POL-0004: Drug good manufacturing practices (GMP) and drug establishment licence (DEL) enforcement policy

April 1, 2022

Canada

Health Canada Santé Canada

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Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or associated regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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The following legend shows the alert used in this document and the way it is intended to be used.

Supplementary information like quotes and legal references.

1.0 Introduction

The *Food and Drugs Act* (the Act) and its *Food and Drug Regulations* (the Regulations) establish a regulatory framework to help protect the health and safety of people who use regulated health products such as drugs. The regulatory framework also helps to prevent deception in relation to these products.

2.0 Purpose

This policy supports the consistent and transparent application of compliance and enforcement (C&E) actions under Canada's Good Manufacturing Practices (GMP) and Drug Establishment Licence (DEL) regulatory scheme. It describes some of the enforcement measures Health Canada will take to ensure regulated parties are complying with the Act and Part C Division 1A (Establishment Licences) and Divisions 2 to 4 (Good Manufacturing Practices) of the Regulations.

3.0 Scope

This policy applies to persons and activities subject to Drug GMP and DEL requirements under Part C Divisions 1A and 2 of the Regulations as well as importers of drugs under exceptional circumstances under Division 10.

This policy applies to the following types of drugs for human and veterinary use:

- Pharmaceutical drugs (including medical gases)
- Active pharmaceutical ingredients (API)
- Vaccines
- Biological drugs (Schedule D of the Act)
- Radiopharmaceutical drugs (Schedule C of the Act)
- Drugs controlled under the *Controlled Drugs and Substances Act* and narcotics as defined in the *Narcotic Control Regulations*
- Drugs containing cannabis as defined in subsection 2(1) of the *Cannabis Act*

This policy applies to any person or party conducting activities regulated under the Act and the Regulations which include, but are not limited to:

- Fabricators
- Packagers/labellers
- Testers
- Distributors

- Importers
- Wholesalers

This policy does not apply to natural health products, medical devices, veterinary health products, antimicrobials, disinfectants, or veterinary biologicals that are regulated by the Canadian Food Inspection Agency (CFIA) and do not require a drug identification number (DIN).

The regulatory landscape is constantly changing to adapt to new sectors and products. As new drugs and activities become available and become subject to Division 1A and 2 of the Regulations, this policy will apply to the oversight of those products and activities, if not explicitly exempt.

4.0 Drug GMP and DEL requirements

GMPs ensure that drugs are consistently produced and controlled to the quality standards appropriate for their intended use, and meet the specifications required by their marketing authorizations. GMP requirements under Part C Divisions 2 to 4 of the Regulations apply to all drug establishments that conduct licensable activities.

A DEL authorizes an establishment to conduct licensable activities in Canada and demonstrates its ability to meet all applicable GMP requirements. Any drug establishment wishing to conduct a licensable activity in Canada must apply for and obtain a DEL prior to conducting that activity. As required by C.01A.005 (1), at the time of application, a company must be able to demonstrate that the applicant's buildings, equipment and proposed practices and procedures meet the applicable requirements of Divisions 2 to 4 of the Regulations.

Health Canada inspectors, designated under the Act, perform inspections as part of the application in order to verify a site's compliance with Division 2 to 4 of the Regulations. They have the authority to inspect any building in Canada where the applicant proposes to conduct a licensable activity or conduct activities requiring compliance with Divisions 2 to 4, including the storage of drugs.

Refer to Health Canada's *GUI-0002: Guidance on Drug Establishment Licences*, and *GUI-0127: Management of Applications and Performance for Drug Establishment Licences* for information on the DEL application process.

Refer to Health Canada's *GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices* for

information on the type of GMP evidence to submit for foreign buildings with DEL applications.

Refer to Health Canada's *GUI-0001: Good manufacturing practices guide for drug products* and *GUI-0104: Good manufacturing practices (GMP) guidelines for active pharmaceutical ingredients* for information on how to comply with GMP regulations for drugs and APIs.

5.0 Roles and responsibilities

5.1 Health Canada

Health Canada is responsible for administering and enforcing the Regulations, which includes enforcement of GMP and DEL requirements.

The Regulatory Operations and Enforcement Branch's (ROEB) mission is to inform and protect the people of Canada from health risks associated with products, substances and the environment. This is done by delivering and conducting compliance and enforcement activities and complementary scientific programs.

