugs Act, 2022). The purpose of these standards is to define procedures that ensure drug production meets quality assurance requirements (Algonquin College, 2020 - c). For example, the International Pharmacopoeia is one of the standards listed under Schedule B. This standard is described as a reference containing a collection of recommended procedures for analysis and specifications used to characterize components of the drug product (The International Pharmacopoeia, 2020). Their activities elaborated under scope and function states that they are necessary in quality control and assurance of the safety and efficacy of medications (The International Pharmacopoeia, 2020). They are stated to have legal status when introduced under national legislation (The International Pharmacopoeia, 2020), therefore, following the standards are a requirement in drug production. Three other standards listed under this Schedule are: The United States Pharmacopoeia (U.S.P), The Canadian Formulary (C.F), and The National Formulary (N.F) (Food and Drugs Act, 2022). Compliance with these standards ensures that the drug product meets quality assurance as part of the requirements for the approval process (Food and Drugs Act, 2022). Once approved the drug product will be included in the DPD.

The DPD is a searchable database of available drug products in Canada (Algonquin College, 2020 - b). The link to the database is found on Health Canada's main webpage under most requested, or alternatively, the link may be found under services and information or under a section called features (Health Canada, 2022 - a). It is accessible by the public and is an important reference tool for regulatory affairs specialists, healthcare professionals, and drug companies. It includes information on the availability of drugs in Canada, product monographs for human drugs and labels for animal drugs (Algonquin College, 2020 - b; Drug Product Database, 2022 - b). It is a dynamic reference because the database is updated nightly to include new and updated information (Algonquin College, 2020 [b]).

The database has a detailed search field in which products may be searched using specific criteria including drug identification number (DIN), anatomical therapeutic channel (ATC), or other criteria such as status, product name, company, active ingredients, active ingredient group (AIG), dosage forms, schedule, biologic biosimilar drug, classes, routes of administration, and species (Drug Product Database, 2022 - a).

In searching for a product by name such as the drug levetiracetam, the first search that appears is a list of returned items in table form that indicate the drugs' status, DIN number, company, product, class, product monograph (PM), Schedule, active ingredient (AI) name, and strengths, respectively (Drug Product Database, 2022 - a). When a general search is conducted using the generic drug name, the table will list all levetiracetam products available on the DPD with their respective DINs and drug companies. Clicking on the link for the DIN will provide specific information for the dosage strength manufactured by the company listed. The DIN number is a unique product identifier. It contains 8 digits and is assigned by Health Canada before a drug is marketed (Drug Product Database, 2022 - b). The DIN identifies characteristics of the drug product in terms of manufacturer, product name, active ingredients, strength of all active ingredients, dosage form and route of administration (Drug Product Database, 2022 - b). In the case of levetiracetam 250 mg with DIN 02285924, the current status is that this is a marketed drug