The Health Product Compliance Directorate (HPCD) within ROEB is responsible for delivering a national compliance monitoring and enforcement program for health products regulated under the Regulations.

The Health Product Inspection and Licensing (HPIL) Division within HPCD is responsible for the inspection and licensing program of drugs.

5.2 Regulated parties (Establishments)

Health Canada requires all persons conducting activities with respect to drugs, to do so in accordance with the Act and its Regulations.

Establishments are responsible for ensuring that they understand their obligations and conduct all licensable activities in accordance with all legislative and regulatory requirements.

Every establishment conducting a licensable activity is required to take all reasonable precautions to protect the health and safety of the public against the risks posed by that activity and the products that they produce/handle.

Establishments who fail to comply with the requirements will be subject to C&E actions.

6.0 Drug GMP and DEL Enforcement Measures

One way Health Canada assesses GMP compliance is by conducting inspections. The frequency and duration of these inspections is based on the inherent risk posed by the nature of the activities performed, and products being handled.

Following an inspection, the establishment must take prompt corrective actions to address the observations noted in the exit notice. The establishment will need to create and implement a corrective action and preventive action (CAPA) plan that includes target dates for completion as well as remediation and mitigation measures.

Refer to *POL-0011: Good manufacturing practices inspection policy for drug establishments* for more information on corrective and preventative actions.

If a GMP inspection outcome is Non-compliant (NC) it means that, at the time of the inspection, an establishment did not demonstrate that the activities it conducts are in compliance with the Act and relevant sections of the Regulations.

When Health Canada identifies non-compliance with GMP and/or DEL requirements, necessary actions will be taken to protect the health and safety of the people of Canada.

When an establishment does not take timely actions to address the non-compliance, or if the actions are considered inadequate by Health Canada, enforcement measures will be taken to mitigate the health risk.

Health Canada manages the risks of non-compliance to public health and safety through various types of C&E actions, which can be applied concurrently. The C&E actions include, but are not limited to:

- increasing inspection frequency
- application of terms and conditions (T&Cs)
- decision to not issue / amend a Drug Establishment Licence
- warning letters
- suspension of a Drug Establishment Licence
- cancellation of a Drug Establishment Licence
- orders

Health Canada's C&E actions and decisions are based on the best available evidence, information and science. Health Canada objectively assesses the evidence and chooses the

actions and tools that are most appropriate for the situation, based on a number of factors at the time. As new information becomes available, the risk may change and require a different approach, resulting in the application of additional or alternative C&E actions.

Refer to Health Canada's *Compliance and enforcement policy framework* and *POL-0001: Compliance and enforcement policy for health products* for more information about the full range of compliance and enforcement actions and tools.

C&E actions may affect the availability of drugs in Canada, including medically necessary drugs. Should there be an anticipated impact on supply, Health Canada will engage in a multi-stakeholder approach to address the drug shortage. Additional mitigation strategies may be leveraged to lessen or minimize the impact of a supply disruption, depending on the context of the shortage and the non-compliance.

Refer to Health Canada's *GUI-0146: Guide on the requirements for providing information related to drug shortages* for more information about drug shortages.

Establishments may be offered an opportunity to be heard (OTBH) before a final licencing decision is made. This process is an important part of procedural fairness. Refer to Health Canada's *Compliance and enforcement policy framework* for more information on procedural fairness.

6.1 Increasing inspection frequency

Health Canada's inspections are based on defined frequencies similar to those of regulators in other jurisdictions. More frequent inspections occur when risks have been identified based on the:

- current state of compliance and compliance history
- size of the establishment
- type and risk of activities
- supply chain importance

Follow up inspections may be carried out in response to the assignment of a NC inspection rating (re-inspection) or when the number or type of observations contained in the previous inspection exit notice require corrective action in a timely manner (re-assessment). These follow up inspections are usually focused on, but not restricted to, those requirements of the Act and the Regulations where contraventions were observed.

Refer to Health Canada's *POL-0011: Good manufacturing practices inspection policy for drug establishments* for more information on the type and frequency of GMP inspections.

6.2 Application of terms and conditions (T&Cs)

Subsection C.01A.008 (4) and C.01A.012 of the Regulations authorize Health Canada to impose or amend T&Cs on the DEL of an establishment. T&Cs help ensure that drugs are safe for use and prevent injury to health. Health Canada may apply, impose or amend T&Cs to a DEL at any point while carrying out its responsibilities as a regulator. When T&Cs are triggered by a C&E action, a written notice will be issued and establishments may be given an OTBH. Failure to comply with T&Cs is a violation of the Act and will lead to additional enforcement action to mitigate and prevent risk to health and safety.

6.3 Decision to not issue / amend a Drug Establishment Licence

First time DEL applicants or establishments wishing to amend their existing DEL as per section C.01A.006 (2) of the Regulations, may not be issued a new or amended DEL, if an inspection results in an NC rating. As the establishment did not demonstrate compliance with Division 2 to 4 of the Regulations, the requirements of section C.01A.005 (1) of the Regulations have not been met. Accordingly, as per section C.01A.008 of the Regulations, a licence cannot be issued/amended given the information required to do so has not been received.

Prior to the decision, an OTBH will be offered.

6.4 Warning Letters

Establishments may receive a warning letter from Health Canada for non-compliance with the Act and/or the Regulations. Health Canada may issue warning letters at any point after detecting non-compliance and it may be Health Canada's first correspondence with an establishment.

When an establishment receives a warning letter, it is responsible for providing Health Canada with any necessary corrective actions to address the non-compliance. Failure to respond to the warning letter will be taken into consideration when further enforcement measures are considered.

6.5 Suspension of a Drug Establishment Licence

As per Section C.01A.016 of the Regulations, if the establishment has contravened any provision of the Act or the Regulations or the establishment has made a false or misleading statement in a DEL application, Health Canada may suspend the licence.

Before suspending an establishment licence, Health Canada will send the establishment a notice of a proposal to suspend the licence which outlines the reasons for the proposed suspension. The establishment will then have an opportunity to be heard. The decision to suspend the licence will consider:

- Any relevant information provided by the establishment as part of their OTBH.
- The compliance history of the establishment under the Act and the Regulations.
- The risk to the health of the consumer if the licence continues in force.

When necessary to prevent risks to the health of consumers, a DEL may be immediately suspended without an OTBH pursuant to Section C.01A.017 of the Regulations.

6.6 Cancellation of a Drug Establishment Licence

Health Canada will cancel a DEL in accordance with Section C.01A.018.1 or C.01A.018.2 of the Regulations in the following scenarios:

- The DEL holder has failed to submit an Annual Licence Review application in accordance with subsection C.01A.009(1) of the Regulations.
- The DEL has been suspended in accordance with C.01A.016 (1), C.01A.017 (1) or C.01A.017.1 and the suspension is still in effect 12 months after the date of suspension.

Prior to the cancellation, an OTBH may be offered.

6.7 Orders

In addition to the powers granted to an inspector under Section 23 of the Act, Health Canada has the power to issue orders. An order is a statutory tool used to compel the person ordered to take an action pursuant to one of following subsections to the Act:

- 22.1(1) provide information, documents, or a sample
- 23(5) stop or move a conveyance
- 25(b) store or move seized product
- 25(c) dispose of seized product
- 27.2(1) remove non-compliant health products imported to Canada or destroy if removal is not possible
- 27.3 take any measures necessary to remedy contravention or prevent it

Failure to abide by an order is a violation of the Act and is subject to enforcement action as per *POL-0001: Compliance and enforcement policy for health products*.

Refer to Health Canada's *POL-0139: Policy on inspector orders for health products* for more information on inspector orders.

7.0 Obstructing, providing false information or failing to provide assistance and other authorities

Through section 23 of the Act, inspectors have the authority to enter any place, including a conveyance, to verify compliance or prevent non-compliance with the Act and the Regulations.

Subsection 23(13) requires the owner or person in charge of a place and any person found in a place entered (including remotely) by an inspector to provide:

- All reasonable assistance.
- Any information that the inspector may reasonably require including information that is necessary to establish their identification to the inspector's satisfaction.

Furthermore, subsection 27.3 (1) states that if the Minister has reasonable grounds to believe that a person has contravened, or is likely to contravene the Act or the Regulations, the Minister may order the person to take any measures that the Minister considers necessary to remedy the contravention or prevent it.