(Health Canada, 2022 - b). The current status date indicates when the drug received this status, and for this product it is 2006-10-20 (Health Canada, 2022 - b). Other statuses the DPD may list for a drug includes approved, authorized by interim order, authorized by interim order revoked, cancelled post market, cancelled pre-market, cancelled (safety issue), cancelled (unreturned annual), dormant, marketed, restricted access (Drug Product Database, 2022 - b). It's important that other statuses are listed so that interested stakeholders may know the status at any time, for example, in cases where access to a drug changed because it was cancelled for safety issues. The original market date is the first recorded date that the product was marketed according to the DPD, and this is the same as the current status date in this case (Health Canada, 2022 - b). The product name is listed as APO levetiracetam. The date of the PM as well as a PDF file link to the PM is available under labelling and indicates that this drug is an anti epileptic medication (Product Monograph, 2021). The PM is provided by the drug manufacturer and contains product specific information including indications for use, dosage, drug interactions, adverse effects and is an important document to be provided by the company during the submission process (Government of Canada, 2014). The company name, Apotex, is the manufacturer of the drug. The class is identified as human meaning it is regulated for use in humans. Other classes a drug may be listed as are for veterinary use, radiopharmaceutical or use as a disinfectant (Drug Product Database, 2022 - b). The dosage form is tablet and the route of administration is oral. Other pharmaceutical or dosage forms for a product may be capsules, powders for injection etcetera. The route of administration is the mechanism by which the drug is introduced into the body such as orally, intravenously, subcutaneously, inhalation or other routes (Drug Product Database, 2022 - b). For example, levetiracetam is also available as an injectable product. The strength of the tablet is 250 mg, which refers to the strength of the active ingredient and is expressed as a unit of dosage such as mg or mL (Drug Product Database, 2022 - b). The number of active ingredients is listed as 1, which indicates that there is 1 active pharmaceutical ingredient that is responsible for therapeutic efficacy. The schedule is prescription, meaning this drug may not be purchased over the counter, but can only be obtained through an authorized prescriber. Every drug is assigned a schedule through the FDA or Controlled Drugs and Substances Act (CDSA) (Drug Product Database, 2022 - b). The ATC for APO levetiracetam is listed as N03AX14 LEVETIRACETAM (Drug Product Database, 2022 - b). The ATC is a classification from the World Health Organization (WHO) based on the drug's mechanism of action on a specific organ system, and therapeutic and chemical properties for the purpose of conducting drug utilization reviews (Health Canada, 2022 - b). APO levetiracetam has an AIG number of 01488430019 (Health Canada, 2022 - b). The AIG number identifies how many active ingredients and how many groups of active ingredients are present in the product (Drug Product Database, 2022 - b). Specifically, it is a 10-digit number, and it specifies products that have the same active ingredients and ingredient strengths (Drug Product database, 2022 - b). The first 2 numbers indicate the number of active ingredients (Drug Product Database, 2022 - b), therefore, 01 for APO levetiracetam indicates that there is 1 active ingredient. The second 5-digit part identifies the group of active ingredients, and the last 3 numbers identifies the active ingredient group strength (Drug Product Database, 2022 - b). There is also a link to a list of other products with the same AIG number so that comparator drugs may be researched to find alternative products with the same therapeutic outcomes.

In summary, this paper provided details on what schedule B standards are and their importance in the drug approval process. An explanation of how to access the DPD and how to search the DPD using a generic drug name, the types of information that are generally provided for individual products as well as explanations of the terminology used are elaborated on. The DPD serves as an important reference tool for the public, drug companies, health care professionals and regulatory affairs specialists.

References:

1. Algonquin College (Brightspace). (2020 - a). Canada's Food and Drugs Act. Retrieved October 2, 2022, from: <https://brightspace.algonquincollege.com/d2l/le/content/468767/viewContent/7176943/View>.
2. Algonquin College (Brightspace). (2020 - b). Health Canada's Drug Products Database. Retrieved October 2, 2022, from: <https://brightspace.algonquincollege.com/d2l/le/content/468767/viewContent/7176948/View>.
3. Algonquin College (Brightspace). (2020 - c). Schedule A to H. Retrieved October 2, 2022, from: <https://brightspace.algonquincollege.com/d2l/le/content/468767/viewContent/7176947/View>
4. Food and Drugs Act. (2022). Justice Laws Website. Retrieved October 2, 2022, from: <https://laws-lois.justice.gc.ca/eng/acts/F-27/page-9.html#h-234789>.
5. Government of Canada. (2014). Guidance Document - Product Monograph. Retrieved October 3, 2022, from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/product-monograph/product-monograph.html>.
6. Health Canada. (2022 - a). Retrieved Oct 2, 2022, from: <https://www.canada.ca/en/health-canada.html>.
7. Health Canada. (2022- b). Product Information from Health Canada. Retrieved October 3, 2022, from: <https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=77141>
8. Product Monograph. APO levetiracetam. (2021). Retrieved Oct 9, 2022, from: https://pdf.hres.ca/dpd_pm/00060549.PDF.
9. The International Pharmacopoeia, 10th Edition, Preface. (2020). Retrieved October 2, 2022, from: <https://digicollections.net/phint/2020/index.html#p/home>.
10. The Drug Product Database. (2022 - a). Drug Product Database online query. Retrieved October 9, 2022, from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>.
11. The Drug Product Database. (2022 - b). Terminology. Retrieved October 3, 2022, from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database/terminology.html>.