If an inspector encounters obstruction while engaged in carrying out his duties or functions under the Act or the Regulations, C&E actions that may be taken are outlined in *POL-0001: Compliance and enforcement policy for health products* which includes referral to law enforcement or recommendation for prosecution following an investigation.

The inspection powers granted to designated inspectors in Section 23 of the Act are designed to help protect the people of Canada from risks posed by regulated products under the Act such as drugs and medical devices. It is considered obstruction under subsection 24(1) to interfere with an inspector or to knowingly make false or misleading statements, orally or in writing, to an inspector engaged in carrying out their duties or functions under the Act or the Regulations. It is further prohibited for any person to remove, alter, or interfere in any way with anything seized by an inspector except with the authority of an inspector.

A contravention may result in prosecution (sections 31 or 31.2 of the Act). If convicted, a person could be liable to pay a fine ranging from $500 to $5,000,000 or imprisonment for a term ranging from three months to two years, or both.

Appendix A – Associated Documents

Legislation

Cannabis Act
https://laws-lois.justice.gc.ca/eng/acts/C-24.5/

Compliance and enforcement policy framework
https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html

Controlled Drugs and Substances Act
http://laws-lois.justice.gc.ca/eng/acts/C-38.8/

Food and Drugs Act
https://laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html

Food and Drug Regulations
https://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/

Narcotic Control Regulations
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/

Guidance and Policy Documents

POL-0001: Compliance and enforcement policy for health products
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html

POL-0011: Good manufacturing practices inspection policy for drug establishments
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/inspection-policy-canadian-drug-establishments.html

POL-0139: Policy on inspector orders for health products
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-inspector-orders-health-products.html

GUI-0001: Good manufacturing practices guide for drug products
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001/document.html

GUI-0002: Guidance on Drug Establishment Licences
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002.html

GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidance-evidence-demonstrate-drug-compliance-foreign-sites-0080.html

GUI-0104: Good manufacturing practices (GMP) guidelines for active pharmaceutical ingredients
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/guidelines-active-pharmaceutical-ingredients-0104/document.html

GUI-0127: Management of Applications and Performance for Drug Establishment Licences
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/management-applications-performance-drug-establishment-licences-0127/document.html

GUI-0146: Guide on the requirements for providing information related to drug shortages
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/guide-requirements-providing-information-shortages.html

Adoption of International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Guidance Document: Q9: Quality Risk Management
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/adoption-international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use.html

Appendix B – Glossary

Acronyms

API Active Pharmaceutical Ingredients

CAPA Corrective Action and Preventive Action

C&E Compliance & Enforcement

CFIA Canadian Food Inspection Agency

DEL Drug Establishment Licence

DIN Drug Identification Number

FDR Food and Drugs Regulations

GMP Good Manufacturing Practices

HPCD Health Product Compliance Directorate

HPIL Health Product Inspection and Licensing

NC Non-compliant

OTBH Opportunity to be Heard

ROEB Regulatory Operations and Enforcement Branch

T&Cs Terms and Conditions

These definitions explain how terms are used in this document. If there is a conflict with a definition in this document and a definition in the Act or Regulations, the definition in the Act or Regulations prevails.

Terms

Compliance – The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

Compliance history – The history of conformity of an establishment licence holder with good manufacturing practices as outlined by legislative or regulatory requirements.

Compliance monitoring – Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the Act and its associated regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys, and a product sampling program.

Corrective actions – Action to eliminate the cause of a detected non-conformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. (ICH Q9 and ISO 9000:2005)

Distributor – A person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug.

Divisions 1A and 2 to 4 of the Regulations apply to the following distributors:
a) a distributor of an active ingredient
b) a distributor of a drug for which the distributor holds the DIN (FDR C.01A.003)

Drug – Includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state, or its symptoms in human beings or animals; (b) restoring, correcting or modifying organic functions in humans beings or animals; or (c) "disinfection" in premises in which food is manufactured, prepared or kept. (Section 2 of the *Food and Drugs Act*)

In Division 1A and Division 2 of the *Food and Drug Regulations*, "drug" does not include any of the following:
(a) a dilute drug premix;
(b) a medicated feed as defined in subsection 2(1) of the *Feeds Regulations*, 1983;
(c) an active ingredient that is for veterinary use and that is not an active pharmaceutical ingredient;
(d) an active pharmaceutical ingredient for veterinary use that is not required to be sold pursuant to a prescription and that is also a natural health product as defined in subsection 1(1) of the *Natural Health Products Regulations*;
(e) a drug that is used only for the purposes of an experimental study in accordance with a certificate issued under section C.08.015 of the *Food and Drug Regulations*. (C.01A.001(2)).

Drug Establishment Licence – A licence issued to a person in Canada to conduct licensable activities in a building which has been inspected and assessed as being in compliance with the relevant requirements of Divisions 2 to 4 of the *Food and Drug Regulations*.

Drug Identification Number (DIN) – An eight (8)-digit numerical code assigned by Health Canada to each drug product marketed under the Act and Regulations. A DIN uniquely identifies the following product characteristics: manufacturer, brand name, medicinal ingredient(s), strength of medicinal ingredients(s), pharmaceutical form, route of administration.

Enforcement – Actions that may be taken to compel or induce compliance in order to mitigate the risk identified by non-compliance with the *Food and Drugs Act* and its associated regulations.

Good Manufacturing Practices – The requirements outlined in Part C, Division 2 (Good Manufacturing Practices) of the *Food and Drug Regulations* and the interpretive guidelines on the subject published by Health Canada.

Import – To import into Canada a drug for the purpose of sale. (FDR C.01A.001(1)).

Inspection – Assessment of compliance against any of the applicable requirements of the *Food and Drugs Act* and its associated Regulations by a designated inspector.

Inspector – Any person designated as an inspector under section 22 of the Act.

Inspector orders – A direction from an inspector that is authorized by statute. Failing to comply with an Order is an offence which can lead to prosecution.

Label – Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. (Section 2 of the Act). The action of labelling refers to affixing the inner or outer label to the drug. (FDR C.01A.001).

Non-Compliant – At the time of the inspection, the regulated party has not demonstrated that the activities it conducts are in compliance with the Act and its associated regulations.

Observation – A deviation or deficiency to GMPs noted by an inspector during the inspection of a drug establishment, and confirmed in writing to the company in the inspection Exit Notice.

Preventive Action – Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. (ICH Q9 and ISO 9000:2005)

Reasonable grounds to believe – Beliefs based on compelling and credible information such as knowledge, experience, expert advice or other information from a reliable source. Vague suspicion, subjective opinion or speculations are not sufficient to meet the requirement of having reasonable grounds of belief.

Re-assessment – A follow-up inspection carried out in situations where the establishment was assigned an overall compliant ("C") inspection rating on the previous inspection, but the number or type of observations contained in the previous inspection exit notice require corrective action in a timely manner. The inspection is focused on, but not restricted to, those requirements of the Act and its associated regulations where contraventions were observed.

Re-inspection – A follow-up inspection carried out in response to the assignment of a non-compliant ("NC") inspection rating. The inspection is focused on, but not restricted to, those requirements of the Act and its associated regulations where contraventions were observed.

Sell – Includes (a) offer for sale, expose for sale or have in possession for sale — or distribute to one or more persons, whether or not the distribution is made for consideration.

Suspension – a licensee is prohibited from conducting the suspended activities until the drug establishment licence is reinstated by the Minister.

Test – To perform the tests, including any examinations, evaluations and assessments, as specified in the Division 2 of the *Food and Drug Regulations*.

Warning letter – A written communication from Health Canada. The letter advises a person that one or more products, practices, processes, or other activities do not comply with the *Food and Drugs Act* or its regulations. The letter provides a summary of the facts, a description of the non-compliance, and the time limit within which the regulated party is expected to respond. The letter states that failure of the responsible party to take appropriate and prompt action to correct the current situation and prevent any future violations may result in further enforcement action without further warning.

Wholesalers – A person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at retail sale: (a) a drug in dosage form that is listed in Schedule C or D to the Act, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001 (1); (b) an active ingredient; or (c) a narcotic as defined in the *Narcotic Control Regulations* (d) a drug containing "cannabis" as defined in subsection 2(1) of the *Cannabis Act*.